PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PARAFENGEN IV solution for infusion

Paracetamol and Ibuprofen

Contains sugar (mannitol 3 285 mg/100 ml)

Anti-oxidant: cysteine hydrochloride monohydrate 0,025 % m/v.

Sodium 35,06 mg per 100 ml (0,35 mg/ml)

Please read this leaflet carefully before you are given PARAFENGEN IV

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- PARAFENGEN IV 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 PARAFENGEN IV is and what it is used for
2. What you need to know before you use PARAFENGEN IV
3. How to use PARAFENGEN IV
4. Possible side effects
5. How to store PARAFENGEN IV
6. Contents of the pack and other information

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

PARAFENGEN IV contains paracetamol 1000 mg and ibuprofen 300 mg per 100 mL vial.

Paracetamol is used to treat pain and it reduces fever. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It relieves pain. PARAFENGEN IV is used for the relief of mild to moderate pain and the reduction of fever in adults, where an intravenous route of administration is considered clinically necessary.

2. What you need to know before you use PARAFENGEN IV

PARAFENGEN IV should not be administered to you

- If you are hypersensitive (allergic) to paracetamol or ibuprofen or any of the other ingredients of PARAFENGEN IV (listed in section 6).
- If you regularly drink large quantities of alcohol.
- If you have severe heart disease or heart failure, renal (kidney) failure severe impaired kidney function or hepatic (liver) failure or liver diseases severe impaired liver function.
- If you vomited blood or material that looks like ground coffee, have (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.
- If you have a peptic ulcer (sore on the lining of the stomach or small intestine), a recent history of one, or have had peptic ulcers before.
- If you have any bleeding.
- If you have asthma, urticaria (itchy, raised, red or skin-coloured swellings) or allergic-type reactions after taking aspirin, or other NSAIDs.
- If you had or need to have coronary artery bypass graft (CABG) surgery.
- If you have spinal cord injuries.
- If you are pregnant, planning to become pregnant or are breastfeeding your baby.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you suffer from kidney disease.

- If you have a genetic abnormality that results in an inadequate amount of glucose-6-phosphate dehydrogenase (G6PD) enzyme in the blood. As a result, paracetamol may trigger the red blood cells to be broken down, resulting in anaemia.
- If you have high blood pressure or heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery.
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- If you suffer from anorexia, malnutrition or dehydration.
- If you have a history of gastrointestinal diseases, e.g., peptic ulcers, ulcerative colitis (inflammation and sores in your digestive tract), Crohn's disease (inflammation of your digestive track), hiatus hernia (stomach pushing through an opening in the diaphragm), gastro-esophageal reflux disease (stomach acid flows back into the tube connecting your mouth and stomach).
- If you suffer from any skin reactions such as Stevens-Johnson syndrome, skin rash or mucosal lesions.
- If you suffer from liver disease.
- If you have blurred vision.

Children and adolescents

This product is not recommended for children under 18 years.

Other medicines and PARAFENGEN IV

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

Tell your doctor or pharmacist if you are taking any of the following:

- Other NSAIDs, including aspirin or products containing paracetamol
- Probenecid (used to treat gout)
- Medicines that can have an effect on the liver, e.g., anticoagulants (blood thinning products like aspirin and warfarin), barbiturates (sleeping tablets), isoniazid (tuberculosis medicine), rifampicin (antibiotic), zidovudine (HIV medicine), and chronic alcohol use

- Phenytoin (used for seizures)
- Chloramphenicol (antibiotic)
- Corticosteroids (used to treat many conditions, such as inflamed areas of the body, allergic reactions, itching, e.g., prednisone, cortisone)
- Selective serotonin reuptake inhibitors (SSRIs) (used to treat depression, e.g., fluoxetine, citalopram, sertraline, paroxetine and escitalopram)
- Medicines that reduce high blood pressure, e.g., ACE-inhibitors such as captopril, beta-blockers (atenolol medicines), angiotensin-II receptor antagonists (losartan)
- Diuretics (water tablets, e.g., furosemide and thiazide)
- Lithium (used to treat some types of depression)
- Methotrexate (used to treat arthritis and some types of cancer)
- Ciclosporin or tacrolimus (immunosuppressive medicine used after organ transplant)
- Busulfan (used for treatment of cancer)
- Diflunisal (used for pain)
- Herbal extracts, like ginkgo biloba
- Quinolone antibiotics (ofloxacin, norfloxacin, ciprofloxacin, moxifloxacin)

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 receiving this medicine.

PARAFENGEN IV should not be administered to you if you are pregnant.

You should not breastfeed your baby while you are being treated with PARAFENGEN IV.

The effects of PARAFENGEN IV on fertility are unknown.

Driving and using machines

It is not always possible to predict to what extent PARAFENGEN IV may interfere with your daily activities. You should make sure that you do not engage in the above activities until you are aware how PARAFENGEN IV affects you.

PARAFENGEN IV may make you feel dizzy, sleepy, cause light-headedness or you can experience visual disturbances (see 4. Possible side effects).

PARAFENGEN IV contains sodium and mannitol

PARAFENGEN IV contains 35,06 mg sodium per 100 ml. Tell your doctor if you are on a low salt diet.

PARAFENGEN IV contains mannitol and may have a laxative effect.

Do not drink alcoholic beverages when receiving PARAFENGEN IV. Combining alcohol with PARAFENGEN IV may lead to liver damage.

3. How to use PARAFENGEN IV

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

PARAFENGEN IV will be given to you by a person who is qualified to do so.

The usual dose is one vial (100 ml) PARAFENGEN IV administered as a 15-minute infusion drip every 6 hours, as necessary. The total daily dose of 4 vials that is 4 000 mg (4 g) paracetamol should not be exceeded.

If you are given more PARAFENGEN IV than you should receive

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

In case of an overdose, symptoms generally appear within 24 hours and include nausea, vomiting, stomach pain, convulsions and you might even become unconscious. If you think you might have been given an overdose, tell a doctor or health care provider immediately due to the risk of irreversible liver damage.

4. Possible side effects

PARAFENGEN IV can have side effects.

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

If any of the following happens, tell your doctor immediately as these can be serious:

- Liver damage: nausea, vomiting, loss of appetite, pale colour of the skin, stomach pain.
- Anaphylactic reaction (sudden allergic reaction) including skin rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or trouble breathing.
- Serious skin reactions, including widespread redness and scaling of the skin, rash on the body where each mark resembles a bullseye, Stevens-Johnson syndrome a rare, serious disorder of your skin and mucous membranes. Often, it begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters.
- Perforation or gastrointestinal bleeding (vomiting blood or material that looks like coffee ground, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhea.

These are all very serious side effects, and you need urgent medical attention. If these effects are not treated, they could be fatal.

Tell your doctor if you notice any of the following:

Frequent

- Dizziness, headache, sleepiness
- Abdominal pain, diarrhoea, indigestion (dyspepsia), nausea, stomach discomfort, vomiting
- Rash, itching
- Pain at injection site, burning sensation, inflammation in the vein used for the infusion
- Decreased appetite

Frequency unknown

- Swelling, fluid retention, hypertension and heart problems (cardiac failure)
- Bleeding or bruising more easily than normal, reddish or purplish blotches under the skin, severe skin reactions such as Stevens Johnson syndrome and toxic epidermal necrolysis
- Excessive sweating, purple-coloured spots on the skin, skin becomes very sensitive to the sun
- PARAFENGEN IV, especially when taken at higher than recommended doses or for a

prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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 Acino Pharma (Pty) Ltd: E-mail: drugsafety_ZA@acino.swiss OR to_SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store PARAFENGEN IV

Store all medicines out of reach of children.

- Store at or below 25 ºC, protect from light.
- Do not refrigerate or freeze.
- Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

Do not use PARAFENGEN IV if you notice particles in the solution or the solution changes colour (it should be a clear colourless solution).

6. Contents of the pack and other information

What PARAFENGEN IV contains

- The active substances are 1 000 mg paracetamol and 300 mg ibuprofen.

- The other ingredients are cysteine hydrochloride monohydrate, disodium phosphate dehydrate, mannitol, water for injection.
- Contains an anti-oxidant (cysteine hydrochloride monohydrate 0,025 % m/v).
- Contains sugar (mannitol 3 285 mg/100 ml).
- Contains sodium 35,06 mg per 100 ml (0,35 mg/ml)

What PARAFENGEN IV looks like and contents of the pack

Clear, colourless solution, free from visible particles

100 ml glass vial closed with a rubber stopper and an aluminium flip-off cap. Supplied in packs of 10 vials.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd.

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1686

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Access to the corresponding Professional Information