

PATIENT INFORMATION LEAFLET FOR PARACETAMOL FRESENIUS 10 mg/ml

Please read this leaflet carefully before PARACETAMOL FRESENIUS 10 mg/ml solution for infusion is given to you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- Paracetamol Fresenius 10 mg/ml 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.

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PARACETAMOL FRESENIUS 10 mg/ml (50 ml)

PARACETAMOL FRESENIUS 10 mg/ml (100 ml)

Solution for intravenous infusion

1. WHAT PARACETAMOL FRESENIUS 10 mg/ml CONTAINS

Paracetamol Fresenius 10 mg/ml (100 ml): Each 100 ml bottle contains 1 g of paracetamol.

Paracetamol Fresenius 10 mg/ml (50 ml): Each 50 ml bottle contains 0,5 g of paracetamol.

Inactive ingredients: Mannitol, water for injection, nitrogen

Contains 0,01 % *m/v* cysteine (as antioxidant)

Osmolality: 280 mOsm/l

2. WHAT PARACETAMOL FRESENIUS 10 mg/ml IS USED FOR

Short-term treatment of mild to moderate pain such as dental procedures and minor bone surgery and the short-term treatment of fever when medicine can not be taken orally.

3. BEFORE YOU RECEIVE PARACETAMOL FRESENIUS 10 mg/ml

PARACETAMOL FRESENIUS 10 mg/ml should not be administered:

- If you are hypersensitive to paracetamol, pro-paracetamol hydrochloride, or any of the ingredients in Paracetamol Fresenius 10 mg/ml (see **WHAT PARACETAMOL FRESENIUS 10 mg/ml CONTAINS**).
- If you have severe liver disease including alcoholic liver disease.
- Patients weighing less than 33 kg.

Take special care with PARACETAMOL FRESENIUS 10 mg/ml:

Tell your doctor:

- If you are able to take medicine orally instead of an infusion.
- If you are using any other medications containing paracetamol.
- If you have any history of liver damage.
- If you have any history of kidney damage.
- If you are using alcohol.
- If you suspect that you may be undernourished or dehydrated.
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while receiving Paracetamol Fresenius 10 mg/ml, please consult your doctor, pharmacist or other healthcare professional for advice.

Special care should be taken if you are pregnant, planning to become pregnant or breastfeeding your baby, as safety in pregnancy and breastfeeding has not been established.

Driving and using machines:

Paracetamol Fresenius 10 mg/ml may cause a feeling of unease or weakness. Do not drive or use machinery until you know how Paracetamol Fresenius 10 mg/ml affects you.

Using other medicines with PARACETAMOL FRESENIUS 10 mg/ml:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Paracetamol Fresenius 10 mg/ml with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

The use of probenecid (medicine for treatment of gout) and salicylamide (medicine for treatment of pain and fever) may interfere with the clearing of paracetamol by the liver.

Phenytoin (medicine used for epilepsy) may cause damage to the liver.

Caution should be taken when using enzyme-inducing substances with Paracetamol Fresenius 10 mg/ml such as barbiturates, rifampicin, isoniazid, anticoagulants, zidovudine and chronic use of alcohol.

4. HOW PARACETAMOL FRESENIUS 10 mg/ml IS ADMINISTERED

For single use only.

The dose of Paracetamol Fresenius 10 mg/ml will be different for different patients.

Paracetamol Fresenius 10 mg/ml is for intravenous use only. Your doctor will decide on a suitable dose and the duration of the treatment based on your specific condition and needs.

If you receive more PARACETAMOL FRESENIUS 10 mg/ml than you should:

Paracetamol Fresenius 10 mg/ml is for intravenous use only. Since your doctor will administer Paracetamol Fresenius 10 mg/ml he/she will control the dosage. 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. You may also have liver damage which will be indicated by high blood levels of liver enzymes.

If you did not receive your PARACETAMOL FRESENIUS 10 mg/ml:

Paracetamol Fresenius 10 mg/ml is for intravenous use only and your doctor will make sure that you receive Paracetamol Fresenius 10 mg/ml at the right time.

5. POSSIBLE SIDE EFFECTS:

Paracetamol Fresenius 10 mg/ml may have side effects. Not all side effects reported for Paracetamol Fresenius 10 mg/ml are included in this leaflet.

Should your general health worsen while receiving Paracetamol Fresenius 10 mg/ml, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may occur less frequently:

- Hypersensitivity and allergic reactions: any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips and rash or itching (especially affecting your whole body), flushing (redness of the skin) should be reported to a doctor immediately.
- Angioedema (swelling of the affected area with a burning sensation).
- Blood disorders characterised by unusual tiredness or weakness
- Low blood pressure, flushing of the skin
- Liver problems
- Skin rash, itching, redness of skin and other skin conditions
- Kidney problems
- General feeling of unease, weakness or discomfort
- Nausea and vomiting, stomach pain

6. STORING AND DISPOSING OF PARACETAMOL FRESENIUS 10 mg/ml

Store at or below 30 °C.

Do not refrigerate or freeze.

Once opened, the contents should be used immediately.

Discard any unused portion.

KEEP OUT OF REACH OF CHILDREN.

7. PRESENTATIONS OF PARACETAMOL FRESENIUS 10 mg/ml

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 50 ml and 100 ml Freeflex[®] bags (polyolefin) closed with stoppers and plastic tamper-evident covers

10, 12 or 20 bottles of 50 ml or 100 ml each are packed with a package insert into a cardboard box.

20, 50 or 60 Freeflex[®] bags of 50 ml and 100 ml are packed with a package insert into a cardboard box.

8. IDENTIFICATION OF PARACETAMOL FRESENIUS 10 mg/ml

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

9. REGISTRATION NUMBERS

Paracetamol Fresenius 10 mg/ml (50 ml): 45/2.7/0531

Paracetamol Fresenius 10 mg/ml (100 ml): 45/2.7/1188

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park,

2 Tonetti Street,

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1682

11. DATE OF PUBLICATION

05 December 2013