Approved Patient Information Leaflet for Medicines for Human Use:

PARATIV 1 g

SCHEDULING STATUS: S3

PARATIV 1 g Solution for Infusion

Each 100 mL bottle contains 1 000 mg of paracetamol

Contains sugar (mannitol: 38,5 mg/mL)

Read all of this leaflet carefully before you are given PARATIV 1 g.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PARATIV 1 g is and what it is used for

PARATIV 1 g is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

PARATIV 1 g is indicated for the short-term treatment of mild to moderate pain, especially following dental procedures and minor orthopaedic surgery, and for the short-term treatment of fever, when oral medicine is unsuitable.

The 100 mL vial is restricted to adults, adolescents and children weighing more than 33 kg.

2. What you need to know before you are given PARATIV 1 g

PARATIV 1 g should not be administered to you if:

- You are hypersensitive (allergic) to the paracetamol or to any of the other ingredients contained in PARATIV 1 g (listed in section 6)
- You are hypersensitive (allergic) to the propacetamol hydrochloride (another analgesic for infusion and a precursor of paracetamol)
- You suffer from severe liver disease.

Warnings and precautions

PARATIV 1 g 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.

Dosages of PARATIV 1 g in excess of those recommended may cause severe liver damage.

PARATIV 1 g can cause serious skin reactions, which can be fatal. Use of the medicine should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity (allergy).

It is recommended to use a suitable oral analgesic (pain relieving medicine) treatment as soon as this is possible.

Take special care with PARATIV 1 g if:

- you suffer from liver or kidney disease, or from alcohol abuse or excessive alcohol intake (3 or more alcoholic drinks every day)
- you suffer from a condition that causes the breakdown of red blood cells, called Glucose 6 Phosphate Dehydrogenase deficiency
- you are taking other medicines containing paracetamol or propacetamol (including prescription and non-prescription medicines). Doses higher than the recommended dose entails risk for very serious liver damage
- in cases of nutritional problems (malnutrition) or dehydration
- you are pregnant or breastfeeding
- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using PARATIV 1 g immediately and contact your doctor.
- you are taking or have recently taken medication, especially probenecid, salicylamide or enzyme-inducing substances.

Inform your doctor before treatment if any of the above-mentioned conditions apply to you.

PARATIV 1 g contains mannitol. Mannitol may cause mild laxative effects.

Other medicines and PARATIV 1 g

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

Do not take anything else containing paracetamol while taking this medicine. This medicine contains paracetamol, and this must be taken into account if other medicines containing

paracetamol or propacetamol are taken, in order not to exceed the recommended daily dose (see following section).

A dose reduction should be considered for concomitant treatment with Probenecid.

Salicylamide may prolong the time that paracetamol remains active in the body.

Caution should be paid to the concomitant intake of enzyme-inducing substances which may increase the risk of paracetamol induced liver injury. These substances include but are not limited to: barbiturates, isoniazid, anticoagulants, zidovudine, amoxicillin + clavulanic acid, and ethanol.

Phenytoin administered concomitantly with PARATIV 1 g may result in decreased paracetamol effectiveness and an increased risk of liver toxicity. Patients receiving phenytoin therapy should avoid large and/or chronic doses of paracetamol. Patients should be monitored for evidence of liver toxicity.

Caution is advised when paracetamol is administered concomitantly with flucloxacillin due to the increased risk of a potentially serious acid-base imbalance being caused in your blood. Close monitoring is recommended.

Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.

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 using this medicine.

Pregnancy

Inform your doctor if you are pregnant. PARATIV 1 g should only be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended dose and duration must be strictly observed.

Breastfeeding

Rash in nursing infants has been reported. Caution should be used when administering PARATIV 1 g to women who are breastfeeding.

PARATIV 1 g contains mannitol. Mannitol may cause mild laxative effects.

3. How to use PARATIV 1 g

DO NOT EXCEED THE RECOMMENDED DOSE.

Do not share medicines prescribed for you with any other person.

Carefully follow all instructions given to you by your doctor, nurse or pharmacist.

You will not be expected to give yourself PARATIV 1 g. It will be given to you by a person who is qualified to do so.

The solution for infusion will be injected directly into your vein (intravenous administration) over 15 minutes.

Your doctor will prescribe the appropriate dose for you. The dose you are given is based on your weight and general condition.

If you have the impression that the effect of PARATIV 1 g, solution for infusion is too strong or too weak, talk to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you are given more PARATIV 1 g than you should

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

Since a health care provider will administer PARATIV 1 g, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PARATIV 1 g

Since a health care provider will administer PARATIV 1 g, it is unlikely that the dose will be missed.

4. Possible side effects

PARATIV 1 g can have side effects.

Not all side effects reported for PARATIV 1 g are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PARATIV 1 g, please consult your health care provider for advice.

If any of the following happens, stop using PARATIV 1 g and tell your doctor immediately

- A serious skin reaction or allergic reaction; redness of the skin, flushing, itching and abnormally rapid beating of the heart.

These are very rare but very serious side effects. If you have them, you may have had a serious reaction to PARATIV 1 g. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Hypersensitivity (allergic) reaction.
- Kidney pain, kidney failure, white blood cells in urine.

- Increased levels of liver enzymes (hepatic transaminases), liver inflammation, pancreas inflammation.
- Low blood platelets (blood cells that help the blood clot when there are injuries to blood vessels) (thrombocytopenia).
- Decrease in number of white blood cells (type of blood cells that are part of your body's immune system and help fight infection and other diseases) (Leukopenia and Neutropenia).
- Decrease in the number of red blood cells (anemia).
- Decrease in the number of red blood cells, white blood cells and platelets (pancytopenia).
- Drop in blood pressure (Hypotension).

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:

- Pain and burning sensation at injection site have been reported.

Less frequent side effects:

- Malaise

Side effects with frequency unknown:

- Erythema, flushing, pruritus and tachycardia have been reported.

The following adverse events have also been reported during postmarketing surveillance but the incidence rate (frequency) is not known.

Low blood platelets, increased heart rate, nausea, vomiting, administration site reaction, liver inflammation (hepatitis), hepatic failure, increased liver enzymes, severe allergic reaction, severe swelling in the deep layers of skin, skin redness (erythema), flushing, itch (pruritus), rash,

skin pustules, skin peeling and blistering (Toxic epidermal necrolysis, Stevens-Johnson syndrome, Fixed drug eruptions (FDE), Drug-induced hypersensitivity syndrome (DIHS)).

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. 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 PARATIV 1 g.

5. How to store PARATIV 1 g

Store all medicines out of reach of children.

Your doctor, pharmacist or healthcare professional knows how to store PARATIV 1 g. The doctor or nurse who is administering PARATIV 1 g to you, will make sure that the medicine is not used after the expiry date printed on the vial. They will also visually inspect the solution before giving it to you. Only clear solution without particles will be used.

Store at or below 25 °C.

Keep in original package.

6. Contents of the pack and other information

What PARATIV 1 g contains

The active substance is Paracetamol.

The other ingredients are Disodium phosphate anhydrous, Hydrochloric acid 5N (pH-adjustment), Mannitol, Sodium hydroxide 5N (pH adjustment), Water for injection

What PARATIV 1 g looks like and contents of the pack

PARATIV 1 g is available in 100 mL polypropylene blow-fill-sealed bottles.

The blow-fill-sealed bottles are over sealed with a molded plastic cap with a rubber gasket and a pull ring, or with plastic caps with embedded elastomers (twin ports), enclosed with a pouch.

Pack size of 10 bottles.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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