

Panadrex

Paracetamol

Suppositories

80, 125, 170 & 250 mg

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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1. What are PANADREX Suppositories and what are they used for?

PANADREX Suppositories contains Paracetamol which belongs to a group of medicines called analgesics and antipyretics. It produces its effects by its action on central and peripheral prostaglandin synthesis inhibition. It is recommended for:

- Mild to moderate pain associated with toothache, earache, sore throat, and teething pain.
- Fever associated with influenza, cold, childhood infections, and reactions to vaccinations.

They are used by children who find it difficult to take paracetamol as tablets or syrup.

2. Before use PANADREX Suppositories

Do not give PANADREX Suppositories for your child in the following cases:

- If he has hypersensitivity to any component of PANADREX Suppositories.
- If he takes other paracetamol containing medication.

Check with your doctor or pharmacist before giving PANADREX Suppositories to your child in the following cases:

- severe kidney problems or severe liver problems.
- If your child is taking any other medicines (mentioned below)
- If you are not sure of the cause of your child's illness or it is accompanied by a rash, breathing difficulties, diarrhea or excessive tiredness or lethargy.

Do not give Panadrex until you get medical advice.

Taking other medicines:

Please tell your doctor or pharmacist if your child is taking, or have recently taken any other medicines. This includes medicines you buy without a prescription and herbal medicines. PANADREX Suppositories can affect the way that some medicines work and some medicines can have an effect on PANADREX Suppositories.

Particularly the following:

- Metoclopramide or domperidone (used to treat nausea and vomiting).
- Colestyramine (used to treat high cholesterol).
- Anticoagulants (drugs that thin the blood, such as warfarin).
- Anticonvulsants (drugs to treat epilepsy).
- Phenothiazines (some antihistamines and antipsychotics).
- Isoniazide (for the treatment of tuberculosis).

3. How to use PANADREX Suppositories?

Always use PANADREX Suppositories as doctor has told you. You should check with doctor or pharmacist if you are not sure.

The dosage of paracetamol is governed by age and body weight and is usually 10-15 mg paracetamol per kg body weight as a single dose and up to 50 mg/kg body weight as a maximum dose per day (24 hours). The recommended usual daily dose depends on the weight of the child. It is determined at 60 mg/kg/day to be spaced out in 4 different intakes per day. **PANADREX 80 mg:** up to 7 kg (about 6 months old) 1 suppository of 80 mg to use it twice if needed after 6 hours .

PANADREX 125 mg: from 8-12 kg (about 1-2 years old) 1 suppository of 125 mg to use it twice if needed after 6 hours.

PANADREX 170 mg: from 12-16 kg (about 2-4 years old) 1 suppository of 170 mg to use it twice if needed after 6 hours.

PANADREX 250 mg: from 17-22 kg (about 4-7 years old) 1 suppository of 250 mg to use it twice if needed after 6 hours.

Do not use more than 4 suppositories per day.

The approximate ages as a function of body weight are given for an example only in case of any doubt the doctor should be consulted. In the event of serious kidney disorder (severe renal insufficiency), intakes should occur at intervals of 8 hours minimum.

Do not exceed 3 days of treatment in the event of fever or 5 days of treatment in the event of pain without the advice of the doctor.

How to use Panadrex Suppositories

1. Your child's bowels need to be empty when you give him this medicine. If your child needs to go to the toilet, make sure that he do it before you give him the suppository.
2. You may find it easier to give your child the suppository if he is lying on his front or side on a bed. Do whichever is more comfortable for your child.
3. Wash your hands. Then peel the wrapping apart to take out the suppository. Do not break the suppository before use.
4. Gently push the suppository into your child's back passage (rectum) with the pointed end first. Then wash your hands.
5. Try to keep your child still for a minute or two.

If you give your child more PANADREX suppositories than you should:

Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

If you forgot to give PANADREX suppositories for your child:

Give it as soon as you remember. However, if it is almost time for the next dose, wait until then, and take the next dose as normal. Do not give a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, PANADREX suppositories can cause side effects, although not everybody gets them.

Tell your doctor as soon as possible if you notice any of these:

- Redness or soreness in or around the back passage.
- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.
- becoming unusually tired, unexpected bruising or bleeding (hematological disorders) and getting more infections (such as colds) than usual. These are

very rare effects in people taking paracetamol. If your child shows any of these signs, stop giving paracetamol and talk to a doctor. Long term use: People who use medicines containing paracetamol every day for a long time (several months or more) could get certain side effects, including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems.

If you notice any side-effects not included in this leaflet please tell your doctor or pharmacist.

5. How to store PANADREX Suppositories?

- Keep in a safe place, out of the reach and sight of children.
- Store below 25°C. Do not freeze.
- Do not take PANADREX Suppositories after the expiry date printed on the packaging. The expiry date refers to the last day of the month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Further Information

What PANADREX Suppositories contains?

Each PANADREX 80 mg Suppository contains: Paracetamol 80 mg

Each PANADREX 125 mg Suppository contains: Paracetamol 125 mg

Each PANADREX 170 mg Suppository contains: Paracetamol 170 mg

Each PANADREX 250 mg Suppository contains: Paracetamol 250 mg

The excipients are: Polyethylene Glycol 1500, Polyethylene Glycol 6000, Methyl Paraben, Propyl Paraben, Butylated Hydroxy Toluene & titanium Dioxide.

What PANADREX Suppository looks like and what are the contents of the pack?

PANADREX Suppository is White, bullet shaped suppository. PANADREX Suppositories are available in Thermoformable, white plain PVC / PE film. PANADREX Suppositories available in strip of 10 suppositories. Not all packs may be marketed.

7. Adverse Drug Reaction (ADR) Reporting

Saudi Arabia, Saudi Food & Drug Authority: National Pharmacovigilance Center To contact Executive Administration for Pharmacovigilance & Crisis Management.

Tel: +966-11-203-8222 ext 2340-2334-2354-2317-2356-2353

Toll Free Phone: 800 249 0000

FAX: +966112057662 E-Mail: npc.drug@sfga.gov.sa WEBSITE: www.sfga.gov.sa/npc

For reporting the adverse drug reactions in other countries please refer to the health authorities.

THIS IS A MEDICINE

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in the medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers - Union of Arab Pharmacists



Marketing Authorization Holder and Manufacturer

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