

Final Approved Patient Information Leaflet for Medicines for Human Use:

PYPATARAN IV

SCHEDULING STATUS

S3

PYPATARAN IV solution for infusion

Paracetamol

Contains sugar (mannitol): 3,447 g/100 mL.

Read all of this leaflet carefully before you are given PYPATARAN

- 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.

What is in this leaflet

1. What PYPATARAN IV is and what it is used for
2. What you need to know before you are given PYPATARAN IV
3. How to receive PYPATARAN IV
4. Possible side effects
5. How to store PYPATARAN IV
6. Contents of the pack and other information

1. What PYPATARAN IV is and what it is used for

The active ingredient in PYPATARAN IV is paracetamol. PYPATARAN IV 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

(bone) surgeries and the short-term treatment of fever where you are unable to swallow medicine.

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 you are given PYPATARAN IV

PYPATARAN IV should not be administered to you:

- if you are hypersensitive (allergic) to paracetamol, paracetamol hydrochloride (another analgesic for infusion and a precursor of paracetamol) or any of the other ingredients of PYPATARAN IV (listed in section 6).
- if you have a severe liver disease.

Warnings and precautions

You must start using a suitable pain medicine that can be taken by mouth as soon as this option is possible.

Talk to your doctor or nurse before receiving PYPATARAN IV:

If you have a liver or kidney disease

- If you drink a lot of alcohol (3 or more alcoholic drinks every day)
- If you take salicylates like aspirin together with PYPATARAN IV, it increases the risk of kidney diseases. Do not exceed the recommended individual dosages for salicylates and PYPATARAN IV.
- If you are taking other medicines containing paracetamol including prescription and non-prescription medicines.
- If you have nutritional problems (malnutrition) or dehydration.
If you have eating disorders, for instance anorexia, bulimia or cachexia.
- If you are taking blood thinning medicines, such as warfarin.

- If you have Glucose 6 Phosphate Dehydrogenase (G6PD) deficiency (as this may lead to anaemia – a condition that develops when your blood produces a lower-than-normal amount of healthy red blood cells).

Take special care with PYPATARAN IV if you develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Your health care provider must immediately discontinued treatment with PYPATARAN IV, if you experience any of these symptoms.

Other medicines and PYPATARAN IV

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

In particular, tell your doctor or nurse if you are taking any of the following medicines before you are given PYPATARAN IV:

- PYPATARAN IV contains paracetamol, and this must be taken into account if other medicines containing paracetamol are taken, in order not to exceed the recommended daily dose (see section 3 below). Inform your doctor if you are taking other medicines containing paracetamol.
- A dose reduction should be considered for concomitant treatment with probenecid (a medicine used to treat gout).
- Metoclopramide may cause PYPATARAN IV to work quicker.
- Salicylamide prolong the removal of paracetamol from your body.

- Salicylates such as aspirin may increase the risk of kidney problems if you take it together with PYPATARAN IV.
- Care should be taken when using the following medicines together with PYPATARAN IV, as the use thereof may increase the risk of paracetamol induced liver toxicity: barbiturates, isoniazid, rifampicin, carbamazepine, zidovudine, amoxicillin, clavulanic acid and ethanol.
- If you are taking phenytoin (for epilepsy), the effectiveness of PYPATARAN IV may be affected.
- Please inform your doctor or pharmacist if you are taking oral anticoagulants (such as warfarin). Closer check-ups of the effect of the anticoagulant might be necessary.
- If used concomitantly with flucloxacillin, an antibiotic, close monitoring is recommended particularly in patients with a risk factor for glutathione deficiency such as severe renal impairment, sepsis, malnutrition and chronic alcoholism.

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, nurse, pharmacist, or other health care provider for advice before you are given PYPATARAN IV.

Inform your doctor if you are pregnant. PYPATARAN IV should only be used during pregnancy if clearly necessary. In this case, your doctor will strictly observe the recommended dosage and duration. If you are breastfeeding, caution is necessary when PYPATARAN IV is administered to you.

Driving and using machines

PYPATARAN IV should not affect your ability to drive.

3. How to receive PYPATARAN IV

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

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

DO NOT EXCEED THE RECOMMENDED DOSE.

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.

Your doctor will tell you how long your treatment with PYPATARAN IV will last. If you have the impression that the effect of PYPATARAN IV is too strong or too weak, tell your doctor, nurse pharmacist or other healthcare provider.

If you are given more PYPATARAN IV than you should receive

Since your healthcare provider will administer PYPATARAN IV, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

PYPATARAN IV 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 Centre must be contacted immediately.

If you missed a dose of PYPATARAN IV

Since your healthcare provider will administer PYPATARAN IV, it is unlikely that the dose will be missed.

4. Possible side effects

PYPATARAN IV can have side effects.

Not all side effects reported for PYPATARAN IV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving PYPATARAN IV, please consult your health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to PYPATARAN IV. 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:

- a serious skin reaction or allergic reaction.

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

Tell your doctor if you notice any of the following:

Less frequent

- a general feeling of discomfort, illness, or unease
- blood disorders
- a drop in blood pressure
- inflammation (swelling) of the liver and pancreas

- changes in laboratory test results, where abnormally high levels of liver enzymes are found during blood tests
- abdominal pain caused by a blocked ureter (the tube that carries urine from the kidney to the bladder)
- kidney failure
- other changes in laboratory test results include abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums.

Frequency unknown

- general swelling of the skin
- nausea (feeling sick) and vomiting (being sick)
- liver failure and liver disorders
- redness of the skin, flushing, itching and rash
- abnormally rapid beating of the heart
- pain and burning sensation at the injection site.

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

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 “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA’s publications:

<http://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of PYPATARAN IV.

5. How to store PYPATARAN IV

Store all medicines out of reach of children.

- Store at or below 30 °C and protected from light.
- Do not refrigerate or freeze.
- Do not use after the expiry date stated on the label / carton

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 PYPATARAN IV contains

- The active substance is paracetamol. Each 1 mL of PYPATARAN IV contains 10 mg of paracetamol. Each 100 mL vial contains 1 g paracetamol.
Contains sugar (mannitol): 3,447 g/100 mL.
- The other ingredients are disodium hydrogen phosphate dihydrate, hydrochloric acid, mannitol, nitrogen, and water for injection.

What PYPATARAN IV looks like and contents of the pack

PYPATARAN IV is a clear solution, colourless to faint yellow or pale yellow.

PYPATARAN IV is packed in a 100 mL clear type I glass bottle with a grey bromobutyl rubber stopper and a blue flip-off seal packed in an outer carton.

Holder of Certificate of Registration

Ascendis Pharma (Pty) Ltd

31 Georgian Crescent East

Bryanston

2191

Ascendis Pharma (Pty) Ltd, Pypataran IV solution for infusion, 10 mg/mL

South Africa

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Access to the corresponding Professional Information