AXCEL MEFENAMIC ACID SUSPENSION

Mefenamic Acid (125mg/5ml)

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What Axcel Mefenamic Acid Suspension is used for

For the relief of mild to moderate pain including:

- Headache.
- Dental pain.
- Postoperative pain and dysmenorrhea (period pain).
- Musculoskeletal and joint disorders such as osteoarthritis (degenerative joint disease) and rheumatoid arthritis (systemic inflammatory disorder that affects joints).
- In children with fever and juvenile rheumatoid arthritis (inflammation of the joint in children).

How Axcel Mefenamic Acid Suspension works

Axcel Mefenamic acid suspension contains a substance called Mefenamic acid. Mefenamic acid is a non-steroidal anti-inflammatory drugs (NSAIDs) which reduces inflammation, pain and fever.

Before you use Axcel Mefenamic Acid Suspension

– <u>When you must not use it</u>

Do not take Axcel Mefenamic Acid Suspension if:

- You are allergic or hypersensitive to Mefenamic Acid or any other ingredients listed at the end of this leaflet.
- If you are suffering with inflammatory bowel disease.

- If you are suffering from stomach and/or intestinal ulceration.
- If you have kidney or liver impairment.

-Before you start to use it

Tell your doctor if you:

- You are allergic to any medicines, food and dyes.
- If you are taking any other medicines (including those not prescribed by your doctor).
- If you have asthma or bronchospasm (constriction of airway).
- If you have bleeding disorder.
- If you have or have had ulceration, bleeding and perforation of stomach and intestinal.
- If you have a history of hypersensitivity to aspirin or other NSAID.
- If you have hypertension (high blood pressure).
- If you have impaired kidney, liver or heart.
- Please consult your doctor before start to use Axcel Mefenamic acid suspension if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Axcel Mefenamic acid suspension against the benefits they expect it will have for you.
- If you are elderly, and suffering from dehydration and kidney disease.
- If you are suffering from menorrhagia (excessive bleeding during menses), lack of response to treatment.
- If you are suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- Axcel Mefenamic Acid Suspension may cause severe skin reaction, e.g. exfoliative dermatitis (scaling of the skin), toxic epidermal necrolysis, Steven-Johnson Syndrome.

Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- <u>Taking other medicines</u>

You should tell your doctor if you are taking any medicine as following as it may interact with your Axcel Mefenamic Acid Suspension.

- More than one NSAID.
- Corticosteroids (medicine that reduces inflammation).
- Oral anticoagulant (a medicine used for blood thinning)
- Lithium (a medicine used for depression)
- Methotrexate (a medicine used to treat rheumatoid arthritis, as well as some types of cancer)
- Cardiac glycosides (a medicine for heart)
- ACE inhibitors, betablocker and diuretics (medicine used to control blood pressure)
- Quinolones (an antibiotic to treat infection)
- Phenytoin (a medicine for fit)
- Sulphonylurea (a medicine for diabetes)

How to use Axcel Mefenamic Acid Suspension

- How much to use

For oral administration only. Shake well before used.

Dosage in adults:

Initially take 20ml (500mg) then 10ml (250mg) 6 hourly.

Dosage in children:

In children over 6 months, take 1ml (25mg) /kg body weight daily in divided dose. Use Axcel Mefenamic Acid Suspension with the maximum of 7 consecutive days.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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Axcel Mefenamic Acid Suspension is not recommended for children below 6 months.

- When to use it

Your doctor will decide when it is appropriate for you to take Axcel Mefenamic Acid Suspension.

- How long to use it

Continue taking Axcel Mefenamic Acid Suspension for as long as doctor recommends.

- If you forget to use it

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

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- <u>If you use too much (overdose)</u>

- Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
- Taking too much Axcel Mefenamic Acid Suspension may cause central nervous system toxicity, e.g. fit or coma.

While you are using it

– Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Mefenamic Acid Suspension.
- Tell your doctor immediately if you become pregnant while talking this medication.

- 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 Mefenamic Acid Suspension to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

 Be careful while driving or operating machinery until you know how Axcel Mefenamic Acid Suspension affects you.

Side effects

Like all medicines, Axcel Mefenamic Acid Suspension 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:

- Stomach and intestinal disturbances.
- Reversible haemolytic anaemia (blood disorder).
- Diarrhoea.
- Skin rashes.
- Kidney failure.
- Bronchospasm (may be worsen if you are suffering from or with a previous history of bronchial asthma or allergic disease).

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 Mefenamic Acid Suspension

-<u>Storage</u>

Keep Axcel Mefenamic Acid Suspension out of reach of children. Keep container well closed.

Store below 30°C. Protect from light.

-<u>Disposal</u>

Do not use Axcel Mefenamic Acid Suspension 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 dipose of medicines no longer required. These measures will help to protect the environment.

Product description

– What it looks like

Axcel Mefenamic Acid Suspension is white colour suspension with strawberry flavour.

-<u>Ingredients</u>

Active Ingredient: Mefenamic Acid

Inactive Ingredients:

Strawberry flavour, Polysorbate 20 (Tween 20), Sodium Citrate, Xanthan Gum, Citric Acid Anhydrous, Refined Sugar, Methylparaben, Saccharin Sodium, Purified Water, Propylene Glycol.

- <u>MAL Number</u> MAL20013770AZ

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

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