

## FENPAED

Ibuprofen, 100 mg/5 ml Oral Suspension

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about FENPAED. It does not contain all the information available on this medicine. **It does not take the place of talking to your doctor or pharmacist.**

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of your child taking FENPAED against the benefits they expect it will have for your child.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

#### What FENPAED is used for

FENPAED is used as a painkiller for relief of mild to moderate muscular pain, headache, earache, sore throat, dental pain and backache. FENPAED can also be used in minor injuries such as sprains and strains. FENPAED reduces temperature in post-immunisation fever, colds and influenza.

#### Before you give FENPAED to your child

##### When you must not give it to your child

DO NOT give FENPAED to your child:

1. If your child has or has ever had a stomach ulcer or other gastric complaint
2. If your child suffers from asthma or if they have had an allergic reaction or wheezing after taking Ibuprofen, aspirin or other anti-inflammatory painkillers
3. If your child is sensitive to any of the ingredients of FENPAED
4. If your child is taking any other anti-inflammatory pain killers (NSAIDs)
5. If your child has or has previously had kidney, heart or severe liver problems

##### Before you start to give it to your child

Before you give FENPAED to your child tell your doctor or pharmacist:

1. If your child suffers from high blood pressure
2. If your child suffers from lupus or a mixed connective tissue disease
3. If your child suffers from a chronic inflammatory intestinal disease such as ulcerative colitis or Crohn's disease
4. If your child is taking any of the following medicines:
  - Diuretics (water tablets)
  - Tablets for high blood pressure
  - Medicines such as warfarin, to prevent blood clots
  - Aspirin, lithium, methotrexate, zidovudine or corticosteroids
  - Any other Ibuprofen preparations, including those you can buy without prescription.

##### Taking other medicines

If your child is taking aspirin, speak to your doctor or pharmacist before you give FENPAED to your child.

Tell your doctor or pharmacist if your child is taking any other medications or has taken any in

the last two weeks, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

FENPAED contains maltitol. If you have been told by your doctor that your child has intolerance to some sugars, please contact your doctor before giving FENPAED to your child. Maltitol may have a mild laxative effect.

This product contains parahydroxybenzoates which may cause allergic reactions in some patients (possibly delayed).

#### How to give FENPAED to your child

##### How much should FENPAED be given to your child

The usual daily dose in children is 20 mg per kg of bodyweight in divided doses which can be given as follows:

- 6 - 12 months: 3 - 4 mL
- 1 - 3 years: 4 - 6 mL
- 3 - 5 years: 6 - 7 mL
- 5 - 7 years: 7 - 9 mL
- 7 - 9 years: 9 - 11 mL
- 9 - 11 years: 11 - 14 mL
- 11 - 12 years: 14 - 15 mL

Do not give to infants under 6 months.

Do not give to children under 12 months except on the advice of a doctor.

**For short term use only.** Unless a doctor has told you to, do not give Fenpaed to any child for more than a few days at a time. Do not exceed the recommended dose, extensive use can be harmful. Consult your doctor promptly if symptoms persist or worsen.

**WARNING: DO NOT EXCEED THE STATED DOSE**

##### How to give FENPAED to your child

Shake the bottle well before measuring the dose.

##### If you forget to give FENPAED to your child

If you forget to give a dose to your child, give it as soon as you remember, unless it is almost time for the next dose. Never double-up on a dose to make up for the missed dose.

##### If you give too much FENPAED to your child or your child takes too much of it accidentally (overdose)

**Immediately contact your doctor, pharmacist or the Poisons Information Centre (Australia: Telephone 13 11 26 or in New Zealand 0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that your child may have taken too much FENPAED. Do this even if there are no signs of discomfort or poisoning. Your child may need urgent medical attention.**

Keep the telephone numbers for these places handy.

##### While you are giving FENPAED to your child

Tell all doctors, dentists and pharmacists who are treating your child that your child is taking FENPAED and before your child starts any new medicine.

**Do not** give FENPAED to anyone else, even if you think his or her symptoms seem similar to your child.

**Do not** give FENPAED to your child to treat any other complaints unless your doctor tells you to.

#### Side effects

Like all medicines FENPAED can have some side effects although these are rare and usually mild. The most common side effect is irritation of the stomach which can cause problems in some patients.

If your child suffers from the following stop giving the medicine and seek immediate medical help:

- Pass blood in their faeces (stools/motions)
- Pass black, tarry stools
- Vomit blood or dark particles that look like ground coffee

If your child experiences any of the following, stop giving the medicine and tell your doctor immediately.

- Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising, lightheadedness or racing heart
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever
- Blurred or disturbed vision
- Hallucination
- Fluid retention, e.g. swollen ankles, not passing enough urine.

Other unusual effects may include headache and occasionally hypersensitivity reactions may occur which can cause skin rashes.

Rarely Crohn's disease or ulcerative colitis or other stomach problems may be exacerbated. Very rarely, blood disorders and liver and kidney problems may occur with Ibuprofen. If any of these become troublesome or last more than a few days, tell your doctor. If your child experiences any other unusual symptoms while taking this medicine, tell your doctor or pharmacist.

#### After you give FENPAED to your child

##### Storage

Store below 25°C. Protect from light.

Do not give FENPAED to your child after the expiry date shown on the bottle.

Keep this medicine out of reach and sight of children.

#### Product description

##### What it looks like

FENPAED is sugar free, white colour suspension with strawberry flavour.

Each bottle contains 100 ml or 200 ml of oral suspension.

##### Ingredients

Each 5 ml of the oral suspension contains 100 mg of Ibuprofen. It also contains glycerol (E422), xanthan gum, maltitol (E965), polysorbate 80, saccharin sodium (E954), citric acid monohydrate, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), purified water and strawberry flavour.

##### Sponsor

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