PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS

Solution for infusion

Paracetamol

Contains mannitol (36,7 mg/mL)

Read all of this leaflet carefully before you are given PARACETAMOL FRESENIUS

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

1. What PARACETAMOL FRESENIUS is and what it is used for

PARACETAMOL FRESENIUS belongs to a group of medicines called antipyretics or antipyretic and anti-inflammatory analgesics.

PARACETAMOL FRESENIUS is used in adults and children of at least 1 year old (and weighing at least 10 kg) for:

- the short-term treatment of mild to moderate pain such as dental procedures, minor surgery, and for
- the short-term treatment of fever when medicine cannot be swallowed.

2. What you need to know before you are given PARACETAMOL FRESENIUS

PARACETAMOL FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to paracetamol, pro-paracetamol hydrochloride, or any of the other ingredients in PARACETAMOL FRESENIUS (listed in section 6).
- if you have severe liver disease including alcoholic liver disease.
- children weighing less than 10 kg (approximately 1 year old).

Warnings and precautions

During treatment with PARACETAMOL FRESENIUS, tell your doctor straight away:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Take special care with PARACETAMOL FRESENIUS:

- if you are able to take medicine orally instead of an infusion
- if you are using any other medicines containing paracetamol

- if you have liver problems or any history of liver damage
- if you suffer from a inherited liver function disorder called Meulengracht Gilbert's syndrome
- if you have kidney problems or any history of kidney damage
- if you have glucose-6-phosphate dehydrogenase deficiency, an enzyme deficiency that may lead to red blood cell breakdown
- if you are using alcohol. Chronic use or excessive alcohol intake, i.e., three or more alcoholic drinks every day
- if you have an eating disorder such as anorexia or bulimia, or suspect that you may be undernourished or dehydrated
- talk to your doctor or pharmacist if you are taking or will be taking flucloxacillin. There is a risk of blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when paracetamol is used concomitantly with flucloxacillin, particularly in certain groups of patients at risk, e.g., patients with severe renal impairment, sepsis or malnutrition, especially if the maximum daily doses of paracetamol are used. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

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

You should switch to taking pain killing tablets or syrup instead of PARACETAMOL FRESENIUS as soon as is possible.

Other medicines and PARACETAMOL FRESENIUS

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

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

- Amoxicillin, clavulanic acid (antibiotics used to treat infection).
- Anticoagulants (medicines used for blood thinning such as warfarin).
- Barbiturates (used for certain mental conditions), including primidone.
- Carbamazepine (used to treat epilepsy and certain nerve conditions).
- Flucloxacillin (an antibiotic used to treat infection), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Isoniazid (used to treat tuberculosis).
- Metoclopramide (used for nausea and stomach problems).
- Phenytoin (medicine used for epilepsy), as it may cause damage to the liver.
- Probenecid (medicine for treatment of gout), as it may interfere with the clearing of paracetamol by the liver.
- Rifampicin (used to treat infections such as tuberculosis).
- Salicylamide (medicine for treatment of pain and fever), as it may interfere with the clearing of paracetamol by the liver.
- Zidovudine (an antiretroviral medicine used in HIV).

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 FRESENIUS.

Driving and using machines

PARACETAMOL FRESENIUS has no influence on the ability to drive or use machines.

3. How PARACETAMOL FRESENIUS will be administered to you

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

PARACETAMOL FRESENIUS will be given to you by injection into a vein (intravenous infusion).

Adults:

The dose of PARACETAMOL FRESENIUS will be different for different patients.

Your doctor will decide on a suitable dose and the duration of the treatment based on your weight, your specific condition and needs.

Children:

Your child's doctor will work out what dose your child should receive, based on his/her weight. PARACETAMOL FRESENIUS is only given to children if they weigh more than 10 kg (approximately 1 year old). Tell your child's doctor if you have given any other paracetamol containing pain medicine to your child. The doctor needs this information to work out how much PARACETAMOL FRESENIUS your child can receive.

If you receive more PARACETAMOL FRESENIUS than you should

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

If you receive higher doses than recommended, it can cause severe liver damage. The symptoms of liver damage are usually seen first after 2 days with the most severe symptoms experienced after 4 – 6 days. You may experience nausea, vomiting, anorexia (refusing to eat), pallor (pale skin) and abdominal pain and your doctor will treat these symptoms symptomatically. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. You may also have liver damage which will be indicated by high blood levels of liver enzymes. Liver damage may lead to brain disease, coma and death.

Prompt treatment is essential. In the event of an overdosage or suspected overdose and notwithstanding the fact that you or your child may not have symptoms, consult a doctor, hospital or poison centre immediately. A delay in starting treatment may mean that the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

If you forget to receive PARACETAMOL FRESENIUS

Since a healthcare provider will administer PARACETAMOL FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

PARACETAMOL FRESENIUS can have side effects.

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

If any of the following happens, stop receiving PARACETAMOL FRESENIUS and tell your doctor immediately:

- Hypersensitivity and allergic reactions: any sudden wheeziness, difficulty in breathing, angioedema (swelling of the affected area with a burning sensation), swelling of the eyelids, face or lips and rash or itching (especially affecting your whole body), flushing (redness of the skin).

These are all very serious side effects. If you have them, you may have had a serious reaction to PARACETAMOL FRESENIUS. You may need urgent medical attention or further hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Blood disorders characterised by unusual tiredness or weakness.
- Low blood pressure.
- Liver problems (you may notice signs like dark urine, pale-coloured stools, yellow skin and eyes, abdominal pain).
- Skin rash, itching, redness of skin and other skin conditions.
- Kidney problems (you may notice signs like cloudy urine, need to urinate frequently, burning urine and back pain).
- General feeling of unease, weakness or discomfort.
- Inflammation of the pancreas, stomach pain.
- Blood and fluid abnormality (high anion gap metabolic acidosis) which occurs when there is an increase in plasma acidity, when paracetamol is used concomitantly with flucloxacillin, generally in the presence of risk factors (see section 2).

Side effects with an unknown frequency:

- A quick heartbeat.
- Nausea and vomiting.
- Pain and burning at the site of the injection.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PARACETAMOL FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store PARACETAMOL FRESENIUS

Store all medicines out of reach of children.

Glass bottles: Store at or below 30 °C.

Free*flex*® bags: Store at or below 25 °C.

Do not refrigerate or freeze.

Once opened, the contents should be used immediately.

For single use only. Discard any unused portion.

Do not use after the expiry date stated on the label.

Do not use if you notice any particulate matter and discolouration.

Return all unused medicine to your pharmacist.

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

Contents of the pack and other information

What PARACETAMOL FRESENIUS contains

The active substance is paracetamol.

Each 1 mL solution contains 10 mg paracetamol.

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: Each 50 mL solution contains 0,5 g of

paracetamol.

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: Each 100 mL solution contains 1 g of paracetamol.

The other ingredients are cysteine, mannitol and water for injection.

Contains mannitol (36,7 mg/mL).

6. What PARACETAMOL FRESENIUS looks like and contents of the pack

Clear, colourless to slightly yellowish solution free from visible particulate contamination.

Packed into 50 mL or 100 mL clear, colourless glass bottles with a red rubber stopper and an aluminium cap, with either a tear-off tab of aluminium or a plastic lid or into 50 mL and 100 mL **Free*flex*®** bags (polyolefin) closed with stoppers and plastic tamper-evident covers.

10, 12 or 20 glass bottles of 50 mL or 100 mL are packed with a leaflet into a cardboard box.

10, 20, 50 or 60 **Free*flex*®** bags of 50 mL or 100 mL are packed with a leaflet into a cardboard box.

Not all pack sizes or container closure systems may be marketed.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street, Halfway House extension 7

Midrand, Gauteng, 1685

South Africa

Telephone number: +27 (0)11 545 0000

This leaflet was last revised in

21 January 2026

Registration numbers

PARACETAMOL 10 mg/mL (50 mL) FRESENIUS: 45/2.7/0531

PARACETAMOL 10 mg/mL (100 mL) FRESENIUS: 45/2.7/1188

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.