SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

VELTEX 75 CR 75 mg capsules

VELTEX 100 CR 100 mg capsules

VELTEX AMPOULES 75 mg injections

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each VELTEX 75 CR capsule contains diclofenac 75 mg as diclofenac sodium.

Each VELTEX 100 CR capsule contains diclofenac 100 mg as diclofenac sodium.

Excipients with known effect

VELTEX 75 CR capsules contain 105,93 mg and VELTEX 100 CR 141,25 mg sugar (sucrose).

Each VELTEX AMPOULES ampoule contains diclofenac 75 mg as diclofenac sodium in 3 ml.

Excipients with known effect

Preservative: Benzyl alcohol 4 % *m/v.*

Contains sodium metabisulphite (antioxidant).

Contains sugar: D-mannitol 18 mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

VELTEX 75 CR: Size 2 hard gelatin capsule with opaque light blue cap and opaque light blue body.

VELTEX 100 CR: Size 2 hard gelatin capsule with opaque red cap and opaque ivory body.

Injection.

VELTEX AMPOULES: 3 ml amber labelled ampoule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VELTEX is indicated in:

Rheumatoid arthritis.

Ankylosing spondylitis.

Osteoarthritis and spondyloarthritis.

Painful musculoskeletal conditions.

Non-articular rheumatism.

Acute attacks of gout.

Painful post-operative and post-traumatic inflammation and swelling.

Pain following dental surgery.

Symptomatic treatment of primary dysmenorrhoea.

VELTEX AMPOULES are specifically used as initial therapy for inflammatory and degenerative rheumatic disease, as well as for painful conditions due to the inflammation of non-rheumatic origin and acute attacks of gout.

4.2 Posology and method of administration

Posology

Adults:

The initial daily dosage is 100 to 150 mg.

In milder cases as well as for maintenance therapy, 75 to 100 mg is usually sufficient.

The maximal daily dose is 150 mg. This dosage is usually administered in two to three fractional doses

When used as an analgesic, the daily dosage should be adjusted to the individual need of the patient and special circumstance, e.g. for the treatment of primary dysmenorrhoea or post-operative pain. In these cases the dosage is 75 to 150 mg and the treatment should commence with the first

symptoms, and depending on the severity, continued for a few days.

In cases where the symptoms are most pronounced during the night or in the early morning, VELTEX CR 100 capsules should be taken preferably in the evening.

Use the lowest effective dose for the shortest possible duration of treatment.

Children: Recommended daily dose of 1 to 3 mg per kg body weight in children able to swallow capsules.

VELTEX AMPOULES: The directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site. After inserting the needle, the plunger should be pulled back to avoid inadvertent intra-arterial injection.

NOT TO BE ADMINISTERED BY INTRAVENOUS INJECTION.

The usual adult dose is 75 mg (3 ml) by deep intra-gluteal injection into the upper outer quadrant once daily. This dose may be repeated after a few hours if required in severe or hospitalised patients. Each injection must be administered at a different site.

Parenteral administration should not be continued for more than two days. Treatment may be continued with oral therapy.

Method of administration

VELTEX AMPOULES: Deep intra-gluteal injection.

VELTEX CR 75 and VELTEX CR 100: For oral use.

The capsule should be swallowed intact with some fluid.

The pellets should never be chewed.

4.3 Contraindications

- Hypersensitivity to diclofenac or to any of the excipients of VELTEX listed in section 6.1.
- In asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other medicines with prostaglandin synthetase inhibiting activity.
- VELTEX should not be used in patients with porphyria.
- Avoid use of NSAIDs in women around 30 weeks gestation and later in pregnancy due to the

risks of oligohydramnios/ foetal renal dysfunction and premature closure of the foetal ductus arteriosus (see section 4.4 and 4.6).

- Not recommended in children under 2 years of age. Not recommended in children unable to swallow capsules.
- Heart failure, established ischaemic heart disease and/or cerebrovascular disease (stroke) and peripheral arterial disease.
- History of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous NSAIDs, including VELTEX.
- Active or history of recurrent ulcer/haemorrhage/perforations.

4.4 Special warnings and precautions for use

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with VELTEX therapy. In view of the VELTEX inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Caution is required in patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) and should only be treated with diclofenac after careful consideration.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs including VELTEX, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.

The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of VELTEX, in patients with a history of ulcers, and the elderly.

When gastrointestinal bleeding or ulceration occurs in patients receiving VELTEX, treatment with VELTEX should be stopped.

VELTEX should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn’s disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolyis have been reported. VELTEX should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Regular use of NSAIDs such as VELTEX during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in utero, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

VELTEX must be given with care to patients with asthma or bronchospasm, bleeding disorders,

patients with peptic ulceration or a history of such ulceration, and with cardiovascular disease.

Patients with gastrointestinal symptoms or with severe hepatic or renal damage should be kept under close surveillance during therapy.

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Patients suffering from impaired hepatic, cardiac or renal functions should be carefully monitored. If peptic ulceration or gastrointestinal bleeding occurs while under treatment the medicine must be withdrawn.

VELTEX may mask the signs and symptoms of infection due to its pharmacodynamic properties. Injections of VELTEX may cause local pain and irritation; abscesses and local necrosis have been reported.

VELTEX capsules contain sucrose.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

VELTEX ampoules contain benzyl alcohol.

Increased risk due to accumulation in young children.

High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

Foetal Toxicity: Limit use of NSAIDs, including VELTEX, between 20 to 30 weeks of pregnancy due to the risk of oligohydramnios/foetal renal dysfunction. Avoid use of NSAIDs in women around 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/foetal renal dysfunction and premature closure of the foetal ductus arteriosus.

If NSAID treatment is necessary between 20 weeks and 30 weeks gestation, limit VELTEX use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if VELTEX treatment extends beyond 48 hours. Discontinue VELTEX if oligohydramnios occurs and follow up according to clinical practice (see section 4.3 and 4.6).

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as VELTEX. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis.

Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here

may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue VELTEX and evaluate the patient immediately.

4.5 Interaction with other medicines and other forms of interaction

VELTEX must be given with care to people who are receiving coumarin anticoagulants. Serious interactions have been reported after the use of high doses of methotrexate in combination with diclofenac.

When given with preparations containing lithium or digoxin it may raise the plasma concentration of these compounds.

Acute allergic reactions have been reported. Because of the possibility of cross sensitivity due to structural relationships that exist among nonsteroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds. Plasma concentrations are significantly decreased by the concomitant administration of doses of aspirin.

Concomitant administration of glucocorticoids or other nonsteroidal anti-inflammatory agents may aggravate gastrointestinal side effects. Dosages may have to be reduced in the elderly.

NSAIDs: use of two or more NSAIDs concomitantly could result in an increase in side effects.

Anticoagulants: VELTEX may enhance the effects of anticoagulants such as warfarin.

Antiplatelet medicines and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding.

4.6 Fertility, pregnancy and lactation

VELTEX should not be given to pregnant or lactating women.

Regular use of NSAIDs during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus in utero and possibly in persistent pulmonary hypertension of the newborn.

The onset of labour may be delayed and its duration increased.

Use of NSAIDs, including VELTEX, can cause premature closure of the foetal ductus arteriosus and foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, the use of VELTEX dose and duration between 20 and 30 weeks of gestation should be limited and avoided at around 30 weeks of gestation and later in pregnancy (see section 4.3 and 4.4).

4.7 Effects on ability to drive and use machines

Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking or receiving VELTEX, should refrain from driving or using machines.

4.8 Undesirable effects

a) Summary of the safety profile

Gastrointestinal disturbances such as nausea, vomiting, abdominal discomfort and diarrhoea may occur. Peptic ulceration and gastrointestinal bleeding have been reported. Other side effects include nervousness, headache, dizziness, depression, drowsiness, insomnia, blurred vision and tinnitus. Oedema and skin reactions such as rashes, urticaria, pruritus and eczema have been reported. Abnormalities of liver function tests, impairment of renal functions, agranulocytosis, aplastic anaemia and thrombocytopenia have been observed. Sensitivity reactions such as bronchospasm or anaphylactoid reactions, jaundice, hepatitis, renal failure and nephrotic syndrome may occur. Other side effects that may occur are minor hearing disorders, irritability, agitation, palpitations, tiredness and increased serum transaminase levels.

Cardiac disorders: Oedema, hypertension and cardiac failure.

Gastrointestinal system disorders: The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.

Skin and subcutaneous tissue disorders: Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) (see section 4.4)

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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Treatment

There is no known antidote.

Treatment should be symptomatic and supportive.

Specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating VELTEX because of its extensive protein binding rate and metabolism.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 3.1 Antirheumatics (Anti-inflammatory agents).

ATC Code: M01AB05

VELTEX is a non-steroidal compound with antirheumatic, anti-inflammatory, analgesic and antipyretic action. *In vitro*, the active substance strongly inhibits prostaglandin synthetase and also has an inhibitory effect on platelet aggregation. VELTEX inhibits prostaglandin biosynthesis and this inhibition has an important bearing on its mechanism of action. Prostaglandins appear to play a major role in causing inflammation, pain and fever.

5.2 Pharmacokinetic properties

Absorption

The micro-pellets contained in the VELTEX capsules will be released in the stomach and, mixed with its content, reach the intestinal tract, where the dissolution occurs slowly. Serum peak levels are achieved within 1 to 3 hours and due to the quantity of diclofenac presented in these micro-pellets an extended plasma concentration is maintained.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

List of excipients for VELTEX 75 CR and VELTEX 100 CR

Eudragit “RS”100 (*Ammonio Methacrylate Copolymer (type B)*)

Maize starch

Paraffin

Macrogol (Polyethylene glycol 4000)

Talc

Composition of the hard capsule

VELTEX 75 CR:

Indigotine (E132)

Titanium oxide (E171)

Gelatine

VELTEX 100 CR:

Eritrosine (E127)

Gelatine

Red iron oxide (E172)

Titanium dioxide (E171)

Yellow iron oxide (E172)

List of excipients for VELTEX AMPOULE:

D-mannitol

benzyl alcohol

propylene glycol

sodium hydroxide

sodium metabisulphite

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

VELTEX 75 CR capsules: 36 months

VELTEX 100 CR capsules: 24 months

VELTEX AMPOULES: 24 months

6.4 Special precautions for storage

VELTEX 75 CR and VELTEX 100 CR capsules:

Store at or below 25 °C.

Protect from light and moisture.

VELTEX AMPOULES:

Protect from heat and light.

Store between 15 °C and 25 °C.

Do not refrigerate.

6.5 Nature and contents of container

VELTEX 75 CR capsules: Amber glass bottles of 6, 10 and 30 capsules.

VELTEX 100 CR capsules: Amber glass bottles of 30 capsules.

VELTEX AMPOULES: Packs of 5 x 3 ml and 50 x 3 ml ampoules.

Not all pack sizes/types are necessarily 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)

VELTEX 75 CR: 27/3.1/0321

VELTEX 100 CR: W/3.1/329

VELTEX AMPOULES: 29/3.1/0394

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 10/12/1992

10. DATE OF REVISION OF THE TEXT

29 May 2023

Namibia		
NS2	Veltex 75 CR Capsules	04/3.1/1023
	Veltex 100 CR Capsules	04/3.1/1022
Botswana		
S2	Veltex 75 CR Capsules	BOT1803288
	Veltex 100 CR Capsules	BOT1803289

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