

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** **S3****PARACETAMOL PAEDIATRIC 100 MG B. BRAUN**

Solution for infusion

PARACETAMOL**Contains sugar: Mannitol**

Read all of this leaflet carefully before you are given PARACETAMOL PAEDIATRIC 100 MG B. BRAUN

- 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 PARACETAMOL PAEDIATRIC 100 MG B. BRAUN is and what it is used for
- 2: What you need to know before you use PARACETAMOL PAEDIATRIC 100 MG B. BRAUN
- 3: How to use PARACETAMOL PAEDIATRIC 100 MG B. BRAUN
- 4: Possible side effects
- 5: How to store PARACETAMOL PAEDIATRIC 100 MG B. BRAUN
- 6: Contents of the pack and other information.

1. What PARACETAMOL PAEDIATRIC 100 MG B. BRAUN is and what it is used for

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

It is used in term newborn infants, infants and toddlers weighing up to 10 kg for

- the short-term treatment of mild to moderate pain, especially following minor surgery.
- The short-term treatment of fever where the oral route is unsuitable.

2. What you need to know before you are given PARACETAMOL PAEDIATRIC 100 MG

B. BRAUN

PARACETAMOL PAEDIATRIC 100 MG B. BRAUN should not be administered to the child

- if the child is hypersensitive (allergic) to paracetamol or to any of the other ingredients of PARACETAMOL PAEDIATRIC 100 MG B. BRAUN (listed in section 6).
- if the child suffers from a severe liver disease.

Warnings and Precautions

Take special care with PARACETAMOL PAEDIATRIC 100 MG B. BRAUN and tell your doctor:

- if your child suffers from liver or severe kidney disease
- if your child is taking other medicines containing paracetamol. In this case your doctor will adjust the dose
- in cases of nutrition problems (states of underfeeding, malnutrition) or dehydration
- if your child suffers from a genetically caused disorder of the enzyme glucose-6-phosphatedehydrogenase (favism, an inherited medical condition which breaks down red blood cells).

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

Prolonged or frequent use of paracetamol is discouraged. It is recommended that this medicine should only be used until your child is able to take pain killers by mouth again.

Your doctor will assure not to give your child doses higher than recommended. This may lead to severe liver damage.

Other medicines and PARACETAMOL PAEDIATRIC 100 MG B. BRAUN

Always tell your healthcare provider if your child is taking any other medicine, (this includes all complementary or traditional medicines).

This is especially important if your child is taking:

- a medicine called *probenecid* (used to treat gout): reduction of the paracetamol dose may be required
- painkillers containing *salicylamide*: adjustment of the dose may be required
- *medicines that activate liver enzymes*: strict control of the paracetamol dose is required in order to avoid liver damage
- any *blood thinning medicines* (anticoagulants such as warfarin): a more careful control of the effect of these medicines may be necessary.

This medicine contains paracetamol, and this must be taken into account if *other medicines containing paracetamol or propacetamol* are taken, in order to avoid overdose (see section 3).

Pregnancy and breastfeeding

Not relevant

Driving and using machines

Not relevant

3. How to use PARACETAMOL PAEDIATRIC 100 MG B. BRAUN**DO NOT EXCEED THE RECOMMENDED DOSE.**

Do not share medicines prescribed for your child with any other person.

You will not be expected to give your child by yourself PARACETAMOL PAEDIATRIC 100 MG B. BRAUN. It will be given to your child by a person who is qualified to do so.

PARACETAMOL PAEDIATRIC 100 MG B. BRAUN 10 mL ampoule is restricted to term newborn infants, infants and toddlers weighing up to 10 kg.

The dose will be individually adjusted by the doctor, based on your child's weight and general condition.

Your doctor will tell you how long the treatment with PARACETAMOL PAEDIATRIC 100 MG B. BRAUN will last. Do not stop treatment early because your child feels better. If you have the impression that the effect of PARACETAMOL PAEDIATRIC 100 MG B. BRAUN is too strong or too weak, tell your doctor or pharmacist.

Method of administration

PARACETAMOL PAEDIATRIC 100 MG B. BRAUN will be given to your child by a doctor through a drip into a vein (intravenous use). This usually takes about 15 minutes. Your child will be closely monitored during and especially towards the end of the infusion.

If you take more PARACETAMOL PAEDIATRIC 100 MG B. BRAUN than you should.

Since a health care provider will administer PARACETAMOL PAEDIATRIC 100 MG B. BRAUN, he/ she will control the dosage. However, in the event of over dosage your doctor will manage over dosage.

In overdose cases, symptoms generally appear within the first 24 hours and include: feeling sick, being sick, anorexia (loss of appetite), pasty skin and abdominal pain. These symptoms could reflect liver injury. In addition, it is possible that the function of your kidneys may be impaired.

If you think your child may have been given an overdose, tell a doctor immediately. Immediate medical advice should be sought in the event of an overdose, even if your child looks well, to avoid risk of serious and irreversible liver damage. If required an antidote may be given to your child.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to use PARACETAMOL PAEDIATRIC 100 MG B. BRAUN

Since a health care provider will administer PARACETAMOL PAEDIATRIC 100 MG B. BRAUN, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

PARACETAMOL PAEDIATRIC 100 MG B. BRAUN can have side effects.

Not all side effects reported for PARACETAMOL PAEDIATRIC 100 MG B. BRAUN, are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking PARACETAMOL PAEDIATRIC 100 MG B. BRAUN, please consult your health care provider for advice.

If any of the following happens, stop using PARACETAMOL PAEDIATRIC 100 MG B. BRAUN, 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
- Fainting.

These are all very serious side effects. If your child has them, they may have had a serious reaction to PARACETAMOL PAEDIATRIC 100 MG B. BRAUN. They may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain
- Changes in the way your child's heart beats, for example, if you notice it beating faster
- Difficulty breathing

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Les frequent side effects:

- Frequent infections
- Bruise easily
- Nausea (feeling sick)
- Abdominal cramps or stomach pains
- Tiredness
- Feeling unwell
- Light headedness
- Flushing
- Decrease urine production
- Itchy or red rash.

If you notice any side effects not mentioned, please inform your doctor or pharmacist.

Reporting of side effects

If your child gets side effects. Talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via 6.04 Adverse Drug Reaction Reporting Form found online under SAHPRA's publications: <https://primaryreporting.who-umc.org/ZA>. By reporting side effects, you can help provide more information on the safety of PARACETAMOL PAEDIATRIC 100 MG B. BRAUN.

5. How to store PARACETAMOL PAEDIATRIC 100 MG B. BRAUN

Store all medicines out of reach of children.

Store at or below 25 °C. Do not refrigerate or freeze.

To store in original container.

Avoid exposure to light.

6. Contents of the pack and other information

What PARACETAMOL PAEDIATRIC 100 MG B. BRAUN, contains

The active substance is paracetamol.

PARACETAMOL PAEDIATRIC 100 MG B. BRAUN: each 10 mL ampoule contains 100 MG paracetamol.

The other ingredients are: mannitol, sodium citrate dihydrate, acetic acid glacial (for pH adjustment), water for injections.

What PARACETAMOL PAEDIATRIC 100 MG B. BRAUN looks like and contents of the pack

The solution is clear and colourless to slightly pinkish-orangish. Perception may vary.

PARACETAMOL PAEDIATRIC 100 MG B. BRAUN is packed in 10 mL ampoules of low-density polyethylene.

Pack size: 20 × 10 mL

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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The leaflet was revised in:

N/A

Registration number

47/2.7/9001

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