Ibuprofen 100 mg/5 ml Oral Suspension contains ibuprofen as the active ingredient. This belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Ibuprofen is given to children as a pain-reliever for mild to moderate muscular pain, headache, sore throat, dental pain and backache. This medicine can also be used in minor aches such as sprains and strains. It also reduces temperature in fever (e.g. post-infection fever), as well as other symptoms of cold and influenza.

2. Before you give Ibuprofen
Do not give this medicine if your child:
- has had allergy or hypersensitivity to Ibuprofen or any of the other ingredients in this medicine (see Section 4 of this leaflet for more information about ingredients);
- has had an allergic reaction or swelling after taking aspirin or other non-steroidal anti-inflammatory painkillers. (Symptoms of a severe allergic reaction are given under Section 4. Possible side effects);
- has ever had a stomach ulcer or a history of taking aspirin or other non-steroidal anti-inflammatory painkillers. (Symptoms of an upper gastrointestinal bleeding are given under Section 4. Possible side effects);
- has had any other non-steroidal anti-inflammatory painkillers (NSAIDs) such as ibuprofen, naproxen, diclofenac, heart, liver or kidney problems;
- has an inherited intolerance of some sugars in less than 3 months old.

If any of these apply, ask for advice from a doctor or pharmacist before giving this medicine.

3. When to Give Ibuprofen

3.1. To children who are not old enough to take tablets

You should dose your child’s treatment with your doctor or pharmacist giving Ibuprofen 100 mg/5 ml Oral Suspension.

Dosage for children
Depending on your child’s age:

- Up to 1 year:
  - a yellow spoon is provided to measure doses of 0.5 ml, 2.5 ml, 5 ml or 10 ml
  - for doses over 10 ml:
    - use a measuring cup
    - measure by volume
  - the dose should be divided into 3 doses per day, but this will depend on your child’s condition

- 1-2 years:
  - a yellow spoon is provided to measure doses of 2.5 ml, 5 ml or 10 ml
  - the dose will depend on how much your child has had previously

- 2-3 years:
  - a yellow spoon is provided to measure doses of 2.5 ml, 5 ml or 10 ml
  - the dose will depend on how much your child has had previously

- 3-6 years:
  - a yellow spoon is provided to measure doses of 2.5 ml, 5 ml or 10 ml
  - the dose will depend on how much your child has had previously

- 6-12 years:
  - a yellow spoon is provided to measure doses of 5 ml
  - the dose will depend on how much your child has had previously

- 12-17 years:
  - a yellow spoon is provided to measure doses of 10 ml
  - the dose will depend on how much your child has had previously

3.2. To children who are old enough to take tablets

Take Ibuprofen 100 mg/5 ml Oral Suspension as directed by your doctor or pharmacist. (A spoon is provided to measure doses of 2.5 ml or 5 ml)

- 3-6 months (weighing over 5 kg) 2.5 ml 3 times a day
- 6 months-2 years 5 ml 3 times a day
- 2-4 years 7.5 ml 3 times a day

Do not give to children under 3 months.

4. Possible Side Effects

Like all medicines, Ibuprofen can cause side-effects although not everybody gets them.

You should stop giving Ibuprofen and seek advice from your doctor if your child experiences a very rare allergic reaction, increased skin reactions, increased sensitivity to sunlight, swelling of the face, tongue, and inflammation of the blood vessels, fever or shock. Skin and mucous membrane reactions may also occur.

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:

- Peeling of the skin or blistering
- Fever or shivering
- Unusual tiredness or weakness
- Difficulty in breathing or wheezing
- Unusual blood in the urine
- Unusual bleeding or bruising
- Symptoms of liver or kidney problems
- Unusual chest pain
- Unusual trouble or pain when urinating
- Changes in the way your child looks or acts
- Rapid heartbeat
- Difficulty in breathing
- Changes in vision
- Headache
- Convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems

Other unusual effects may include:

- Uncommon:
  - Nausea
  - Vomiting
  - Stomach pains
  - Diarrhoea

- Rare:
  - Unexplained stomach pain, indigestion, heartburn, feeling sick and/or vomiting
  - Severe sore throat with high fever or unexplained bleeding, bruising and tiredness

5. How to Store Ibuprofen

Keep the medicine out of the sight and reach of children. Do not use after the expiry date shown on the bottle.

6. Contents of the pack and other information

The medicine comes in amber glass bottles or polyethylene bottles of: 50 ml, 100 ml, 150 ml or 200 ml with a child-resistant closure.

6.1 This leaflet was prepared in June 2018

6.2 Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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