

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

REOPARA 10 mg/ml Solution for Infusion

Paracetamol

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or your pharmacist.

What is in this leaflet

1. What REOPARA 1g is and what it is used for
2. What you need to know before REOPARA 1g is administered to you
3. How REOPARA 1g will be administered to you
4. Possible side effects
5. How to store REOPARA 1g
6. Contents of the pack and other information

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

REOPARA 1g is an analgesic (it relieves pain), so it is used for the short-term treatment of mild to moderate pain, especially following dental procedures and minor orthopaedic surgery and the short-term treatment of fever where the oral route is unsuitable.

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It is restricted to use in adults and children weighing more than 33 kg (approximately 11 years old).

2. What you need to know before REOPARA 1g is administered to you

REOPARA 1g should not be administered to you:

- If you are hypersensitive (allergic) to paracetamol, or any of the other ingredients.
- If you have severe liver disease

Warnings and precautions

Special care should be taken with REOPARA 1g:

- If you have liver problems, including conditions such as hepatitis or Gilbert's syndrome, or if you are recovering from any liver disease.
- If you are taking any other medicine that contains paracetamol (also called acetaminophen) — taking too much paracetamol can cause serious liver damage, even if you don't feel unwell right away.
- Prescription and non-prescription medicines
- If you have nutritional problems i.e. anorexia bulimia or cachexia (malnutrition) or dehydration i.e Vomiting and Diarrhoea.
- If you drink alcohol regularly, especially if you consume 3 or more alcoholic drinks per day.
- If you have a rare condition called G6PD deficiency, as REOPARA 1g may cause a type of anaemia in these patients.
- If you have kidney disease or your kidneys are not working properly.

Other medicines and REOPARA 1g

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Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Before taking REOPARA 1g, please tell your healthcare provider if you are using any of the following medicines, as they may interact with REOPARA 1g and affect how it works or increase the risk of side effects:

- **Probenecid:** This medicine can slow down the clearance of REOPARA 1g from your body. Your doctor may need to adjust your dose.
- **Salicylamide:** This may make REOPARA 1g stay longer in your body.
- **Medicines that increase liver enzymes:** Some medicines like barbiturates, isoniazid, anticoagulants, zidovudine, amoxicillin with clavulanic acid, and alcohol can increase the risk of liver damage when taken with REOPARA 1g.
- **Phenytoin:** Taking REOPARA 1g with phenytoin may reduce REOPARA's effectiveness and increase the risk of liver damage. Your doctor will monitor you carefully.
- **Flucloxacillin:** Using REOPARA 1g with flucloxacillin may increase the risk of a rare but serious acid-base imbalance, especially if you have kidney problems, infection, malnutrition, or drink alcohol heavily. Close monitoring may be needed.

REOPARA 1g can also affect how other medicines work, especially:

- **Blood thinners (anticoagulants):** Taking REOPARA 1g with blood thinners such as warfarin may affect how your blood clots. Your doctor will monitor your blood regularly during treatment and for a week after stopping REOPARA 1g.

Always inform your doctor or pharmacist about all medicines you are taking before starting REOPARA 1g.

REOPARA 1g with food and drink

REOPARA 1g can be used with or without food.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Driving and using machines

REOPARA 1g has no influence on the ability to drive and use machines

It is not always possible to predict to what extent REOPARA 1g may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which REOPARA 1g affects them.

REOPARA 1g contains Sodium Metabisulphite

This product contains Sodium Metabisulphite (E223); may rarely cause hypersensitivity reactions and bronchospasm.

3. How REOPARA 1g will be administered to you

DO NOT EXCEED THE RECOMMENDED DOSE.

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

The paracetamol solution is administered as an intravenous infusion over 15 minutes. Your doctor will prescribe the appropriate dose for you. The dose you are given is based on your weight.

If you use more REOPARA 1g than you should:

Since a healthcare professional will administer this medicine, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

REOPARA 1g contains paracetamol which may be fatal in overdose. In the event of over dosage or suspected over dosage and notwithstanding the fact that a person may be asymptomatic, the nearest doctor, hospital or Poison Center must be contacted immediately

If you forget to receive REOPARA 1g

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

4. Possible side effects

REOPARA 1g can have side effects.

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

If any of the following happens, stop taking REOPARA 1g and tell your doctor immediately or go to the nearest hospital, as these are very serious side effects:

- Swelling of the face, lips, mouth, throat, hands, or feet, which may cause difficulty in swallowing or breathing
- Sudden rash, itching, hives, or flushing
- Severe dizziness or fainting
- Serious skin reactions such as blistering, peeling, widespread rash, toxic epidermal necrolysis (TEN), or acute generalised exanthematous pustulosis (AGEP)
- Signs of liver problems such as yellowing of the skin or eyes, dark urine, tiredness, loss of appetite, or abdominal pain

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

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

- Fast heartbeat
- Anaphylactic reaction (severe allergic reaction) including angio-oedema

Frequent side effects:

- Nausea
- Vomiting

Less frequent side effects:

- Redness of the skin
- Rash
- Itching
- Hives
- Flushing
- Pain or discomfort at the site where the medicine is given

Frequency unknown:

- Liver problems, including severe liver injury such as fulminant hepatitis, hepatic necrosis, or liver failure

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform

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(whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of REOPARA 1g Solution for Infusion.

5. How to store REOPARA 1g

- Store all medicines out of reach of children.
- Store at or below 30°C. Do not refrigerate or freeze. Once opened, the bottle should be used immediately. Protect from Light.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use after the expiry date stated on the label.

6. Contents of the pack and other information

What REOPARA 1g contains:

Each ml contains 10 mg paracetamol as active ingredient.

Excipients:

Sodium metabisulphite, disodium edetate, mannitol, disodium hydrogen phosphate dihydrate, sodium hydroxide, citric acid monohydrate, hydrochloric acid, water for injection.

What REOPARA 1g looks like and contents of the pack

A clear, colourless solution

REOPARA 1g is filled in 100 ml USP Type II colourless glass bottle with gray bromobutyl rubber stopper and blue colored flip of seal.

Holder of Certificate of Registration

Qhayisa 2014 Trading and projects Pty Ltd t/a

REOPARA 10 mg/ml Solution for Infusion

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REOPARA 1g is manufactured by

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