SCHEDULING STATUS: **S2**

LENBUCOD, 10 mg/ 200 mg/ 350 mg film-coated tablets
Codeine phosphate, ibuprofen and paracetamol
Sugar free

Read all of this leaflet carefully because it contains important information for you.
LENBUCOD is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use LENBUCOD carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LENBUCOD with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after five days.

What is in this leaflet

1. What LENBUCOD is and what it is used for

LENBUCOD belongs to a group of medicines called analgesics which works by reducing pain. LENBUCOD is indicated for the relief of mild to moderate pain (caused by inflammation) with or without fever, for a maximum period of 5 days.

2. What you need to know before you take LENBUCOD

Do not take LENBUCOD:

- If you are hypersensitive (allergic) to paracetamol, ibuprofen, codeine phosphate or any of the other ingredients of LENBUCOD (listed in section 6).
- If you may have reacted to any other anti-inflammatory medicine (commonly known as NSAIDs) with sensitivity reactions like asthma, acute rhinitis (runny nose), angioedema (swelling) and urticaria (itchy skin rash).

- If you have had bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces), perforation or the formation of ulcers in your digestive tract after you have taken other NSAIDs (e.g. aspirin, or other ibuprofen-containing medicines).
- If you have an active or a history of gastrointestinal (stomach or small intestine) ulcers, perforation or bleeding that repeatedly reoccurs.
- If you have any active bleeding (including bleeding in the brain).
- If you suffer from a condition of unknown origin resulting in abnormal formation of blood cells.
- If you have or previously have had medical problems with your kidney or liver (see section 2, Other medicines and LENBUCOD).
- If you have had any cardiovascular disease (you may have had chest pain, tightness, discomfort, or shortness of breath; pain, numbness, weakness or coldness in your legs or arms if the blood vessels in those parts of your body are narrowed).
- If you have had severe heart failure secondary to chronic lung disease (e.g. chronic obstructive pulmonary disease or pneumonitis).
- If you have breathing problems (such as bronchial asthma, uncontrolled asthma, an asthma attack or spasm of your airways).
- If you have polyps (abnormal tissue growth) on the lining of the nose or sinuses associated with aspirin-induced bronchospasm (difficulty breathing).
- If you have had an operation on the biliary tract (for example your liver, gall bladder or bile ducts).
- If you regularly drink large quantities of alcohol.
- If you have previously had head injuries, or if you have a condition in which the pressure in your skull has increased.
- If you have breathing problems, especially in the presence of cyanosis (a bluish colour of the skin, nails and around the eyes), and coughing up fluid or mucus from your lungs.
- If you are taking coumarin-type blood thinners, such as warfarin to prevent blood clots.
- If you are taking medicines to treat depression or bipolar disorder called monoamine oxidase inhibitors or have taken these medicines within the last 14 days (see section 2, Other medicines and LENBUCOD).
- If you are suffering from severe dehydration due to vomiting, diarrhoea or insufficient fluid intake.
- If you are in the third trimester of pregnancy (from 28 weeks onwards).
- If you are breastfeeding.

- If you/your child are under 12 years old.
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

Ibuprofen as in LENBUCOD

Take special care with LENBUCOD:

- If you have had gastrointestinal disease e.g. ulcerative colitis (inflammation and sores in your digestive tract), Crohn's disease (inflammation of your digestive track), hiatus hernia (stomach pushing through an opening in the diaphragm), gastroesophageal reflux disease (stomach acid flows back into the food pipe), as LENBUCOD can cause these conditions to worsen.
- If you have high blood pressure.
- If you have a medical condition affecting your kidney or liver.
- If you have disturbances in the formation of blood cells.
- If you have blood thickening disorders or anaemia.
- If you suffer from allergies including hay fever, chronic rhinitis (inflammation of the inner lining of the nose for longer than 4 days), swelling of the sinuses or adenoids (glands located above the roof of the mouth, behind the nose).
- If you suffer from asthma or chronic obstructive disorders of the breathing airway.
- If you have had any recent major surgery.
- If you are an elderly person, you may have a higher possibility of abdominal side effects. The risk for complications (which can be life-threatening) such as bleeding, perforation or ulceration of the digestive tract is also higher in the elderly patients.
- If you have had history of gastrointestinal problems, especially if this has been complicated by perforation or accompanied by bleeding. You should report any unusual symptoms affecting your abdomen, especially if these symptoms occur at the start of therapy. If bleeding or ulceration of the digestive tract occurs, the treatment should be stopped.
- If you are using other anti-inflammatory medicines (NSAIDs), corticosteroids (e.g. prednisone), anti-platelet medicines (e.g. acetylsalicylic acid (aspirin)), selective serotonin reuptake inhibitors (antidepressants such as citalopram) or anticoagulants (warfarin or heparin), the risk of ulceration or bleeding is increased, and caution should be advised (see section 2, Other medicines and LENBUCOD).

- If you are currently taking low-dose aspirin for the prevention of heart attack or stroke, as you may experience more gastrointestinal adverse reactions.
- If you have high blood pressure or heart failure as LENBUCOD may cause water retention, which can result in heart failure.
- If you have a severe skin reaction, including blistering and peeling of the skin (e.g. Stevens-Johnson syndrome). Stop taking LENBUCOD at the first appearance of skin rash, or any other sign of hypersensitivity and go to your doctor or nearest hospital.
- If you have chickenpox (varicella virus infection), as you are more prone to develop skin and soft tissue infections.
- If you have impaired liver or kidney function.
- If you are elderly, taking medicines such as ACE inhibitors (e.g. enalapril) and diuretics (water tablets), history of liver or kidney dysfunction or heart failure, as it can provoke renal failure.
- If you have a history of asthma, as the use of LENBUCOD may worsen your asthma.
- If you have an infection, as LENBUCOD can hide symptoms such as fever and inflammation, which can affect the timely treatment of infection.
- If you suffer from systemic autoimmune disease e.g. Systemic Lupus Erythematosus (SLE), mixed connective tissue diseases or a similar condition.
- If you have porphyria (a disorder resulting from the build-up of certain chemicals related to red blood cell proteins),
- If you have a headache, stiff neck, nausea, vomiting, fever or disorientation, as the use of LENBUCOD may cause meningitis.
- If you experience hypersensitivity reactions, treatment must be stopped.
- Bronchospasm (constriction of the airways), angioedema (welts forming, swelling or redness) or urticaria (hives and itching) may be precipitated in patients with history of or are suffering from chronic rhinitis (inflammation of the inner lining of the nose for longer than four days),

  bronchial asthma, nasal polyps, sinusitis, adenoids (glands located above the roof of the mouth, behind the nose) or allergic diseases.
- Long-term use of LENBUCOD for headache can make them worse.
- Continuous use of analgesics (painkillers, such as LENBUCOD) may cause permanent damage to your kidneys.
- If you are consuming alcohol, LENBUCOD may increase the effect of alcohol on the central nervous system or increase the risk of gastrointestinal problems, eye symptoms,

weight gain, fluid retention (accumulation of fluid in body tissues and cavities) or skin rash.

- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs, including ibuprofen as contained in LENBUCOD, at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 28 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby.
- If you have a serious skin reaction known as Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS), (life-threatening condition which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat).

Paracetamol as in LENBUCOD

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Take special care with LENBUCOD:

- If you have liver or kidney problems or struggle with alcohol dependency, your doctor should monitor you more closely.
- If you take more paracetamol, as in LENBUCOD, you may cause severe damage to your liver. The risk for liver damage is especially high in alcoholics, and the consumption of alcohol should be avoided.
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients receiving paracetamol. If the patient experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using LENBUCOD immediately and contact your doctor (see Section 4).

Codeine as in LENBUCOD

Take special care with LENBUCOD:

- *Tolerance dependence, and addiction:*

Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders.

LENBUCOD contains codeine, which is an opioid medicine.
Repeated use of LENBUCOD may result in you becoming accustomed to it (needing to take higher doses). Repeated use of LENBUCOD may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.
If you are taking LENBUCOD for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).
If you experience any of the following signs whilst taking LENBUCOD, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- **You need to take this medicine for longer than advised**
- **You need to take more than the recommended dose**
- **You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'**
- **You have made repeated, unsuccessful attempts to quit or control the use of this medicine**
- **When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')**

- *Opioid induced hyperalgesia*
  Taking opioid medications for too long can paradoxically induce or sensitise patients to acute pain. This condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).
- If you take more tablets than recommended or if you use the tablets for a longer period of time than recommended, it may lead to dependency and addiction.
- If you have acute abdominal (stomach) problems, as the use of LENBUCOD may mask the symptoms, making it difficult for your doctor to treat you.
- If you have asthma or lung diseases.

- If you have an irregular heartbeat or convulsion (seizures), as LENBUCOD can make this condition worse.
- If you have a history of or having alcohol or drug dependency, or have a history of alcohol or drug abuse. The consumption of alcohol together with LENBUCOD should be avoided.
- If you have gallbladder disease or gallstones, as this may cause spasms in the biliary tract.
- If you have had recent surgery of the digestive tract.
- If you have a decreased liver function.
- If you have kidney impairment (decreased kidney function), since the use of LENBUCOD may lead to urinary retention. This may lead to an increase in adverse effects, due to the accumulation of LENBUCOD.
- If you have an under active thyroid gland (a condition where the thyroid gland does not produce enough hormones), may cause difficulty breathing and problems with your central nervous system.
- If you have adrenocortical insufficiency (e.g. Addison's disease, a condition where your body doesn't produce certain hormones).
- If you have inflammatory or obstructive bowel disorders (such a chronic ulcerating colitis).
- If you have an enlarged prostate gland, obstruction or dysfunctions of the urinary tract or having recently undergone surgery, as urinary retention may be worsened.
- If you are in shock.
- If used with anti-diarrhoeal medicines (such as diphenoxylate) as there is a risk of severe constipation.
- If you have myasthenia gravis (a neuromuscular disorder).
- If you have pain and fever that get worse, if new symptoms appear or if redness or swelling is present, as these could be sign of a serious infection. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult your health care provider immediately.
- If you are an elderly patient or you are in a compromised medical state, your dosage should be reduced.

Children

LENBUCOD is contraindicated in children under 12 years of age.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and LENBUCOD

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines).

Ibuprofen as in LENBUCOD

The combined use of:

- Anti-platelet medicine such as aspirin should be avoided, as its intended blood thinning effect may be lowered and may increase the risk of side effects.
- Non-steroidal anti-inflammatory medicine, including COX-2 inhibitors should be avoided, since the use of two or more anti-inflammatory medicines may cause an increase in stomach or bowel side effects (such as bleeding or ulcers).
- The combined use of anti-coagulants (blood thinning medicines), such as heparin or warfarin, and LENBUCOD, as the effect of the anti-coagulant may be enhanced.
- Methotrexate (used for some inflammatory diseases and some cancers) should be avoided since the toxicity of methotrexate may increase the risk of side effects.
- Corticosteroids such as prednisone and cortisone (medicines that lowers the inflammation response in the body) should be used with caution as the risk of gastrointestinal adverse reactions may increase (such as bleeding or ulceration).
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used in the treatment of depression) and anti-platelet medicines (medicines that reduce the risk of forming blood clots), increases the risk of gastrointestinal bleeding and ulceration.
- Anti-hypertensives (medicines used to treat high blood pressure such as ACE inhibitors, beta-blockers, angiotensin-II receptor antagonists or diuretics (water tablets)) should be used with caution if you have decreased kidney function since the effects of these medicines may lead to further kidney failure.
- The use of captopril with LENBUCOD counteracts the sodium excreting effect of captopril.
- Aminoglycoside antibiotics (used to treat bacterial infections), since LENBUCOD may decrease excretion of aminoglycosides, and increase their toxicity.
- Sulphonylureas (medicines used to treat diabetes) since the effect of sulphonylureas may be enhanced. Your blood glucose levels should be closely monitored.

- LENBUCOD may worsen cardiac failure, decrease the rate of filtration in the kidneys and increase the levels of cardiac glycosides e.g. digoxin, (medicines used to treat heart problems) in the plasma.
- The combined administration of LENBUCOD with digoxin, phenytoin (medicine used to treat epilepsy) or lithium (used to treat certain mental illnesses), as the level of these medicines may be increased.
- Ciclosporin or tacrolimus (medicines used to treat some inflammatory diseases and after transplants) and certain NSAIDs can lead to the risk of developing kidney toxicity and kidney damage. This effect cannot be ruled out for the combination of ciclosporin and ibuprofen, as in LENBUCOD, either.
- Cholestyramine, used in lowering your cholesterol levels and ibuprofen (as in LENBUCOD) causes a prolonged and reduced absorption of ibuprofen. You should take these medicines at least one hour apart.
- Mifepristone (a medicine used to end pregnancy), as LENBUCOD can reduce the intended effect of mifepristone, when used within an interval
  period of eight to twelve days after mifepristone administration.
- Probenecid or sulfinpyrazone (medicines used to treat gout), may cause a delay in the elimination of ibuprofen (as in LENBUCOD). The action of these medicines to reduce gout, may be decreased.
- Quinolone antibiotics (medicines used to treat infections) with LENBUCOD, may increase your chances of convulsions (seizures).
- Zidovudine (medicine used in HIV-infection), since toxicity may occur in the blood, bleeding in a joint may occur (also known as haemarthrosis) and the accumulation of blood outside of veins and arteries. Your health care professional should monitor your blood counts one to two weeks after starting combination therapy.
- Ritonavir (medicine used in HIV-infection) may increase the concentration of NSAIDs such as ibuprofen (as in LENBUCOD)
- Bone marrow depressants e.g. azathioprine - using LENBUCOD and these medicines may lead to reduction in blood platelets, which increases risk of bleeding or bruising, and reduction in the number of white blood cells which makes infections more likely.
- Alcohol, bisphosphonates (medicines used to treat osteoporosis) or oxypentifylline (medicines used to increase blood circulation), since the risk bleeding and ulceration is increased when used with LENBUCOD.

- Baclofen (medicine used to treat muscle spasticity - an abnormal increase in muscle tone or stiffness of muscle) should be used with caution since the risk for baclofen toxicity may be higher.
- Voriconazole and fluconazole (also known as CYP2C9 inhibitors) (medicines used for fungal infections), as the effect of LENBUCOD may increase. The dose of LENBUCOD should therefore be lowered.
- Gingko biloba (an herbal medicine) as there is a chance you may experience bleeding side effects more easily if you are taking this with LENBUCOD.

Paracetamol as in LENBUCOD

The concomitant use of:

- Liver enzyme-inducing or other medicines that can lead to liver damage, as there is an increased risk of liver toxicity, as well as a lowered effect of paracetamol.
- Metoclopramide (medicine used to treat nausea), since the way paracetamol (as in LENBUCOD) is absorbed in the body, may be altered.
- Cholestyramine (medicine used to lower your cholesterol levels), as the absorption of paracetamol (as in LENBUCOD) is reduced when given within one hour of cholestyramine.
- Probenecid (medicines used to treat gout), since the way LENBUCOD is eliminated by the body may be altered.

Codeine as in LENBUCOD

The concomitant use of:

- Monoamine oxidase inhibitors (usually used to treat depression or bipolar disorder), if you are using this medication or have used it within the last 14 days. Sometimes fatal reactions may occur.
- Alcohol or other central nervous system depressants (e.g. calming or tranquilizing medications, hypnotics, anaesthetics, sedatives and medicines known as phenothiazines) may lead to increased side effects such as drowsiness and impaired concentration, caused by codeine.
- Anticholinergics (atropine or antihistamines such as diphenhydramine), as it may cause severe constipation
- Medicines used to treat diarrhoea, as it may cause severe constipation and central nervous system depression.
- Blood pressure lowering medicines, since the effects of these medicines may be increased when used together with codeine as in LENBUCOD.

LENBUCOD with alcohol

Do not drink alcohol whilst taking this LENBUCOD. Alcohol may make you feel more drowsy, increase your risk of having a peptic ulcer and bleeding, and increase your risk of liver damage.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

You should not take LENBUCOD if you are already at 20 weeks or later in your pregnancy. Taking NSAIDS, including ibuprofen as contained in LENBUCOD at around 20 weeks of pregnancy or later may harm your unborn baby (see 'Warnings and precautions' above). LENBUCOD must not be taken at 20 weeks or later in your pregnancy since it may cause major heart, lung and kidney disorders in the unborn child (see 'Do not take LENBUCOD' above). If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery.

Breastfeeding

You should not take LENBUCOD if you are breastfeeding your baby.
Breastfed infants of mothers taking codeine may be at an increased risk of toxicity from its metabolite morphine.

Fertility

LENBUCOD belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

LENBUCOD may cause dizziness, visual disturbances, drowsiness or loss of attention, which could have an influence on the ability to drive and to perform or execute tasks (see Possible side effects).

It is not always possible to predict to what extent LENBUCOD may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which LENBUCOD affects you.

3. How to take LENBUCOD

Do not share medicines prescribed for you with any other person.
Always take LENBUCOD exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.
Use the lowest effective dose for the shortest possible duration of treatment.
DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose for adults and children over the age of 12 years is:
Take one to two (1 to 2) tablets six (6) hourly if necessary, and not more than six tablets within a twenty-four hour period.
Consult your health care provider if you require further treatment after five days.
LENBUCOD is contraindicated in children under 12 years of age.

If you take more LENBUCOD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Immediate medical attention is critical. Even if you do not show symptoms of an overdose, immediately go to your nearest hospital or Poison Centre.

Ibuprofen as in LENBUCOD

The most frequently reported symptoms of overdose include nausea,
abdominal pain, lethargy (state of sleepiness or deep unresponsiveness and inactivity), vomiting, blurred vision, drowsiness and other central nervous system (CNS) symptoms (such as headache, dizziness, ringing in the ears known as tinnitus, convulsion, and loss of consciousness). Other symptoms of an overdose may include nystagmus (involuntary

rhythmic motion of the eyes), feeling or being cold, bleeding in the digestive tract bleeding, coma, apnoea (short periods of no breathing) and diarrhoea. Disorientation, excitation, fainting and cardiovascular toxicity, including low blood pressure, and slow or fast heartbeats have been reported. In cases of significant overdose, renal failure and liver damage are possible.

In more serious poisoning, toxicity is seen in the central nervous system, displaying as vertigo (having no balance or feeling that the world is spinning), dizziness, drowsiness, occasionally excitation and loss of consciousness or coma.

Your asthma may also be worsened.

LENBUCOD contains paracetamol and an overdose, can be fatal.
The symptoms of an overdose can include nausea, vomiting, anorexia and stomach pain.
You may show signs of liver damage only 12 to 48 hours, or later, after an overdosage. This may lead to coma or death. Kidney failure as well as metabolic acidosis (the buildup of acid in the body due to kidney disease or kidney failure) and heart rhythm problems may occur.

If you forget to take LENBUCOD
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
LENBUCOD can have side effects.
Not all side effects reported for LENBUCOD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LENBUCOD, please consult your health care provider for advice.

If any of the following happens, stop taking LENBUCOD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Blisters on your skin or inside your mouth, nose, vagina or bottom, as these may be due to serious allergic reactions known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN).
- Rapid heartbeat (also known was tachycardia), drop in blood pressure to a point of life-

threatening shock.

- Mouth ulcers, cold sores and ulcers or soreness of your tongue.
- Skin lumps or hives (raised, red or white, itchy patches of skin).
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day).

These are all very serious side effects. If you have them, you may have had a serious reaction to LENBUCOD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Shortness of breath, chest pains or swelling (which may be a symptom of heart failure).
- Pain in the chest (also known as angina pectoris).
- Fast or irregular heartbeats.
- A blockage of blood flow to the heart muscle, also known as a heart attack (myocardial infarction).
- Difficulty breathing (respiratory depression) or a build-up of fluid in the lungs (known as pulmonary oedema).
- Bronchospasm (where your airways go into spasm making it difficult to breathe which may cause wheezing or coughing).
- Inflammatory lung disorder with symptoms of coughing and rapid, shallow breathing (alveolitis), as well as the infiltration of white blood cells into the lungs (known as pulmonary eosinophilia), causing a dry cough, fever, rapid breathing and shortness of breath.
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick), vomiting (being sick), diarrhoea or constipation and dry mouth.
- Bleeding in the stomach or intestine (gastrointestinal haemorrhage) e.g. black, tarry stools (melaena) or vomiting blood (haematemesis), or sometimes to a life-threatening extent and ulcers.
- Inflammation of the bowels or the worsening of inflammation of the colon (colitis) and digestive tract (Crohn’s disease), as well as complications of diverticula of the large bowel (perforation or fistula), bloating and decreased appetite.
- Yellowing of skin or the whites of your eyes (jaundice or hepatitis).
- Kidney or liver failure.
- Aseptic meningitis (inflammation of the protective membranes covering the brain) with symptoms including stiff neck, headache, nausea, vomiting, fever or disorientation.

- Asthma attacks.
- Increased pressure inside your skull.
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness.
- Heartburn, indigestion, abdominal cramps and pain, nausea constipation, diarrhoea, vomiting and wind, decreased appetite.
- Skin rash, itchiness (known as pruritis).

Less frequent side effects:

- Inflammation of the nose (rhinitis).
- Changes in certain components of your blood that can include fever, sore throat, mouth ulcers, flu-like symptoms, fatigue nose and skin bleedings.
- Confusional state, nervousness, sleeplessness, depression, restlessness, anxiety, changes in mood, hallucination, feeling that the world is spinning.
- Drowsiness, headache, fatigue, agitation, irritability,
- Blurred vision and other eye reactions such as double vision.
- Ringing in the ears.
- Rhinitis (seasonal runny nose), and bronchospasm and respiratory depression (difficulty breathing).
- Abnormalities of liver function tests, inflammation of the liver, liver dysfunction.
- Photosensitivity reaction (a condition where your skin is extremely sensitive to sunlight) and other skin reactions.
- Impairment of kidney function, kidney pain and inflammation of the kidneys, and other changes to your normal kidney function.
- Changes in certain substances in your blood

- Inflammation of the pancreas.
- Feeling of extreme happiness.
- Changes in the way your heart beats.
- Feeling faint upon standing (orthostatic hypotension).
- Nausea, vomiting, constipation or dry mouth.
- Pain in your upper abdomen, caused by spasm of your gallbladder or -tube.
- Difficulties in passing urine, ureteric or biliary spasm.
- Drop in body temperature (hypothermia).
- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.

Side effects of an unknown frequency:

- A decrease in the number of white blood cells (neutropenia).
- An abnormal sensation, typically tingling or pricking (‘pins and needles’) also known as paraesthesia.
- Changes in your eyesight.
- Changes in your hearing and a sensation that the world is spinning (vertigo).
- Swelling (oedema), high blood pressure and heart failure.
- Lung problems.
- Liver damage caused by a toxicity of your liver.
- Feeling unwell (malaise).
- It can also cause very low levels of potassium in your blood (see section 2)
- LENBUCOD, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis) (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.
- Facial swelling, scaly flaky skin, a pink or red rash with or without pus-filled bumps ore blisters and ulcers or soreness of your tongue, Blisters on your skin or inside your mouth, swollen saliva glands. The appearance of a rash or sunburn when you have been outside (even on a cloudy day).
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), dry mouth, headache, seizures, fever and coma.

- Skin lumps or hives (raised, red or white, itchy patches of skin), burning and pain (Fixed drug eruptions).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LENBUCOD.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store LENBUCOD

Store all medicines out of reach of children.

- Store at or below 25 ºC.
- Do not use after the expiry date stated on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LENBUCOD contains

The active substances are codeine phosphate 10 mg, ibuprofen 200 mg and paracetamol 350 mg.

The other ingredients are:

Colloidal silicon dioxide, colour FD&C blue no. 1 aluminium lake, glycerol monocaprylocaprate, macrogol (PEG) polyvinyl alcohol graft copolymer, microcrystalline cellulose PH102, polyvinyl alcohol, pregelatinised starch, stearic acid, talc.

What LENBUCOD looks like and contents of the pack

LENBUCOD is a blue, oblong, double convex, film-coated tablet.

LENBUCOD (30 tablets) is packed in a white high-density polyethylene (HDPE) bottle, fitted with a white polypropylene (PP) closure which is sealed with a heat induction liner.

Holder of Certificate of Registration

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Registration number

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PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS:

S2

LENBUCOD, 10 mg/ 200 mg/ 350 mg filmbedekte tablette

Kodeïenfosfaat, ibuprofeen en parasetamol

Suikervry

Lees die hele voubiljet noukeurig deur, want dit bevat belangrike inligting vir u.

LENBUCOD is beskikbaar sonder 'n doktersvoorskrif vir u om 'n minder ernstige toestand te behandel. U moet LENBUCOD steeds versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Moenie LENBUCOD met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet u dokter raadpleeg indien u simptome vererger of nie na vyf dae verbeter nie.

Wat in hierdie voubiljet is

1. Wat LENBUCOD is en waarvoor dit gebruik word

LENBUCOD behoort tot 'n groep medisynes wat analgetika genoem word en wat werk deur pyn te verlig. LENBUCOD is aangedui vir die verligting van ligte tot matige pyn (wat deur

inflammasie veroorsaak word) met of sonder koors, vir ’n maksimum tydperk van 5 dae.

2. Wat u moet weet voordat u LENBUCOD gebruik

Moenie LENBUCOD gebruik nie:

- Indien u hipersensitief (allergies) is vir parasetamol, ibuprofeen, kodeïenfosfaat of enige van die ander bestanddele van LENBUCOD (gelys in afdeling 6).
- Indien u ’n reaksie gehad het vir enige ander anti-inflammatoriese medisyne (algemeen bekend as NSAIMs) met sensitiwiteitsreaksies soos asma, akute rinitis (loopneus), angio-edeem (swelling) en urtikaria (jeukende veluitslag).
- Indien u enige bloeding in die spysverteringskanaal (dit kan bloed in braaksel, bloed tydens ontlasting, vars bloed in stoelgang of swart, teeragtige stoelgang insluit), perforasie of die vorming van sere in die spysverteringskanaal na die neem van ander NSAIMs (bv. aspirien, of ander ibuprofeen-bevattende medisynes) gehad het.
- Indien u ‘n aktiewe gastroïntestinale (maag of dunderm)-seer het, perforasie of bloeding wat herhaaldelik terugkom het, of geskiedenis daarvan.
- Indien u enige aktiewe bloeding (insluitend bloeding op die brein) het.
- Indien u aan enige toestand van onbekende oorsaak ly wat abnormale vorming van bloedselle as gevolg het.
- Indien u mediese probleme met u niere of lewer het, of gehad het (sien afdeling 2, Ander medisyne en LENBUCOD).
- Indien u enige kardiovaskulêre siekte gehad het (u mag dalk borspyn, beklemming, ongemak of kortasem; pyn, gevoelloosheid, swakheid of koue gevoel in u bene of arms as die bloedvate in hierdie dele van u liggaam vernou is, ervaar).
- Indien u ernstige hartversaking sekondêr tot chroniese longsiekte het (bv. chroniese obstruktiewe longsiekte of longontsteking).
- Indien u asemhalingsprobleme het (soos bronchiale asma, onbeheerde asma, ’n asma aanval of spasma van die lugweë).
- Indien u poliepe (abnormale weefsel-groeisels) op die voering van u neus of sinusse

het, wat met aspirien-geïnduseerde bronchospasma (moeite om asem te haal), gepaard gaan.

- Indien u ’n operasie van die galweë gehad het (byvoorbeeld die lewer, galblaas of galbuis).
- Indien u gereeld groot hoeveelhede alkohol drink.
- Indien u voorheen kopbeserings gehad het, of indien u ’n toestand het waar die druk in u kopbeen verhoog is.
- Indien u asemhalingsprobleme, veral in die teenwoordigheid van sianose het (’n blouerige kleur van die vel, naels en om die oë), en vog of slym uit die longe ophoes.
- Indien u kumarien-tipe bloed-verdunners, soos warfarien, gebruik om bloedklonte te voorkom.
- Indien u medisyne gebruik om depressie of bipolêre versteuring, wat monoamienoksidase inhibeerders genoem word, gebruik of in die laaste 14 dae gebruik het (sien afdeling 2, Ander medisyne en LENBUCOD).
- Indien u aan erge dehidrasie as gevolg van braking, diarree of onvoldoende vog-inname ly.
- Indien u in die derde trimester van swangerskap is (vanaf 28 weke en daarna).
- Indien u u baba borsvoed.
- Indien u/u kind jonger as 12 jaar is.
- Vir pynverligting in kinders en adolessente (0-18 jarige ouderdom) na die verwydering van mangels of adenoïdes, as gevolg van obstruktiewe slaapapnee sindroom.

Waarskuwings en voorsorgmaatreëls

Ibuprofeen soos in LENBUCOD

Neem spesiale sorg met LENBUCOD:

- Indien u gastroïntestinale siekte, bv. ulseratiewe kolitis (inflammasie en sere in u spysverteringskanaal), Crohn se siekte (inflammasie van u spysverteringskanaal), hiatus-breuk (maag druk deur ’n opening in die diafragma), gastro-esofageale

refluksiekte (maagsuur vloei terug na die slukderm), aangesien LENBUCOD kan veroorsaak dat hierdie toestande vererger.

- Indien u hoë bloeddruk het
- Indien u ’n mediese toestand het wat u niere of lewer aantas.
- Indien u versteurings in die vorming van bloedselle het.
- Indien u versteurings van bloedverdikking, of bloedarmoede het.
- Indien u aan allergieë ly, insluitend hooikoors, chroniese rinitis (inflammasie van die binneste voering van die neus vir langer as 4 dae), swelling van die sinusse of adenoïede (kliere wat bo die verhemelte, agter die neus geleë is).
- Indien u aan asma of chroniese obstruktiewe versteurings van die lugweg ly.
- Indien u onlangs enige groot operasies ondergaan het.
- Indien u ’n bejaarde persoon is, is u kans om abdominale newe-effekte te ervaar, hoër. Die risiko vir komplikasies (wat lewensbedreigend kan wees) soos bloeding, perforasie of seervorming van die spysverteringskanaal is ook hoër by bejaarde pasiënte.
- Indien u ’n geskiedenis van gastroïntestinale probleme het, veral as dit gekompliseerd is deur perforasie, of met bloeding gepaard gaan. U moet enige ongewone simptome wat u buik beïnvloed aanmeld, veral indien hierdie simptome by die aanvang van behandeling voorkom. Indien bloeding of seervorming van die spysverteringskanaal voorkom, moet die behandeling onmiddellik gestaak word.
- Indien u ander anti-inflammatoriese medisyne (NSAIMs), kortikosteroïede (bv. prednisoon), anti-plaatjie medisyne (bv. asetielsalisielsuur (aspirien)), selektiewe serotonien heropname inhibeerders (antidepressante soos sitalopraam) of antikoagulante (warfarien of heparien) gebruik, word die risiko van seervorming of bloeding verhoog, en versigtigheid moet aanbeveel word (sien afdeling 2, Ander medisyne en LENBUCOD).
- Indien u tans lae dosis aspirien gebruik vir die voorkoming van hartaanval of beroerte, want u kan meer ongewenste gastroïntestinale reaksies ervaar.

- Indien u hoë bloeddruk of hartversaking het, want LENBUCOD kan vloeistofretensie veroorsaak wat hartversaking tot gevolg kan hê.
- Indien u ernstige velreaksie het, wat blaasvorming en afskilfering van die vel (bv. Stevens-Johnson-sindroom) insluit. Staak gebruik van LENBUCOD by die eerste voorkoms van veluitslag, of enige ander teken van hipersensitiwiteit, en gaan na u dokter of naaste hospitaal.
- Indien u waterpokkies het (*varicella* virusinfeksie), want u is meer geneig om vel- en sagteweefsel-infeksies te ontwikkel,
- Indien u verminderde lewer- of nierfunksie het.
- Indien u bejaard is, medisyne soos AOE-inhibeerders (bv. enalapriel) en diuretika (waterpille) gebruik, geskiedenis van lewer- of nierdisfunksie of hartversaking het, want dit kan nierversaking veroorsaak.
- Indien u ’n geskiedenis van asma het, want die gebruik van LENBUCOD kan u asma vererger.
- Indien u ’n infeksie het, want LENBUCOD kan simptome soos koors en inflammasie maskeer, wat kan keer dat infeksie betyds behandel word.
- Indien u aan sistemiese outo-imuunsiekte ly, bv. Sistemiese Lupus Eritematose (SLE), gemengde bindweefselsiektes of soortgelyke toestande.
- Indien u porfirie het (’n toestand wat die opbou van sekere chemikalieë verwant aan rooibloedsel-proteïene tot gevolg het).
- Indien u hoofpyn, stywe nek, naarheid, braking, koors of disoriëntasie ervaar, want die gebruik van LENBUCOD kan breinvliesontsteking veroorsaak.
- Indien u hipersensitiewe reaksies ervaar, behandeling moet gestaak word.
- Bronchospasma (vernouing van die lugweë), angio-edeem (knoppe wat vorm, swelling of rooiheid) of urtikaria (galbulte en jeukerigheid) kan ontwikkel by pasiënte wat geskiedenis het van, of aan chroniese rinitis (inflammasie van die binneste voering van die neus vir langer as vier dae), bronchiale asma, poliepe in die neus, sinusitis,

adenoïede (kliere wat bo die verhemelte, agter die neus geleë is) of allergiese siektes ly.

- Langtermyn gebruik van LENBUCOD vir hoofpyn kan dit vererger.
- Voortdurende gebruik van analgetika (pynstillers, soos LENBUCOD) kan permanente skade aan u niere aanrig.
- Indien u alkohol gebruik, kan LENBUCOD die uitwerking van alkohol op die sentrale senuweestelsel, of die risiko van gastroïntestinale probleme, oogsimptome, gewigstoename, vloeistofretensie (opeenhoping van vloeistof in die liggaamsweefsel en -holtes) of veluitslag, verhoog.
- Lig u gesondheidsorgverskaffer in indien u swanger is of beplan om swanger te raak. Gebruik van NSAIMs, insluitend ibuprofeen soos in LENBUCOD bevat, teen omtrent 20 weke van swangerskap of later, kan u ongebore baba skaad. Indien u nodig het om NSAIMs vir langer as 2 dae te gebruik, tussen 20 en 28 weke van u swangerskap, mag u gesondheidsorgverskaffer die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor.
- Indien u ’n ernstige velreaksie bekend as Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome (GRESS) het (lewensbedreigende toestand wat soos ‘n griepagtige infeksie lyk, ander simptome kan uitslag, swelling van die gesig, abdominale pyn en abnormale hartklop insluit).

Parasetamol soos in LENBUCOD

Hierdie produk bevat parasetamol wat dodelik kan wees met oordosering. In die geval van oordosering of vermoedelike oordosering, en nieteenstaande die feit dat die persoon asimptomaties kan wees, moet die naaste dokter, hospitaal of gifhulpsentrum onmiddellik gekontak word.

Neem spesiale sorg met LENBUCOD:

- Indien u lewer- of nierprobleme het, of sukkel met alkohol-afhanklikheid, u dokter sal u meer sorgvuldig moet monitor.
- Indien u ekstra parasetamol gebruik, soos wat ook in LENBUCOD voorkom, kan u ernstige skade aan u lewer aanrig. Die risiko van lewerskade is veral hoog vir alkoholiste, en die gebruik van alkohol moet vermy word.
- Ernstige velreaksies soos toksiese epidermale nekrolise (TEN), Stevens-Johnson-sindroom (SJS), akute algemene eksantematiese pustulose (AAEP), Geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS)/ Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (GIHS) en terugslag geneesmiddel uitslag (TGE) is aangemeld by pasiënte wat parasetamol gebruik. Indien die pasiënt enige tekens van ernstige velreaksies soos swelling, jeukerigheid of erge rooi uitslag ervaar, staak gebruik van LENBUCOD onmiddellik en kontak u dokter (**sien Afdeling 4**).

Kodeïen soos in LENBUCOD

Neem spesiale sorg met LENBUCOD:

- Verdraagsaamheid, afhanklikheid en verslawing:
  Toenemende risiko van verslawing in pasiënte met persoonlike of familiegeskiedenis van middelmisbruik of geestesgesondheidsversteurings.

LENBUCOD bevat kodeïen, wat ’n opioïed-medisyne is.
Herhalende gebruik van LENBUCOD kan veroorsaak dat u gewoond raak daaraan (u benodig ’n hoër dosis) . Herhaalde gebruik van LENBUCOD kan ook tot afhanklikheid, misbruik en verslawing lei, wat tot ’n lewensbedreigende oordosis kan lei.
Indien u LENBUCOD vir langer as die voorgestelde tyd, of teen ’n hoër dosis as wat voorgestel word, gebruik, loop u ’n groter risiko vir ernstige nadele. Dit sluit ernstige

nadele aan die maag/derms en niere, asook baie lae vlakke van kalium in u bloed in. Hierdie effekte kan dodelik wees (sien afdeling 4).

Indien u enige van die volgende tekens tydens gebruik van LENBUCOD ervaar, raadpleeg u dokter of apteker, want dit kan ’n aanduiding wees dat u afhanklik of verslaaf is.

- **U moet hierdie medisyne vir langer gebruik as wat aanbeveel is**
- **U moet meer as die voorgestelde dosis gebruik**
- **U moet hierdie medisyne vir redes gebruik wat nie medies van aard is nie, byvoorbeeld, ‘om kalm te bly’ of om ‘u te help om te slaap’**
- **U het herhaaldelik en onsuksesvol probeer om op te hou, of om te beheer hoe u hierdie medisyne gebruik**
- **Wanneer u hierdie medisyne staak, voel u onwel, en u voel beter wanneer u hierdie medisyne weer gebruik (‘onttrekkingseffek’)**

- *Opioïed-geïnduseerde hiperalgesie*

  Die langdurige gebruik van opioïed-medisyne kan teenstrydig pasiënte sensitiseer tot akute pyn, of dit veroorsaak. Hierdie toestand word opioïed-geïnduseerde hiperalgesie genoem. Die tipe pyn wat ervaar word mag dieselfde of anders wees as die onderliggende pyn, en in sommige gevalle kan pasiënte pyn vanaf gewoonlik nie-pynlike stimuli ervaar (allodenie).
- Indien u meer pille neem as wat voorgeskryf is, of u gebruik die pille vir langer as voorgeskryf, kan dit lei tot afhanklikheid en verslawing.
- Indien u akute abdominale (maag) probleme het, want die gebruik van LENBUCOD kan die simptome maskeer, wat dit moeilik maak vir u dokter om u te behandel.
- Indien u asma of longsiektes het
- Indien u ongereelde hartklop of stuiptrekkings (stuipaanvalle) het, want LENBUCOD kan hierdie toestand vererger.

- Indien u ’n geskiedenis het, of u is afhanklik van alkohol of dwelms. Die gebruik van alkohol saam met LENBUCOD moet vermy word.
- Indien u galblaassiekte of galstene het, want dit kan spasmas in die galbuis veroorsaak.
- Indien u onlangs ’n operasie aan die spysverteringskanaal gehad het.
- Indien u verlaagde lewerfunksie het.
- Indien u nierinperking het (verlaagde nierfunksie), want die gebruik van LENBUCOD kan lei tot urienretensie. Dit kan lei tot toename in newe-effekte as gevolg van die opbou van LENBUCOD.
- Indien u ’n onderaktiewe skildklier het (’n toestand waar die skildklier nie genoeg hormone vervaardig nie), kan u dit moeilik vind om asem te haal, en probleme met u sentrale senuweestelsel veroorsaak.
- Indien u adrenokortikale ontoereikendheid het (bv. Addison se siekte, ’n toestand waar u liggaam nie genoeg van sekere hormone vervaardig nie).
- Indien u inflammatoriese of obstruktiewe dermversteurings (soos chroniese ulseratiewe kolitis) het.
- Indien u ’n vergrote prostaatklier, obstruksie of wanfunksie van die urienwegstelsel het, of onlangs ’n operasie ondergaan het, want urienretensie kan vererger.
- Indien u in skok is.
- Indien u medisyne teen diarree gebruik (soos difenoksilaat), want daar is ’n risiko van erge hardlywigheid.
- Indien u *myasthenia gravis* het (’n neuromuskulêre versteuring).
- Indien u pyn en koors het wat vererger, indien nuwe simptome verskyn of as rooiheid of swelling voorkom, want hierdie kan tekens wees van ernstige infeksie. Indien u hierdie medisyne gebruik terwyl u infeksie het en u simptome van die infeksie hou aan of vererger, raadpleeg u gesondheidsorgverskaffer onmiddellik.
- Indien u ’n bejaarde pasiënt is of as u in ’n verswakte mediese toestand is, moet u dosis verminder word.

Kinders

LENBUCOD is teenaangedui in kinders onder 12 jarige ouderdom.

Gebruik in kinders met asemhalingsprobleme

Kodeïene word nie aanbeveel by kinders met asemhalingsprobleme nie, aangesien die simptome van morfien-toksisiteit erger mag wees in hierdie kinders.

Ander medisyne en LENBUCOD:

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne gebruik.

(Dit sluit alle komplementêre en tradisionele medisyne in).

Ibuprofeen soos in LENBUCOD

Die gelyktydige gebruik van:

- Anti-plaatjie medisyne soos aspirien moet vermy word, want die doel daarvan, om bloed te verdun, kan verlaag word en kan die risiko van newe-effekte verhoog.
- Nie-steroïed anti-inflammatoriese medisyne, insluitend COX-2 inhibeerders, moet vermy word, aangesien die gebruik van twee of meer anti-inflammatoriese medisynes ’n toename in newe-effekte van die maag of derms (soos bloeding of maagsere) tot gevolg kan hê.
- Die gelyktydige gebruik van antikoagulante (bloedverdunnende medisyne), soos heparien of warfarien, en LENBUCOD, moet vermy word, aangesien die uitwerking van die antikoagulant verhoog kan word.
- Metotreksaat (gebruik vir sommige inflammatoriese siektes en sommige kankers) moet vermy word, aangesien die toksisiteit van metotreksaat die risiko van newe-effekte kan verhoog.
- Kortikosteroïede soos prednisoon en kortisoon (medisyne wat die inflammatoriese reaksie in die liggaam verlaag) moet versigtig gebruik word, aangesien die risiko van gastroïntestinale newe-effekte (soos bloeding of seervorming) verhoog kan wees.

- Selektiewe serotonien heropname inhibeerders (SSHIs) (medisynes wat vir die behandeling van depressie gebruik word) en anti-plaatjie medisyne (medisynes wat die vorming van bloedklonte voorkom), verhoog die risiko van gastroïntestinale bloeding en ulserasie.
- Anti-hipertensiewe middels (medisynes wat vir die behandeling van hoë bloeddruk gebruik word, soos AOE-inhibeerders, beta-blokkers, angiotensien-II-reseptor antagoniste of diuretika (waterpille)) moet versigtig gebruik word indien u verlaagde nierfunksie het, want die uitwerking van hierdie medisynes kan tot verdere nierversaking lei.
- Die gebruik van kaptopriel saam met LENBUCOD werk die natrium-uitskeidingseffek van kaptopriel teë.
- Aminoglikosied-antibiotika (gebruik om bakteriese infeksies te behandel), aangesien LENBUCOD kan die uitskeiding van aminoglikosiede verminder en hulle toksisiteit verhoog.
- Sulfonielurea-middels (medisynes wat gebruik word om diabetes te behandel), aangesien die uitwerking van sulfonielurea verhoog kan wees. U bloedglukosevlakke moet noukeurig gemonitor word.
- LENBUCOD kan hartversaking vererger, die spoed van filtrasie in die niere verlaag en die vlakke van hartglikosiede, bv. digoksien, in die plasma verhoog (medisyne wat gebruik word om hartprobleme te behandel).
- Die gelyktydige toediening van LENBUCOD met digoksien, fenitoïen (medisyne wat gebruik word om epilepsie te behandel) of litium (wat gebruik word om sekere geestessiektes te behandel), kan die vlak van hierdie medisynes verhoog.
- Siklosporien of takrolimus (medisynes wat gebruik word om sommige inflammatoriese siektes te behandel, en gebruik word ná oorplantings) en sekere NSAIMs kan lei tot die risiko van ontwikkeling van niervergiftiging en nierskade. Hierdie effek kan nie vir die kombinasie van siklosporien en ibuprofeen, soos gevind in LENBUCOD, uitgeskakel word nie.

- Cholestiramien, wat gebruik word om u cholesterol-vlakke te verlaag en ibuprofeen (soos in LENBUCOD) veroorsaak ’n verlengde en verlaagde opname van ibuprofeen. U moet hierdie medisynes ten minste ’n uur uitmekaar neem.
- Mifepristoon (’n medisyne wat gebruik word om swangerskap te beëindig), aangesien LENBUCOD die beoogde uitwerking van mifepristoon kan verminder, wanneer dit binne ’n interval periode van agt tot twaalf dae ná mifepristoon toegedien word.
- Probenesied of sulfinpirasoon (medisyne wat gebruik word om jig te behandel), kan ’n vertraging in die uitskeiding van ibuprofeen (soos in LENBUCOD) veroorsaak. Die aksie van hierdie medisynes om jig te verminder, kan ook verlaag word.
- Kinoloon-antibiotika (medisynes wat gebruik word om infeksies te behandel) saam met LENBUCOD kan u kanse om stuiptrekkings (stuipaanvalle) te kry, verhoog.
- Sidovudien (medisyne gebruik tydens MIV-infeksie), aangesien toksisiteit in die bloed kan voorkom, bloeding in ’n gewrig kan voorkom (ook bekend as hemartrose), en die versameling van bloed buite die are of slagare veroorsaak. U gesondheidsorg kundige moet u bloedtellings monitor vir een tot twee weke na aanvang van kombinasie-behandeling.
- Ritonavir (medisyne wat gebruik word vir behandeling van MIV-infeksie) kan die konsentrasie van NSAIMs soos ibuprofeen (soos in LENBUCOD) verhoog.
- Beenmurg-onderdrukkers bv. azatioprien - gebruik van LENBUCOD en hierdie medisynes kan lei tot vermindering van bloedplaatjies, wat die risiko van bloeding of kneusing verhoog, en afname in die hoeveelheid wit bloedselle veroorsaak, wat infeksies meer waarskynlik maak.
- Alkohol, bisfosfonate (medisynes wat gebruik word om osteoporose te behandel) of oksipentifilien (medisyne wat gebruik word om bloedsirkulasie te verhoog), kan die risiko vir bloeding en seervorming verhoog wanneer dit saam met LENBUCOD gebruik word.
- Baklofeen (medisyne vir die behandeling van spierspastisiteit – ’n abnormale toename in spiertonus of styfheid van die spier) moet versigtigheid gebruik word, aangesien die risiko vir baklofeen-vergiftiging hoër kan wees.

- Vorikonasool en flukonasool (ook bekend as CYP2C9-inhibeerders) (medisynes wat vir swaminfeksies gebruik word) kan die uitwerking van LENBUCOD verhoog. Die dosis van LENBUCOD moet dus verlaag word.
- *Ginkgo biloba* (’n kruiemedisyne), aangesien daar is ’n kans is dat u bloedingsnewe-effekte meer geredelik kan ervaar indien u dit saam met LENBUCOD gebruik.

Parasetamol soos in LENBUCOD

Die gelyktydige gebruik van:

- Lewerensiem-induserende, of ander medisynes wat tot lewerskade kan lei, aangesien daar ’n verhoogde risiko van lewervergiftiging, sowel as ’n verlaagde effek van parasetamol is.
- Metoklopramied (medisyne vir behandeling van naarheid), aangesien die manier waarop parasetamol (soos in LENBUCOD) in die liggaam opgeneem word, verander kan word.
- Cholestiramien (medisyne wat gebruik word om u cholesterolvlakke te verlaag), aangesien die opname van parasetamol (soos in LENBUCOD) verlaag kan wees wanneer dit binne een uur ná gebruik van cholestiramien geneem word.
- Probenesied (medisyne vir die behandeling van jig), aangesien die manier hoe LENBUCOD in die liggaam geëlimineer word, kan verander.

Kodeïen soos in LENBUCOD

Die gelyktydige gebruik van:

- Monoamienoksidase inhibeerders (gewoonlik gebruik vir die behandeling van depressie of bipolêre versteuring), indien u hierdie medisyne gebruik, of in die laaste 14 dae gebruik het. Dodelike reaksies kan soms voorkom.
- Alkohol of ander sentrale senuweestelsel-onderdrukkers (bv. kalmerende of ontspanningsmiddels, hipnotika, verdowingsmiddels, slaapmiddels en medisyne bekend

as fenotiasiene) kan lei tot verhoogde newe-effekte soos lomerigheid en ingeperkte konsentrasie, wat deur kodeïen veroorsaak word.

- Anticholinergiese middels (atropien of antihistamiene soos difenhidramien), aangesien dit erge hardlywigheid kan veroorsaak.
- Medisyne vir die behandeling van diarree, aangesien dit tot erge hardlywigheid en sentrale senuweestelsel-onderdrukking kan lei.
- Medisynes wat bloeddruk verlaag, aangesien die uitwerking van hierdie medisynes verhoog kan wees wanneer dit saam met kodeïen, soos in LENBUCOD, gebruik word.

LENBUCOD met alkohol

Moenie alkohol drink terwyl u LENBUCOD gebruik nie. Alkohol kan u meer lomerig laat voel, u risiko om ‘n maagseer en bloeding te kry verhoog, en u risiko vir lewerskade verhoog.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u kan dalk swanger wees, of beplan om ’n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik.

Swangerskap

U moenie LENBUCOD gebruik indien u alreeds 20 weke of langer swanger is nie. Gebruik van NSAIMs, insluitend ibuprofeen soos bevat in LENBUCOD, teen ongeveer 20 weke van swangerskap of later kan u ongebore baba benadeel (sien ‘Waarskuwing en voorsorgmaatreëls’ hierbo). LENBUCOD moenie teen 20 weke of later in u swangerskap geneem word nie, aangesien dit ernstige hart-, long- en lewerversteurings in die ongebore kind kan veroorsaak (sien ‘Moenie LENBUCOD gebruik nie’ hierbo). Indien teen die einde van swangerskap gebruik word, kan dit bloedingsgeneigdheid in beide die moeder en die kind veroorsaak en die krag van baarmoeder-kontraksies verswak, wat geboorte kan vertraag.

Borsvoeding

U moenie LENBUCOD gebruik as u borsvoed nie.

Babas van moeders wat kodeïen gebruik tydens borsvoeding kan ŉ verhoogde risiko hê van toksisiteit van die morfien-metaboliet.

Vrugbaarheid

LENBUCOD behoort tot ŉ groep medisynes (NSAIMs) wat vrugbaarheid in vroue kan verlaag. Hierdie uitwerking is omkeerbaar met staking van die medisyne.

Bestuur en hantering van masjinerie

LENBUCOD kan duiseligheid, versteurde sig, lomerigheid of verlies van konsentrasie veroorsaak, wat die vermoë om te bestuur en take te verrig of deur te voer, kan beïnvloed (sien Moontlike newe-effekte).

Dit is nie altyd moontlik om te voorspel tot watter mate LENBUCOD met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie enige aktiwiteite verrig wat breinwaaksaamheid, oordeel en/of klankkoördinasie en sig vereis, bv. bestuur, ry, vlieg, seil of hantering van masjinerie/toerusting, totdat u bewus is van die mate waartoe LENBUCOD u beïnvloed nie.

3. Hoe om LENBUCOD te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Gebruik LENBUCOD altyd presies soos beskryf in hierdie voubiljet, of soos deur u dokter, apteker of verpleegkundige voorgeskryf is. Bevestig met u dokter, apteker of verpleegkundige indien u onseker is.

Gebruik die laagste effektiewe dosis vir die korste moontlike duur van behandeling.
MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.

Die algemene dosis vir volwassenes en kinders ouer as 12 jaar is:
Neem een tot twee (1 tot 2) tablette ses-uurliks (6-uurliks) indien nodig, en nie meer as ses tablette in ‘n periode van vier-en-twintig uur nie.
Raadpleeg u gesondheidsorgverskaffer indien u verdere behandeling na vyf dae benodig.
LENBUCOD is teenaangedui in kinders onder die ouderdom van 12 jaar.

Indien u meer LENBUCOD gebruik indien wat u moes
In geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Onmiddellike mediese aandag is krities. Selfs al toon u nie enige simptome van ‘n oordosis nie, gaan onmiddellik na u naaste hospitaal of gifhulpsentrum.

Ibuprofeen soos in LENBUCOD
Die mees algemene aangemelde simptome van oordosering is naarheid, abnormale pyn, lusteloosheid (toestand van slaperigheid of ernstige onvermoë om te reageer en onaktiwiteit), braking, versteurde visie, duiseligheid en ander sentrale senuweestelsel (SSS) simptome (soos hoofpyn, duiseligheid, gesuis in die ore bekend as tinnitus, stuiptrekkings, en verlies van bewussyn). Ander simptome van ’n oordosis kan nistagmus (onwillekeurige ritmiese beweging van die oë), koue gevoel, bloeding van die spysverteringskanaal, koma, apnee (kort periodes van geen asemhaling) en diarree insluit. Disoriëntasie, opgewerktheid, floutes en kardiovaskulêre toksisiteit, insluitend lae bloeddruk, en stadige of vinnige hartklop, is aangemeld. In gevalle van beduidende oordosering is nier- en lewerskade moontlik.

In meer ernstige vergiftiging word toksisiteit in die sentrale senuweestelsel opgemerk, wat voorkom as vertigo (geen balans of gevoel dat die aarde spin), duiseligheid, lomerigheid, somtydse opgewerktheid en verlies van bewussyn of koma.

U asma kan ook vererger.

LENBUCOD bevat parasetamol en ’n oordosis kan dodelik wees.
Die simptome van ’n oordosis sluit naarheid, braking, anoreksie en maagpyn in. Tekens van lewerskade kan eers na 12 tot 48 uur, of later ná oordosis duidelik word. Dit kan lei tot koma of dood. Nierversaking sowel as metaboliese asidose (die opbou van suur in die liggaam as gevolg van niersiekte of nierversaking) en hartritme-probleme kan voorkom.

Indien u vergeet om LENBUCOD te gebruik
Moenie ’n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte
LENBUCOD kan newe-effekte hê
Nie alle newe-effekte wat vir LENBUCOD aangemeld is word in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak, of u ervaar enige nadelige gevolge tydens gebruik van LENBUCOD, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Staak gebruik van LENBUCOD indien enige van die volgende gebeur en lig onmiddellik u dokter in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, tong en mond of keel, wat dit moeilik maak om te sluk of asem te haal.
- Veluitslag of jeukerigheid.
- Blase op u vel of binne-in u mond, neus, vagina of boude, aangesien hierdie alles as gevolg van ernstige allergiese reaksies bekend as Stevens-Johnson se Sindroom (SJS) of toksiese epidermale nekrolise (TEN) kan wees.
- Vinnige hartklop (ook bekend as tagikardie), afname in bloeddruk tot ’n punt van lewensbedreigende skok.

- Mondsere, koorsblare en sere op, of pynlike tong.
- Velknoppe of galbulte (geswelde, rooi of wit, jeukerige dele van die vel).
- Die voorkoms van ‘n veluitslag of sonbrand wanneer u buite was (selfs op ‘n bewolkte dag).

Hierdie is alles ernstige newe-effekte. Indien u enige van hulle ervaar, het u dalk ’n ernstige reaksie teenoor LENBUCOD gehad. U mag dringende mediese aandag of hospitalisasie benodig.

Lig u dokter onmiddellik in, of gaan na u naaste hospitaal indien u enige van die volgende opmerk:

- Kortasem, borspyn of swelling (wat ’n simptoom van hartversaking kan wees).
- Pyn in die bors (ook bekend as *angina pectoris*).
- Vinnige of ongereelde hartklop.
- ’n Blokkasie van bloedvloei na die hartspier, ook bekend as ’n hartaanval (miokardiale infarksie).
- Sukkel om asem te haal (respiratoriese depressie) of ’n opbou van vloeistof in die longe (bekend as pulmonale edeem).
- Bronchospasma (waar u lugweë in ’n spasma gaan wat dit moeilik maak om asem te haal, wat hyging en hoes kan veroorsaak).
- Inflammatoriese long-versteuring met simptome van hoes en vinnige, vlak asemhaling (alveolitis), sowel as die infiltrasie van wit bloedselle in die longe (bekend as pulmonale eosinofilie) wat ’n droë hoes, koors, vinnige asemhaling en asemnood veroorsaak.
- Maagpyn, slegte spysvertering, sooibrand, winderigheid, naarheid (siek gevoel), braking (opgooi), diarree of hardlywigheid en droë mond.
- Bloeding in die maag of derms (gastroïntestinale bloeding) bv. swart, teeragtige stoelgang (melena) of bloed braak (hematemese), somtyds in ’n lewensbedreigende mate en maagsere.
- Inflammasie van die derms of verergering van inflammasie van die dikderm (kolitis) en

spysverteringskanaal (Crohn se siekte), sowel as komplikasies van uitstulping van die dikderm (perforasie of fistel), opgeblasenheid en verminderde eetlus.

- Vergeling van die vel of die wit van u oë (geelsug of hepatitis).
- Nier- of lewerversaking.
- Aseptiese meningitis (inflammasie van die beskermende membrane wat die brein bedek) met simptome wat stywe nek, hoofpyn, naarheid, braking, koors en disoriëntasie insluit.
- Asma aanvalle.
- Verhoogde druk binne u kopbeen.
- ’n Ernstige velreaksie bekend as GRESS-sindroom kan voorkom. Simptome van GRESS sluit in: veluitslag, koors, swelling van limfkliere en ’n toename van eosinofiele (’n tipe wit bloedsel).
- ’n Rooi, skubberige, wydverspreide veluitslag met bulte onder die vel en blase wat hoofsaaklik in velvoue, romp en boonste ledemate voorkom met gepaardgaande koors by die aanvang van behandeling (akute algemene eksantematiese pustulose).

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Lig u dokter in indien u enige van die volgende opmerk:

Gereelde newe-effekte:

- Duiseligheid.
- Sooibrand, slegte spysvertering, maagkrampe en -pyn, naarheid, hardlywigheid, diarree, braking en winderigheid, verminderde eetlus.
- Veluitslag, jeukerigheid (bekend as pruritus).

Minder gereelde newe-effekte:

- Inflammasie in die neus (rinitis).

- Verandering van sekere komponente van u bloed wat kan insluit koors, seer keel, mondsere, griepagtige simptome, moegheid, neus- en velbloedings.
- Verwarde toestand, senuweeagtigheid, slapeloosheid, depressie, rusteloosheid, angs, gemoedsveranderinge, hallusinasie, gevoel dat die aarde draai.
- Lomerigheid, hoofpyn, moegheid, opgewerktheid, prikkelbaarheid,
- Versteurde sig en ander oog-reaksies soos dubbelvisie.
- Gelui in die ore.
- Rinitis (seisoenale loopneus), bronchospasma en respiratoriese onderdrukking (sukkel om asem te haal).
- Abnormaliteite van lewerfunksietoetse, inflammasie van die lewer, lewer-disfunksie.
- Fotosensitiwiteitsreaksie ('n toestand waar u vel uitermatig sensitief is vir sonlig) en ander velreaksies.
- Inperking van nierfunksie, nierpyn en inflammasie van die niere, en ander veranderinge van u normale nierfunksie.
- Verandering van sekere stowwe in u bloed
- Inflammasie van die pankreas.
- Voel oormatig gelukkig.
- Verandering in die manier hoe u hart klop.
- Voel flou wanneer u staan (ortostatiese hipotensie).
- Naarheid, braking, hardlywigheid of droë mond.
- Pyn in die bokant van die buik, wat veroorsaak word deur spasma van u galblaas of -buis.
- Sukkel om te urineer, spasma van die uretra of die galbuis.
- Verlaging van liggaamstemperatuur (hipotermie).
- Abdominale pyn, wat die risiko van inflammasie van die pankreas insluit, wat erge pyn in die buik en rug veroorsaak.

Newe-effekte van onbekende frekwensie:

- ’n Afname in die aantal wit bloedselle (neutropenie).
- ’n Abnormale sensasie, tipies tinteling of prikkeling (‘naalde-en-spelde’) ook bekend as parestesie.
- Veranderinge in u sig.
- Veranderinge in u gehoor en ’n sensasie dat die aarde draai (vertigo).
- Swelling (edeem), hoë bloeddruk en hartversaking.
- Longprobleme.
- Lewerskade wat deur vergiftiging van u lewer veroorsaak word.
- Onwel-gevoel (malaise).
- Dit kan ook baie lae vlakke van kalium in u bloed veroorsaak (sien afdeling 2)
- LENBUCOD kan, veral wanneer dit teen hoër as aanbevole dosisse of vir langdurige tydperke geneem word, skade aan u niere veroorsaak en hulle verhoed om sure behoorlik uit u bloed na die urien te verwyder (renale tubulêre asidose) (sien afdeling 2). Hierdie is ’n baie ernstige toestand en sal onmiddellike behandeling vereis. Tekens en simptome sluit spierswakheid en lighoofdigheid in.
- Swelling van die gesig, skubberige, afskilferende vel, ’n pienk of rooi veluitslag met of sonder etter-gevulde knoppe of blase en sere op, of pynlike tong, Blase op die vel in u mond, geswelde spoegkliere. Die voorkoms van ’n veluitslag of sonbrand wanneer u buite was (selfs op ’n bewolkte dag).
- Ernstige velreaksies soos swelling, jeukerigheid, erge rooi veluitslag, veral as dit u hele liggaam bedek (lyk soos allergiese bulte), droë mond, hoofpyn, stuiptrekkings, koors en koma.
- Knoppe of galbulte op die vel (opgehewe, rooi of wit, jeukerige dele vel), brandgevoel en pyn (terugslag geneesmiddel uitslag).

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. U kan newe-effekte ook by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en elektroniese aanmeldingsplatform (who-umc.org) op die SAHPRA se webwerf. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van LENBUCOD te verskaf.

Om newe-effekte direk by die HRS aan te meld, kontak +27 11 635 0134 of epos Adcock.aereports@adcock.com.

5. Hoe om LENBUCOD te bêre

Bêre alle medisyne buite bereik van kinders.

- Bêre teen of benede 25 ºC.
- Moenie gebruik ná die vervaldatum soos op die houer aangedui nie.
- Neem alle ongebruikte medisyne na u apteker terug.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van verpakking en ander inligting

Wat LENBUCOD bevat

Die aktiewe bestanddele is kodeïenfosfaat 10 mg, ibuprofeen 200 mg en parasetamol 350 mg.

Die ander bestanddele is:

Kolloïdale silikondioksied, FD&C blou nr. 1 aluminium-lak kleursel, gliserolmonokaprielokapraat, makrogol (PEG) polivinielalkohol ent-kopolimeer, mikrokristallyne sellulose PH102, voorafgegelatiniseerde stysel, steariensuur, talk.

Hoe LENBUCOD lyk en inhoud van die verpakking

LENBUCOD is 'n blou, langwerpige, dubbel-konvekse, filmbedekte tablet.

LENBUCOD (30 tablette) is verpak in ’n wit hoë-digtheid poliëtileen (HDPE) bottel, met ’n wit polipropileen (PP) deksel wat geseël is met ’n hitte-induksie voering.

Houer van Registrasiesertifikaat

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Hierdie voubiljet is mees onlangs hersien op

6 Februarie 2025

Registrasienommer

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