PROFESSIONAL INFORMATION
STOPAYNE TABLETS
SCHEDULING STATUS S5

1. NAME OF THE MEDICINE
STOPAYNE TABLETS, tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

Meprobamate	150 mg
Codeine phosphate	8 mg
Paracetamol	320 mg
Caffeine anhydrous	32 mg

Excipients with known effect:
Contains sugar (lactose monohydrate): 1 mg
Contains the colouring agent sunset yellow FCF (E 110)
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets. Light green, round biconvex tablets, scored on one side and RIO embossed on the other side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
STOPAYNE TABLETS relieve mild to moderate pain and fever, and pain associated with tension.

4.2 Posology and method of administration
Posology
DO NOT EXCEED THE RECOMMENDED DOSE.
Adult dosage: Two tablets three or four times a day as required. Do not use continuously for more than ten days without consulting your doctor.

Special populations
No information available.

Paediatric population
No information available.

Method of administration
Oral.

4.3 Contraindications
Hypersensitivity to any of the active ingredients or to any of the excipients of STOPAYNE TABLETS (see section 2 and section 6.1).

STOPAYNE TABLETS should not be given to patients with acute intermittent porphyria or a history of epilepsy.

STOPAYNE TABLETS is contraindicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

STOPAYNE TABLETS is contraindicated in patients taking monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

4.4 Special warnings and precautions for use
STOPAYNE TABLETS are not recommended for use by pregnant or breastfeeding women (see section 4.6).
Do not use continuously for more than ten days without consulting your doctor.
Consult your doctor if no relief is obtained with the recommended dosage.

Paracetamol
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.
Paracetamol dosages in excess of those recommended may cause severe liver damage.
Patients suffering from liver of kidney disease should take paracetamol under medical supervision.

Codeine
Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.
Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics, sedatives, and phenothiazines.
The prolonged use of high doses of codeine has produced dependence of the morphine type.

Caffeine
Caffeine should be given with care to patients with a history of peptic ulceration.

Meprobamate
Patients receiving meprobamate should be warned that their tolerance to ingested alcohol and other depressants of the central nervous system may be lowered with consequent impairment of judgement and co-ordination. Symptoms of porphyria may be exacerbated (see section 4.3). Prolonged use of meprobamate may lead to the development of dependence of the barbiturate-alcohol type. Meprobamate may induce the hepatic microsomal enzymes involved in drug metabolism.

Contains the colouring agent sunset yellow FCF (E 110), which may cause allergic type reactions (including bronchial asthma) in certain individuals.

Contains 1 mg lactose monohydrate per tablet. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interactions with other medicines and other forms of interaction
No information available.

Paediatric population
No information available.

4.6 Fertility, pregnancy and lactation
Pregnancy
STOPAYNE TABLETS is not recommended for use by pregnant women.

Breastfeeding
STOPAYNE TABLETS is not recommended for use by breastfeeding women.

Fertility
No information available.

4.7 Effects on ability to drive and use machines
The use of this medicine may cause drowsiness and care should be taken when driving or operating machinery. Reduce dosage if necessary.

4.8 Undesirable effects
Sensitivity reactions resulting in reversible skin rash or blood disorders may occur.

a. Summary of the safety profile
No information available.

b. Tabulated summary of adverse reactions

Codeine	
SYSTEM ORGAN CLASS	**ADVERSE REACTIONS**
Psychiatric disorders	Changes of mood.
Nervous system disorders	Drowsiness, confusion, vertigo, restlessness, orthostatic hypotension and raised intracranial pressure may occur.
Eye disorders	Miosis.
Cardiac disorders	Bradycardia, palpitations.
Gastrointestinal disorders	Codeine may cause nausea, vomiting, constipation, and dry mouth.
Skin and subcutaneous tissue disorders	Sweating and facial flushing. Reactions such as urticaria and pruritus may occur.
Renal and urinary disorders	Micturition may be difficult and there may be ureteric or biliary spasm.
General disorders and administration site conditions	Hypothermia.
Caffeine	
SYSTEM ORGAN CLASS	**ADVERSE REACTIONS**
Nervous system disorders	Caffeine may cause restlessness, excitement, muscle tremor.
Eye disorders	Scintillating scotoma.
Ear and labyrinth disorders	Tinnitus.
Cardiac disorders	Tachycardia and extrasystoles.
Gastrointestinal disorders	Caffeine increases gastric secretions and may cause gastric ulceration.
Meprobamate	
SYSTEM ORGAN CLASS	**ADVERSE REACTIONS**
Blood and lymphatic system disorders	Blood disorders including agranulocytosis, eosinophilia, leukopenia, thrombocytopenia, and aplastic anaemia have been reported.
Nervous system disorders	The most frequent side effect of meprobamate is drowsiness. Paraesthesia, weakness, headache, excitement, dizziness, ataxia.
Eye disorders	Disturbances of vision.
Cardiac disorders	Hypotension, tachycardia and cardiac arrhythmias may occur.
Gastrointestinal disorders	Nausea, vomiting, diarrhoea.
Skin and subcutaneous tissue disorders	Hypersensitivity reactions may occur. They may be limited to skin rashes, urticaria and purpura or may be more severe with angioneurotic oedema, bronchospasm, or anuria. Erythema multiforme has been reported.

Post marketing experience
No information available.

c. Description of selected adverse reactions
No information available.

d. Paediatric population
No information available.

e. Other special population(s)
No information available.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose
In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre. Symptoms of overdosage include nausea and vomiting. Liver damage, which may be fatal, may only appear after a few days. Kidney failure has been described following acute intoxication.

Acute meprobamate overdosage can produce stupor, coma, convulsions, shock, circulatory and respiratory collapse. Because meprobamate is rapidly absorbed from the gastrointestinal tract, gastric lavage must be carried out shortly after ingestion and must be thorough.

In paracetamol overdose prompt treatment is essential. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 to 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of medicine that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia, and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of sever liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

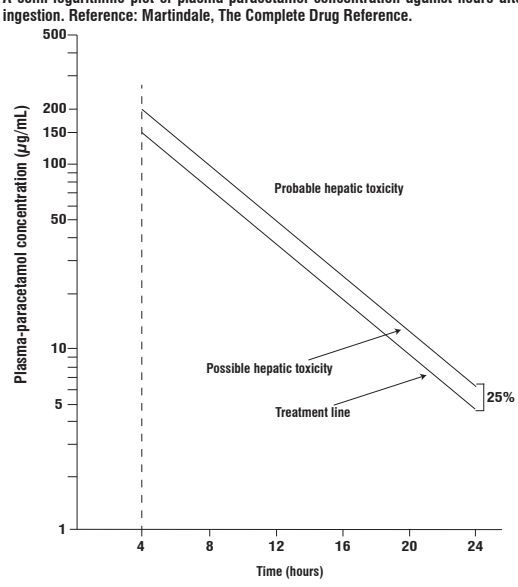
Treatment for paracetamol overdosage:
Although evidence is limited it is recommended that any adult person who has ingested 5 to 10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 mL dextrose injection given **intravenously (IV)** over 15 minutes, followed by an infusion of 50 mg/kg in 500 mL dextrose injection over the next four hours, and then 100 mg/kg in 1 000 mL dextrose injection over the next sixteen hours. T**he volume of intravenous fluid should be modified for children.**

Although the oral formulation is not the treatment of choice,
140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.

A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion. Reference: Martindale, The Complete Drug Reference.



Those whose plasma paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line". Prothrombin index correlates best with survival.

For overdose with an extended/modified release preparation the value of the nomogram is unknown. As there is no information on the plasma levels of paracetamol after an overdose of extended/modified release paracetamol preparations, all patients with suspected or known overdose with such preparations should receive N-acetylcysteine. Because of lack of data for extended/modified release formulations, a level below the "treatment line" of the nomogram may not exclude the possibility of toxicity.

Monitor all patients with significant ingestions for at least ninety-six hours.

5. PHARMACOLOGICAL PROPERTIES
Category and class: A 2.8 Analgesic combinations.
STOPAYNE TABLETS have analgesic, antipyretic and tranquilising properties.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Brilliant blue FCF (E133)
Gelatine.
Lactose monohydrate.
Magnesium stearate.
Povidone.
Pregelatinized starch.
Purified talc.
Quinoline yellow (E104).
Sodium starch glycolate.
Sunset yellow FCF (E110).

6.2 Incompatibilities
No data available.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from light and moisture.

6.5 Nature and contents of container
PVC/PVDC/Aluminium blister strips in an outer carton.
or
White HDPE bottles with white HDPE screw caps in an outer carton.
Pack sizes: 100 or 1 000 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)
B 866 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of registration: 19 November 1986

10. DATE OF REVISION OF THE TEXT
05 June 2021

PATIENT INFORMATION LEAFLET
STOPAYNE TABLETS
SCHEDULING STATUS S5

STOPAYNE TABLETS
Meprobamate, Codeine phosphate, Paracetamol and Caffeine
Contains sugar (lactose monohydrate): 1 mg

Read all of this leaflet carefully before you start taking STOPAYNE TABLETS
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- STOPAYNE TABLETS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What STOPAYNE TABLETS is and what it is used for
STOPAYNE TABLETS contain the active ingredients Paracetamol 320 mg, Codeine phosphate 8 mg, Caffeine anhydrous 32 mg and Meprobamate 150 mg.
STOPAYNE TABLETS is used for the short-term treatment of mild to moderate pain and fever, and pain associated with tension.

2. What you need to know before you take STOPAYNE TABLETS
Do not take STOPAYNE TABLETS
- if you have ever had an allergic reaction to paracetamol, codeine phosphate, caffeine, meprobamate or any of the other ingredients in the tablets (these are listed in section 6),
- if you have porphyria (a rare inherited blood disorder),
- if you have a history of fits (epilepsy),
- if you have any lung/airway (respiratory) problems, especially in the presence of cyanosis (condition where your skin or lips turn blue due to an insufficient level of oxygen in the blood) and excessive mucus and fluid secretion in the airways,
- if you are experiencing an asthma attack or heart failure (secondary to a chronic lung disease),
- if you had an operation on the biliary tract (liver, gall bladder and bile ducts),
- if you suffer from acute alcoholism (alcohol poisoning due to rapid and excessive alcohol intake),
- if you suffer from a head injury or any conditions in which intracranial pressure is raised (a rise in the pressure around your brain),
- if you are taking an antidepressant in the class called monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

Warnings and precautions
Take special care with STOPAYNE TABLETS and tell your doctor:
- if you are pregnant or breastfeeding as STOPAYNE TABLETS is not recommended for use during pregnancy or breastfeeding,
- if your symptoms do not improve on the recommended dosage as prescribed by your doctor,
- if you have a history of liver or kidney disease as paracetamol intake must then be carefully monitored and controlled by your doctor,
- if you are suffering from hypothyroidism (underactive thyroid gland), adrenocortical insufficiency (condition in which the adrenal glands do not produce enough steroid hormones), prostatic hypertrophy (enlarged prostate gland) or shock,
- if you suffer from or have ever suffered from inflammatory or obstructive bowel disorders, such as ulcers (peptic ulceration), small bowel obstruction (blockage of the bowel), etc,
- if you are using anaesthetics, hypnotics, sedatives, phenothiazines and alcohol as these may, in combination with STOPAYNE TABLETS, enhance impairment of judgement and coordination (feeling dizzy or drowsy). See **"Other medicines and STOPAYNE TABLETS"**.

Do not use STOPAYNE TABLETS for more than ten (10) days at a time without consulting your doctor. If you use STOPAYNE TABLETS for too long or continuously, it may cause dependency and addiction. This can give you withdrawal symptoms from the medicine when you stop taking it. See section 3 **"If you stop taking/using STOPAYNE TABLETS"**.

STOPAYNE TABLETS contains paracetamol, which my may be fatal or cause severe liver damage in overdose. Contact the nearest doctor, hospital or poison centre

immediately following overdose or suspected overdose. See section 3, **"If you take more STOPAYNE TABLETS than you should"**.

The dosage of STOPAYNE TABLETS should be reduced in the elderly and in weakened (frail) patients.

STOPAYNE TABLETS contains:
• Lactose monohydrate: Patients with the rare hereditary conditions of lactose or galactose intolerance should not take STOPAYNE TABLETS.
• Sunset yellow FCF, E110 (colouring agent): May cause allergic type reactions (including asthma attack) in certain individuals.

Children
No data are available on the use of STOPAYNE TABLETS in children.

Other medicines and STOPAYNE TABLETS
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Some medicines may increase or decrease the effects of STOPAYNE TABLETS, and your doctor may wish to monitor you carefully if you are taking any of the following:
• Alcohol,
• Medication to numb sensation in certain areas of the body or induce sleep (anaesthetics),
• Sleeping pills (hypnotics),
• Tranquillisers (sedatives) used to make you feel more relaxed,
• Phenothiazines, such as chlorpromazine or prochlorperazine. This is a class of medicines used for mental disorders such as schizophrenia or psychotic disorders.

Pregnancy and breastfeeding
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 STOPAYNE TABLETS.
STOPAYNE TABLETS is, however, not recommended for use by pregnant or breastfeeding women.

Driving and using machines
It is not always possible to predict to what extent STOPAYNE TABLETS may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which STOPAYNE TABLETS affects them. STOPAYNE TABLETS, however, may cause drowsiness and care should be taken when driving or operating machinery.

3. How to take STOPAYNE TABLETS
Do not share medicines prescribed for you with any other person.
Always take STOPAYNE TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose of STOPAYNE TABLETS is two tablets three to four times daily as required. Take the tablets with a sufficient quantity of liquid (e.g., one glass of water).

Your doctor will tell you how long your treatment with STOPAYNE TABLETS will last. However, it is not recommended to use continuously for more than ten days. If you have the impression that the effect of STOPAYNE TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more STOPAYNE TABLETS than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Specialised treatment is essential as soon as possible.

Symptoms
The most common symptoms of STOPAYNE TABLETS overdosage is nausea and vomiting. Additional symptoms resulting from meprobamate may include stupor (state of speechlessness, motionlessness, and unresponsiveness to stimulation, but are otherwise completely conscious), coma, convulsions (fits), shock, problems with your blood vessels (circulatory collapse) and breathing (respiratory system/respiratory collapse).

Symptoms of paracetamol overdosage in the first 24 hours include pallor (unhealthy pale appearance), nausea, vomiting, loss of appetite and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. Liver damage may lead to brain damage, coma and death. Kidney failure may develop even in the absence of sever liver damage and heart rhythm problems (arrhythmias) have also been reported.

If you forget to take / missed a dose of STOPAYNE TABLETS
If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking/using STOPAYNE TABLETS
This medicine contains codeine and meprobamate and can cause addiction if you take it continuously for more than ten days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

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

If any of the following happens, stop using STOPAYNE TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:
• skin rashes, urticaria (red, itchy welts that result from a skin reaction) and purpura (blood spots, which are purple-coloured spots on the skin),
• swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
• erythema multiforme (skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring).
These are all very serious side effects. If you have them, you may have had a serious reaction to STOPAYNE TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
• Mood changes,
• Drowsiness, confusion, vertigo (feeling off balance), orthostatic hypotension (a sudden drop in blood pressure when you stand from a seated or lying down position) and raised intracranial pressure (rise in pressure around your brain),
• Caffeine may cause restlessness, excitement, muscle tremor (spasms or twitching),
• Meprobamate may cause drowsiness, paraesthesia (tingling or pricking / "pins and needles"), weakness, headache, excitement, dizziness, ataxia (slurred speech, stumbling, falling, and incoordination),
• Miosis (constriction of the pupils / small pupils) and scintillating scotoma (visual aura or blind spot that affects a part of your vision), other vision disturbances,
• Ringing or buzzing noise in one or both ears,
• Codeine may cause nausea, vomiting, constipation, and dry mouth,
• Caffeine increases gastric secretions (such as stomach acid) and may cause stomach ulcers,
• Sweating, facial flushing (blushing), urticaria (skin rash) and pruritus (unpleasant itch),
• Difficulty in urination, spasms in urinary tract causing lower abdominal pain, spasm is the bile duct causing upper abdominal pain,
• Drop in body temperature (hypothermia),
• Tachycardia (rapid heartbeat), extrasystoles (skipped heartbeats). Hypotension (low blood pressure), cardiac arrhythmias (improper heartbeat),
• Blood disorders including agranulocytosis (lowered white blood cell count), eosinophilia (high level of white blood cells), leukopenia (low level of white blood cells), thrombocytopenia (low blood plate count) and aplastic anaemia (a rare condition in which the body stops producing enough new blood cells).
• Skin and subcutaneous tissue disorders (see above hypersensitivity reactions that may occur).

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STOPAYNE TABLETS.

5. How to store STOPAYNE TABLETS
Store all medicines out of reach of children.
Store at or below 25 °C. Protect from light and moisture.
Do not use after the expiry date stated on the box and HDPE bottle or blister.
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 STOPAYNE TABLETS contains
The active substances are paracetamol, codeine phosphate, caffeine and meprobamate.

The other ingredients of STOPAYNE TABLETS are:
Brilliant blue FCF (E133), gelatine, lactose monohydrate, magnesium stearate, povidone, pregelatinised starch, purified talc, quinoline yellow (E104), sodium starch glycolate, sunset yellow FCF (E110).

What STOPAYNE TABLETS looks like and contents of the pack
Light green, round biconvex tablets, scored on one side and RIO embossed on the other side.
STOPAYNE TABLETS is packaged into PVC/PVDC/Aluminium blister strips in an outer carton, or in white HDPE bottles with white HDPE screw caps in an outer carton.
Pack sizes: 100 or 1 000 tablets. Not all pack sizes may be marketed.

Holder of Certificate of Registration
Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK /232625

This leaflet was last revised in
05 June 2021

Registration number
B 866 (Act 101/1965)

PASIENTINLIGTINGSTUK
SKEDULERINGSTATUS S5

STOPAYNE TABLETS
Meprobamaat, Kodeïenfosfaat, Parasetamol en Kafeïen
Bevat suiker (laktosemonohidraat): 1 mg

Lees hierdie hele inligtingstuk noukeurig deur voordat u begin om STOPAYNE TABLETS te neem
• Hou hierdie inligtingstuk. U moet dit dalk weer lees.
• Indien u enige verdere vrae het, vra asseblief u dokter of apteker.
• STOPAYNE TABLETS is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al het hulle dieselfde simptome as u.

Wat is in hierdie inligtingstuk

1.Wat STOPAYNE TABLETS is en waarvoor dit gebruik word
STOPAYNE TABLETS bevat die aktiewe bestanddele Parasetamol 320 mg, Kodeïenfosfaat 8 mg, Kafeïen anhidries 32 mg en Meprobamaat 150 mg.
STOPAYNE TABLETS word gebruik vir die korttermyn behandeling van ligte tot matige pyn en koors, en pyn wat verband hou met spanning.

2.Wat u moet weet voordat u STOPAYNE TABLETS neem
Moenie STOPAYNE TABLETS neem
• indien u ooit 'n allergiese reaksie op parasetamol, kodeïenfosfaat, kafeïen, meprobamaat of enige van die ander bestanddele in die tablette (hierdie is gelys in afdeling 6) gehad het,
• indien u porfirie het ('n skaars oorerflike bloedversteuring),
• indien u 'n geskiedenis van aanvalle (epilepsie) het,
• indien u enige long/lugweg (respiratoriese) probleme het, veral in die teenwoordigheid van sianose (toestand waar u vel of lippe blou word as gevolg van onvoldoende suurstof in die bloed) en oormatige slym- en vloeistofafskeiding in die lugweë,
• indien u 'n asma-aanval of hartversaking ervaar (sekondêr tot 'n chroniese longsiekte),
• indien u 'n operasie aan die galweg (lewer, galblaas en galbuise) gehad het,
• indien u aan akute alkoholisme ly (alkoholvergiftiging as gevolg van vinnige en oormatige inname van alkohol),
• indien u ly aan 'n kopbesering of enige ander toestande waarin intrakraniale druk verhoog is ('n toename in die druk rondom u brein),
• indien u 'n antidepressant in die klas neem wat monoamienoksidase-inhibeerders genoem word, of binne veertien dae nadat u sodanige behandeling gestaak het.

Waarskuwings en spesiale voorsorgmaatreëls
Neem spesiale sorg met STOPAYNE TABLETS en vertel u dokter:
• indien u swanger is of borsvoed, aangesien STOPAYNE TABLETS nie aanbeveel word vir gebruik in swangerskap en borsvoeding nie,
• indien u simptome nie op die aanbevole dosis, soos voorgeskryf deur u dokter, verbeter nie,
• indien u 'n geskiedenis van lewer- of niersiekte het, aangesien parasetamol inname versigtig deur u dokter gemonitor en beheer moet word,
• indien u ly aan hipotireose (onderaktiewe skildklier), adrenokortikale ontoereikenheid (toestand waarin die byniere nie genoeg steroïedhormone produseer nie), prostaat hipertrofie (vergrote prostaatklier) of skok,
• indien u aan inflammatoriese- of obstruktiewe dermversteurings ly of gely het, soos ulkusse (peptiese ulserasie), dundermobstruksie (verstopping van die derm), ens,
• indien u anestetika, hipnotika, kalmeermiddels, fenotiasiene en alkohol gebruik, aangesien dit, in kombinasie met STOPAYNE TABLETS, die inkorting van oordeel en koördinasie (duiselig of lomerig voel) intensifeer. Sien **"Ander medisyne en STOPAYNE TABLETS"**.

Moenie STOPAYNE TABLETS vir meer as tien (10) dae op 'n slag gebruik sonder om u dokter te raadpleeg nie. Indien u STOPAYNE TABLETS te lank of aanhoudend gebruik, kan dit afhanklikheid en verslawing veroorsaak. Dit kan u onttrekkingsimptome van die medisyne gee indien u ophou om dit te gebruik. Sien afdeling 3 **"Indien u ophou om STOPAYNE TABLETS te neem/gebruik"**.

STOPAYNE TABLETS bevat parasetamol, wat dodelik kan wees of ernstige leweskade kan veroorsaak as gevolg van oordosering. Kontak die naaste dokter, hospitaal of gifbeheersentrum onmiddellik na oordosering of vermoedelike oordosering. Sien afdeling 3, **"Indien u meer STOPAYNE TABLETS neem as wat u moet"**.

Die dosering van STOPAYNE TABLETS moet verminder word by bejaardes en verswakte (broos) pasiënte.

STOPAYNE TABLETS bevat:
• Laktosemonohidraat: Pasiënte met die seldsame oorerflike toestande van laktose of galaktose-onverdraagsaamheid moet nie STOPAYNE TABLETS neem nie.
• Sonsondergangeel FCF, E110 (kleurmiddel): Kan allergiese-tipe reaksies (insluitend asma-aanval) by sekere individue veroorsaak.

Kinders
Geen data is beskikbaar oor die gebruik van STOPAYNE TABLETS by kinders nie.

Ander medisyne en STOPAYNE TABLETS
Vertel altyd u gesondheidsorgkundige indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Sommige medisyne kan die effekte van STOPAYNE TABLETS verhoog of verlaag, en u dokter wil u noukeurig monitor indien u enige van die volgende neem:
• Alkohol,
• Medikasie om gevoelloosheid in sekere dele van die liggaam te veroorsaak of slaap te induseer (anestetika),
• Slaappille (hipnotika),
• Kalmeermiddels wat gebruik word om u ontspanne laat voel,
• Fenotiasiene, soos chloorpromasien of prochloorperasien. Dit is 'n klas medisyne wat gebruik word vir geestesversteurings soos skisofrenie of psigotiese versteurings.

Swangerskap en borsvoeding
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 gesondheidsorgkundige vir advies voordat u STOPAYNE TABLETS neem.
STOPAYNE TABLETS word egter nie aanbeveel vir gebruik deur swanger of borsvoedende vroue nie.

Bestuur en gebruik van masjiene
Dit is nie altyd moontlik om te bepaal tot watter mate STOPAYNE TABLETS met u daaglikse aktiwiteite kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle weet tot watter mate STOPAYNE TABLETS hulle beïnvloed nie. STOPAYNE TABLETS kan egter lomerigheid veroorsaak en sorg moet geneem word tydens bestuur of wanneer masjiene gebruik word.

3.Hoe om STOPAYNE TABLETS te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem STOPAYNE TABLETS altyd presies soos u dokter of apteker u vertel het. Raadpleeg u dokter of apteker indien u onseker is.

Die gewone volwasse dosis van STOPAYNE TABLETS is twee tablette drie tot vier keer per dag soos benodig. Neem die tablette met 'n genoegsame hoeveelheid vloeistof (bv. een glas water).

U dokter sal u vertel hoe lank u behandeling met STOPAYNE TABLETS sal duur. Dit word egter nie aanbeveel om langer as tien dae aanhoudend te gebruik nie. Indien u die indruk het dat die effek van STOPAYNE TABLETS te sterk of te swak is, vertel dit aan u dokter of apteker.

Indien u meer STOPAYNE TABLETS neem as wat u moet
In die geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum selfs al voel u goed. Dit is omdat te veel parasetamol vertraagde, ernstige lewerskade kan veroorsaak. Gespesialiseerde behandeling is so spoedig moontlik noodsaaklik.

Simptome
Die mees algemene simptome van STOPAYNE TABLETS oordosering is naarheid en braking. Bykomende simptome as gevolg van meprbamaat kan insluit stomheid (toestand van sprakeloosheid, bewegingloosheid en geen reaksie vir stimulasie nie, maar is andersins heeltemal by hul bewussyn), koma, konvulsies (aanvalle), skok. probleme met u bloedvate (ineenstorting van die bloedsomloop) en probleme met asemhaling (respiratoriese stelsel/respiratoriese ineenstorting).

Simptome van parasetamol oordosering in die eerste 24 uur sluit in bleekheid (ongesonde bleek voorkoms), naarheid, braking, verlies aan eetlus en moontlike abdominale pyn. Ligte simptome gedurende die eerste twee dae van akute vergiftiging weerspieël nie die moontlike erns van die oordosering nie. Lewerskade kan lei tot breinskade, koma en dood. Nierversaking kan ontwikkel , selfs in die afwesigheid van ernstige lewerskade en hartritme probleme (aritmie) is ook gerapporteer.

Indien u 'n dosis mis of vergeet om STOPAYNE TABLETS te neem
Indien u 'n dosis mis, neem dit so gou as moontlik. Indien dit egter amper tyd is vir die volgende dosis, los die gemiste dosis en gaan terug na u gewone doseringskedule. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u ophou om STOPAYNE TABLETS te neem/gebruik
Die medisyne bevat kodeïen en meprobamaat en kan verslawing veroorsaak indien u dit aanhoudend vir meer as tien dae neem. Wanneer u ophou om dit te neem kan u onttrekkings simptome kry.
U moet met u dokter of apteker praat indien u dink dat u aan onttrekkings simptome ly.

4.Moontlike newe-effekte
STOPAYNE TABLETS kan newe-effekte hê.
Nie alle newe-effekte wat vir STOPAYNE TABLETS gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ervaar terwyl u STOPAYNE TABLETS neem, raadpleeg u gesondheidsorgkundige vir advies

Indien enige van die volgende gebeur, hou op om STOPAYNE TABLETS te gebruik en vertel u dokter onmiddellik of gaan na die ongevalle afdeling van u naaste hospitaal:
• veluitslag, urtikarie (rooi, jeukerige hale as gevolg van 'n velreaksie) en purpura (bloedvlekke, wat perskleurige vlekke op die vel is),
• swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk en asemhaling kan veroorsaak,
• multivorme eriteem (vel of mondletsels wat 'n pienk-rooi middel, omring deur 'n ligte rand en 'n buitenste pienk-rooi ring het).
Hierdie is alles baie ernstige newe-effekte. Indien u dit het, het u dalk 'n ernstige reaksie op STOPAYNE TABLETS gehad. U benodig dalk dringende mediese hulp of hospitalisasie.

Vertel u dokter indien u enige van die volgende opmerk:
• Gemoedsveranderinge,
• Lomerigheid, verwardheid, vertigo (voel van balans af), ortostatiese hipotensie ('n skielike val in bloeddruk wanneer u vanuit 'n sittende of lêende posisie opstaan) en verhoogde intrakraniale druk (toename in druk rondom u brein).
• Kafeïen kan rusteloosheid, opgewondenheid, spierbewings (spasmas of rukkings) veroorsaak,
• Meprobamaat kan lomerigheid, parastesie (tinteling of prikkeling / "spelde en naalde"), swakheid, hoofpyn, opgewondenheid, duiseligheid, ataksie (onduidelike spraak, struikel, val en gebrek aan koördinasie) veroorsaak,
• Miose (vernouing van die pupille / klein pupille) en skitterende skotoma (visuele aura of blinde kol wat 'n gedeelte van u visie beïnvloed), ander visieversteurings,
• Lui of bruisende geluid in een of beide ore,
• Kodeïen kan naarheid, braking, hardlywigheid en droë mond veroorsaak,
• Kafeïen kan gastriese uitskeidings verhoog (soos maagsuur) en kan maagsere veroorsaak,
• Sweet, bloos in die gesig, urtikarie (veluitslag) en pruritus (onaangename jeuk),
• Probleme met urinering, spasmas in die urienweg wat laer abdominale pyn veroorsaak, spasma in die galbuis wat boonste abdominale pyn veroorsaak,
• Daling in liggaamstemperatuur (hipotermie),
• Tagikardie (vinnige hartklop), ekstrasistoles (oorgeslaande hartkloppe). Hipotensie (lae bloeddruk), hartaritmieë (onbehoorlike hartklop),
• Bloedversteurings insluitend agranulositose (verlaagde witbloedseltelling), eosinofilie (hoë vlak van witbloedselle), leukopenie (lae vlak van witbloedselle), trombositopenie (lae bloedplaattelling), en aplastiese anemie ('n seldsame toestand waar die liggaam ophou om genoeg nuwe bloedselle te produseer),
• Vel- en subkutaneuse weefselversteurings (sien hipersensitiwiteitsreaksies wat kan plaasvind).

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

Rapportering van newe-effekte
Indien u newe-effekte kry, praat met u dokter of apteker. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. U kan ook newe-effekte rapporteer aan SAHPRA via die **6.04 Adverse Drug Reaction Reporting Form,** gevind aanlyn onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rapporteer, kan u help om meer inligting oor die veiligheid van STOPAYNE TABLETS te voorsien.

5.Hoe om STOPAYNE TABLETS te bêre
Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 25 °C. Beskerm teen lig en vog.
Moenie gebruik na die vervaldatum wat op die boks en HDPE houer of stulpstrook aangedui is nie.
Neem alle ongebruikte medisyne terug na u apteker. Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6.Inhoud van die verpakking en ander inligting
Wat STOPAYNE TABLETS bevat
Die aktiewe bestanddele is parasetamol, kodeïenfosfaat, kafeïen en meprobamaat.

Die ander bestanddele van STOPAYNE TABLETS is:
Briljante blou FCF (E133), gelatien, laktosemonohidraat, magnesiumstearaat, povidoon, voorgegelatiniseerde stysel, gesuiwerde talk, kinoliengeel (E104), natriumstyselglikolaat, sonsonderganggeel FCF (E110).

Hoe STOPAYNE TABLETS lyk en inhoud van die verpakking
Liggroen, ronde bikonvekse tablette, gekeep aan die een kant en RIO gebosseleer aan die ander kant.
STOPAYNE TABLES is verpak in PVC/PVDC/Aluminium stulpstroke in 'n buitenste karton of in wit HDPE bottels met wit HDPE skroefdoppe in 'n buitenste karton.
Verpakkingsgroottes: 100 of 1 000 tablette. Nie alle verpakkingsgroottes word noodwendig bemark nie.

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