

AXCEL IBUPROFEN PAEDIATRIC SYRUP

Ibuprofen (100mg/5ml)

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What Axcel Ibuprofen Paediatric Syrup is used for

Axcel Ibuprofen Paediatric Syrup is used for the relief of fever associated with cold and flu, pain from teething and toothache, earache, sore throats, headache, minor aches and sprains and relief inflammation of muscles and joints.

How Axcel Ibuprofen Paediatric Syrup works

Axcel Ibuprofen Paediatric Syrup contains a substance called Ibuprofen. Ibuprofen is a non-steroidal anti-inflammatory agent (NSAIDs) which can reduce inflammation, fever and pain.

Before you use Axcel Ibuprofen Paediatric Syrup syrup

– When you must not use it

Do not take Axcel Ibuprofen Paediatric Syrup:

- If your child is allergic or hypersensitive to ibuprofen, any other non-steroidal anti-inflammatory drugs (NSAIDs) or Aspirin (medication used to reduce fever, reduce pain and prevent blood clot).
- If your child has or has had stomach ulceration.

– Before you start to use it

Tell your doctor:

- If your child is allergic to any medicines, food and dyes.

- If your child has asthma or bronchospasm (constriction of the airway).
- If your child has suffering from bleeding disorder.
- If your child has or has had ulceration, bleeding and perforation of the stomach and intestinal.
- If your child has hypertension (high blood pressure).
- If your child has impaired kidney, liver of heart.
- If your child suffering from connective tissue disorder, e.g. systemic lupus erythematosus (SLE).
- If your child has vision problem.
- If your child has collagen disease.
- If your child has dyspepsia (discomfort at the epigastric region due to digestion problem).

Axcel Ibuprofen Paediatric Syrup may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

– Taking other medicines

You should tell your doctor if your child is taking the following medicine as it may interact with your child Axcel Ibuprofen Paediatric Syrup:

- Anticoagulant, a medicine used for blood thinning. e.g. Warfarin.
- Lithium, a medicine to treat depression.
- Methotrexate, a medicine used to treat rheumatoid arthritis (systemic inflammatory disorder that affects joints), as well as some types of cancers.
- Cardiac glycosides, a heart medicine. e.g. Digoxin.
- Antihypertensive, medicines used to control blood pressure, such as ACE inhibitor, Beta blocker and Diuretic.
- Antibiotic, medicines used for infection such as Quinolones.

- Phenytoin, a medicine used for fit.
- Sulphonylurea antidiabetics, medicines used for diabetes.
- Other NSAID.
- Corticosteroids, medicines used to reduce inflammation.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking this medication.

How to use Axcel Ibuprofen Paediatric Syrup

This medicine is intended for oral administration only.

Shake well before used.

– How much to use

The daily dosage is 20-40mg/kg body weight in divided doses.

Baby under 6 months old: initially 2.5ml (50mg) followed by 2.5ml (50mg) 6 hours later if required, not more than 5ml (100mg) in 24 hour.

Babies 6-12 months: 2.5ml (50mg) three to four times a day.

Children:

1-3 years:	5ml (100mg) 3 times a day
4-6 years:	7.5ml (150mg) 3 times a day
7-9 years:	10ml (200mg) 3 times a day
10-12 years:	15ml (300mg) 3 times a day

– When to use it

Your doctor will decide when it is appropriate for your child to take Axcel Ibuprofen Paediatric Syrup according to the indication.

– How long to use it

Continue taking Axcel Ibuprofen Paediatric Syrup for as long as doctor recommends.

– If you forget to use it

Consult your doctor or pharmacist on what you should do if your child forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your child next dose, wait until then take the medicine and skip the

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missed dose. Do not take a double dose to make up for the missed dose.

– If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think your child or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. Your child may need urgent medical attention.

Taking too many of this medication may cause:

1. Coma.
2. Hyperkalaemia (high level of potassium in your body).
3. Heart problem.
4. Metabolic acidosis (the chemical balance of acids and bases in your blood gets thrown off).
5. Pyrexia (fever).
6. Respiratory failure.

While you are using it

– Things you must do

- Take your child medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating your child that your child are taking Axcel Ibuprofen Paediatric Syrup.

– Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Ibuprofen Paediatric Syrup to anyone else, even if they have the same symptoms or condition as your child.

– Things to be careful of

- Use of Axcel Ibuprofen Paediatric Syrup during pregnancy and lactation should be avoided if possible.

Side effects

Like all medicines, Axcel Ibuprofen Paediatric Syrup can cause side effects although not everybody gets them. You are advised to consult doctor/pharmacist for further

information. The following side effects have been reported:

– Very common side effects

- Stomach and intestinal disturbance such as abdominal discomfort, nausea and vomiting, abdominal pain, stomach and intestinal bleeding or activation of stomach ulcer.

– Common side effects

- Headache.
- Dizziness.
- Nervousness.
- Tinnitus (ringing in the ears).
- Depression.
- Drowsiness.
- Insomnia (difficult to fall into sleep).
- Hypersensitivity reactions which include fever, asthma and rashes.
- Hepatotoxicity (damage to the liver).
- Aseptic meningitis (inflammation of the lining of the brain).
- Visual disturbances.

– Rare side effects

- Aplastic anaemia (blood disorder).
- Agranulocytosis (blood disorder).
- Thrombocytopenia (blood disorder).
- Toxic amblyopia (vision problem).
- Acute renal failure (acute kidney problem).
- Fluid retention.
- Nephrotic syndrome (kidney problem)

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting).

Storage and disposal of Axcel Ibuprofen Paediatric Syrup

– Storage

Keep Axcel Ibuprofen Paediatric Syrup out of reach of children. Keep container well closed. Store below 30°C. Protect from light.

– Disposal

Do not use Axcel Ibuprofen Paediatric Syrup after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

– How it looks like

Axcel Ibuprofen Paediatric Syrup is orange colour syrup with orange flavour.

– Ingredients

Active Ingredient:

Ibuprofen

Inactive Ingredients:

Refined Sugar, Sorbitol 70%, Saccharin Sodium, Sodium Benzoate, Xanthan Gum, Citric Acid Anhydrous, Sunset Yellow, Orange Flavour, Sodium Citrate, Sodium Chloride, Simethicone Emulsion 30%. Polysorbate 80, Purified water.

– MAL Number

MAL20002268AZ

Manufacturer and product registration holder

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