PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PARACETAMOL BIOTECH IV 10 mg/mL solution for infusion

Paracetamol

Sugar free.

Read all of this leaflet carefully before PARACETAMOL BIOTECH IV is administered to you.

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

What is in this leaflet

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

1. What PARACETAMOL BIOTECH IV is and what it is used for

PARACETAMOL BIOTECH IV is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

PARACETAMOL BIOTECH IV is used for the short-term treatment (not exceeding 24 hours) of mild to moderate pain and/ or fever, when the oral route is unsuitable.

2. What you need to know before PARACETAMOL BIOTECH IV is administered

PARACETAMOL BIOTECH IV should not be administered to you:

- If you are hypersensitive (allergic) to paracetamol or paracetamol hydrochloride or any of the other ingredients of PARACETAMOL BIOTECH IV listed in section 6;
- If you have a severe liver disease or insufficiency or alcoholic liver disease;
- In children weighing less than 33 kg (approximately 11 years old).

Warnings and precautions

Tell your doctor or healthcare provider before being given PARACETAMOL BIOTECH IV infusion:

- If you take other medicines containing paracetamol.
- If you take salicylates like aspirin together with PARACETAMOL BIOTECH IV it increases the risk of kidney diseases. Do not exceed the recommended individual dosages for salicylates and PARACETAMOL BIOTECH IV.
- If you are taking blood thinning medicines, such as warfarin.
- If you drink a lot of alcohol (3 or more alcoholic drinks every day), suffer from a liver disease or suffer from malnutrition. PARACETAMOL BIOTECH IV may cause some serious harm to your liver.
- If you have liver or kidney disease (also see "PARACETAMOL BIOTECH IV contains propylene glycol" below).
- If you have eating disorders, for instance anorexia, bulimia or cachexia.
- If you have glucose 6 phosphate dehydrogenase deficiency (when someone doesn't have enough of the enzyme G6PD, which protects red blood cells).
- If you have dehydration after vomiting and/or diarrhoea.

Take special care with PARACETAMOL BIOTECH 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 PARACETAMOL BIOTECH IV, if you experience any of these symptoms.

If any of these apply to you, tell your doctor or healthcare provider before being given the infusion of PARACETAMOL BIOTECH IV.

You will be switched to a suitable oral pain treatment as soon as possible.

PARACETAMOL BIOTECH IV contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that you may not have symptoms, the nearest doctor, hospital or poison centre must be contacted immediately.

Symptoms and signs of liver damage are usually seen first after two days with a maximum usually after 4 - 6 days. Treatment with an antidote should be given as soon as possible as PARACETAMOL BIOTECH IV overdose may be fatal.

Children and adolescents

PARACETAMOL BIOTECH IV is not indicated for use in children weighing less than 33 kg (approximately 11 years old).

Other medicines and PARACETAMOL BIOTECH IV

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

The following medicines may interact with PARACETAMOL BIOTECH IV:

- Probenecid may influence the excretion of PARACETAMOL BIOTECH IV.
- Metoclopramide may cause PARACETAMOL BIOTECH 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 PARACETAMOL BIOTECH IV.
- Flucloxacillin may cause a build-up of acid in your body.
- Barbiturates and/ or primidone may reduce the effectivity of PARACETAMOL BIOTECH IV.
- Care should be taken when using the following medicines together with PARACETAMOL BIOTECH IV, as the use thereof may increase the risk of paracetamol induced liver toxicity: isoniazid, rifampicin, carbamazepine, phenytoin, zidovudine, amoxicillin, clavulanic acid and ethanol.
- Coumarin (such as warfarin) and/or indandione derivates used together with PARACETAMOL BIOTECH IV may increase the risk of bleeding. You should increase your monitoring of INR values during treatment with high doses of PARACETAMOL BIOTECH IV and a week after treatment with PARACETAMOL BIOTECH IV was stopped.

PARACETAMOL BIOTECH IV with food and drink

PARACETAMOL BIOTECH IV can be administered with or without food.

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 healthcare provider for advice before receiving PARACETAMOL BIOTECH IV.

Also see “PARACETAMOL BIOTECH IV contains propylene glycol” below.

There is no information on how PARACETAMOL BIOTECH IV affects the ability to have children.

Driving and using machines

PARACETAMOL BIOTECH IV should have no influence on your ability to drive or to use machines.

It is not always possible to predict to what extent PARACETAMOL BIOTECH IV may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving a vehicle or use machines until they are aware of the measure to which PARACETAMOL BIOTECH IV affects them.

PARACETAMOL BIOTECH IV contains propylene glycol

PARACETAMOL BIOTECH IV contains 800 mg propylene glycol in each 100 mL vial which is equivalent to 8 mg/mL.

If you suffer from a liver or kidney disease, or you are pregnant or breastfeeding, do not receive PARACETAMOL BIOTECH IV unless recommended by your doctor. Your doctor may carry out extra check while you are receiving PARACETAMOL BIOTECH IV.

PARACETAMOL BIOTECH IV contains sodium

PARACETAMOL BIOTECH IV contains 200 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 10 % of the recommended maximum daily dietary intake of sodium for an adult.

PARACETAMOL BIOTECH IV contains sodium metabisulphite

May rarely cause severe hypersensitivity reactions and bronchospasm.

3. How PARACETAMOL BIOTECH IV is administered

You will not be expected to give yourself PARACETAMOL BIOTECH IV. PARACETAMOL BIOTECH IV is usually given by a doctor or nurse who will inject the medicine into a vein.

Your doctor will prescribe the appropriate dose for you. The dose you are given is, based on your weight. The maximum daily dose is 4 g for adults (weighing over 50 kg) and 3 g for patients weighing between 50 kg and 33 kg.

Do not exceed the recommended dose.

For patients with severe kidney problems the minimum dosing interval between administrations should be at least every 6 hours, and a lower dose will be given.

Your doctor will tell you how long your treatment with PARACETAMOL BIOTECH IV will last. If you have the impression that the effect of PARACETAMOL BIOTECH IV is too strong or too weak, tell your doctor.

If you receive more PARACETAMOL BIOTECH IV than you should

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

Your doctor will treat the symptoms of an overdosage. Inform your doctor if you feel nauseous, vomit or have stomach pain.

If you forget to receive PARACETAMOL BIOTECH IV

Since a health care provider will administer PARACETAMOL BIOTECH IV, it is unlikely that the dose will be missed.

4. Possible side effects

PARACETAMOL BIOTECH IV can have side effects.

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

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

- swelling of the hands, feet, ankles, face, eyelids, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itchiness of the skin,
- fainting,
- painful skin rash accompanied by flu, and blistering (peeling) of the skin, mouth, eyes and genitals.

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

- liver disease characterised by general feeling of discomfort or uneasiness, muscle and joint aches, fever, diarrhoea, nausea, vomiting, yellowing of eyes and skin, dark urine, loss of appetite, tiredness and sweating,
- severe pain in the kidneys (lower back area),
- kidney failure characterised by vomiting and/or diarrhoea, nausea, weight loss, more frequent and nightly urination,
- inflammation of the pancreas characterised by severe upper abdominal burning pain radiating to the back, nausea, and vomiting that is worsened with eating,
- changes in the way your heart beats, e.g., heart rate that exceeds the normal range,
- skin reactions such as toxic epidermal necrolysis (TEN), Stevens-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 (see “Warnings and precautions”).

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- weakness or fatigue, shortness of breath, sometimes poor concentration,
- low blood pressure,
- other changes in laboratory test results which may result in regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells) can occur.

Side effects of unknown frequency:

- skin irritations, rashes, itching,
- nausea and vomiting,
- pain and burning sensation at injection site.

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 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 PARACETAMOL BIOTECH IV.

5. How to store PARACETAMOL BIOTECH IV

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from light.

Do not refrigerate or freeze.

Do not administer if visible particles are present.

Use immediately after opening. Discard remaining portion.

6. Contents of the pack and other information

What PARACETAMOL BIOTECH IV contains:

The active substance is 10 mg per mL paracetamol.

The other ingredients are citric acid monohydrate, disodium hydrogen phosphate dihydrate, nitrogen gas, propylene glycol (E 1520), sodium metabisulphite (E 223), sodium chloride, water for injection.

What PARACETAMOL BIOTECH IV looks like and contents of the pack

The solution for infusion is a clear, colourless solution.

PARACETAMOL BIOTECH IV is available in the following presentations:

- 100 mL sterile, clear colourless type I glass vial with bromobutyl rubber stopper and purple aluminium seal and flip-off cap.
- 100 mL sterile, translucent white LDPE plastic Euro head bottle with cream-coloured latex rubber disc and transparent or opaque Snap-fit cap.
- 100 mL sterile, translucent white LDPE plastic nipple head bottle.
- 100 mL sterile, translucent white LDPE plastic Euro head bottle with hermetic seal.

Not all pack types are marketed.

Holder of certificate of registration

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