PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

FENAMIN SUSPENSION

Each 5 ml suspension contains 50 mg mefenamic acid

Contains sugar: Sorbitol 2,1 g

Contains sweetener: Sodium cyclamate 24 mg, saccharin sodium 1 mg

Read all of this leaflet carefully because it contains important information for you.

FENAMIN SUSPENSION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FENAMIN SUSPENSION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FENAMIN SUSPENSION with any other person.
- Ask your health care provider if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What FENAMIN SUSPENSION is and what it is used for.
2. What you need to know before you take FENAMIN SUSPENSION.
3. How to take FENAMIN SUSPENSION.
4. Possible side effects.
5. How to store FENAMIN SUSPENSION.
6. Contents of the pack and other information.

1. What FENAMIN SUSPENSION is and what it is used for

FENAMIN SUSPENSION contains mefenamic acid as an active substance. Mefenamic acid is a non-steroidal anti-inflammatory drug (NSAID) with antipyretic (helps against fever) and analgesic (pain-killing) properties.

FENAMIN SUSPENSION is used for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days.

2. What you need to know before you take FENAMIN SUSPENSION

Do not take FENAMIN SUSPENSION:

- If you are hypersensitive (allergic) to or have had an allergic reaction to mefenamic acid or aspirin or other related painkillers (NSAIDs), or any other ingredient in FENAMIN SUSPENSION, (listed in section 6).
- If you have ever had symptoms of bronchospasm, allergic rhinitis, or urticaria after using a NSAID.
- If you have or ever had a stomach ulcer, perforation or bleeding due to the use of NSAIDs.
- If you have inflammatory bowel disease such as ulcerative colitis and Crohn's disease (inflammatory conditions of the small intestine or colon).
- If you have epilepsy (a disorder that causes seizures).
- If you have a liver or kidney problem.
- If you have heart problems.
- If you have been treated for pain after coronary artery bypass.
- graft (CABG) surgery.
- If you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.

Warning and precautions

Special care should be taken with FENAMIN SUSPENSION if you:

- Are asthmatic or suffer from bowel problems, or any allergic reactions e.g., hay fever.
- Suffer from heart problems, have had a previous stroke or think that you may be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- The elderly have an increased frequency of side effects to NSAIDs such as FENAMIN SUSPENSION, especially gastrointestinal bleeding and perforation (PUBs), which may be fatal.
- Suffer from a bleeding disorder.
- Are dehydrated or suffer from renal disease.
- If you suffer from fluid retention, as FENAMIN may make this worse.
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- Develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Children

No information available.

Other medicines with FENAMIN SUSPENSION

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

The use of FENAMIN SUSPENSION together with the following medicines may cause side effects:

- Some medicines that are anticoagulants (i.e., thin blood/ prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine) may affect or be affected by treatment with FENAMIN SUSPENSION.
- Antiplatelet medicines, used to prevent blood clots and serotonin reuptake inhibitors (SSRIs), used for the treatment of depression.
- Lithium - the levels of Lithium in your blood may be increased.
- Any other anti-inflammatory pain killer, including aspirin.
- Corticosteroids: increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs).

FENAMIN SUSPENSION with food and drink

FENAMIN SUSPENSION must be taken with food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your healthcare provider for advice before taking FENAMIN SUSPENSION.

Driving and using machinery

FENAMIN SUSPENSION may make you feel dizzy, drowsy or tired and may cause visual disturbances. If FENAMIN SUSPENSION affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

It is not always possible to predict to what extent FENAMIN SUSPENSION may interfere with daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FENAMIN SUSPENSION affects them.

FENAMIN SUSPENSION contains sorbitol and may have a laxative effect.

FENAMIN SUSPENSION contains sorbitol which may have an effect on the control of you blood sugar if you have diabetes mellitus.

If you have been told that you have an intolerance to some sugars, you should not take FENAMIN SUSPENSION.

3. How to take FENAMIN SUSPENSION

Do not share medicines prescribed for you with any other person. Always take FENAMIN SUSPENSION exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. FENAMIN SUSPENSION must be taken with meals.

The usual adult dose is:

Relief of mild to moderate pain: 500 mg three times a day.

Acute pain: An initial dosage of 500 mg, thereafter 250 mg every 6 hours.

Children

The dosage for children is 25 mg per kg body-weight daily in divided doses.

6 months to 1 year: One medicine measure (5 ml), dose may be repeated up to three times a day.

2 years to 4 years: Two medicine measures (10 ml), dose may be repeated up to three times a day.

5 years to 8 years: Three medicine measures (15 ml), dose may be repeated up to three times a day.

9 years to 12 years: Four medicine measures (20 ml), dose may be repeated up to three times a day.

FENAMIN SUSPENSION should not be given for longer than 5 days.

If you take more FENAMIN SUSPENSION than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FENAMIN SUSPENSION

Take your missed dose as soon as you remember, if within a few hours after missing a dose. If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten dose.

4. Possible side effects

FENAMIN SUSPENSION can have side effects.

Not all side effects reported for FENAMIN SUSPENSION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FENAMIN SUSPENSION, please consult your healthcare provider for advice.

If any of the following happens, stop taking FENAMIN SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which
- may cause difficulty in swallowing or breathing;
- rash and itching;
- severe skin reactions.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FENAMIN SUSPENSION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Pass blood in your faeces (stools);
- pass black tarry stools;
- vomit any blood or dark particles that look like coffee grounds;
- unexplained wheezing, shortness of breath, or bruising;
- hallucinations;
- medicines such as FENAMIN SUSPENSION have been associated with a small increased risk of heart attack (myocardial infarction) or stroke;
- blood disorders, kidney problems, liver problems may occur rarely with FENAMIN SUSPENSION;
- FENAMIN SUSPENSION has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Diarrhoea, feeling sick and/or vomiting, unexplained stomach pain or other abnormal stomach symptoms.

Less frequent side effects:

- Seeing/hearing strange things;
- fluid retention (e.g., swollen ankles);
- headache, dizziness;

- constipation, flatulence (wind).

The following side effects have been reported but the frequency is unknown:

- Indigestion, heartburn;
- blurred or disturbed vision.
- blistering of the skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more information on the safety of FENAMIN SUSPENSION. May also report to Adcock Ingram Pharmacovigilance department by using the following email: Adcock.AEReports@adcock.com , or fax to +27 86 553 0128 or call 011 635 0134.

5. How to store FENAMIN SUSPENSION

Store in a cool dry place at or below 25 °C.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

Keep in original packaging until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What FENAMIN SUSPENSION contains

The active substance is mefenamic acid.

Each 5 ml contains 50 mg of mefenamic acid.

The other ingredients are:

butyl hydroxybenzoate, disodium edetate, flavour tutti-frutti, flavour vanilla, guar gum, methyl hydroxybenzoate, propyl hydroxybenzoate, purified water, saccharin sodium, simethicone emulsion, sodium chloride, sodium cyclamate, sodium lauryl sulphate, sorbitol (70 %) solution (E 420), titanium dioxide (C.I. 77891) (E 171), xanthan gum, sodium citrate, citric acid monohydrate.

Preservatives:

Butyl hydroxybenzoate	0,015 % m/v
Methyl hydroxybenzoate (E 218)	0,030 % m/v
Propyl hydroxybenzoate (E 216)	0,015 % m/v

Methyl hydroxybenzoate and Propyl hydroxybenzoate may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.

Contains sugar: Sorbitol 2,1 g.

This medicine contains 2,1 g sorbitol in each 5 ml, which is equivalent to 2,1 g/5 ml.

Contains sweetener: Sodium cyclamate 24 mg, saccharin sodium 1 mg.

What FENAMIN SUSPENSION looks like and contents of the pack.

An off-white suspension with a fruity odour.

100 or 200 ml are packed into a round, amber glass bottle and sealed with a white, polypropylene childproof cap with a low-density polyethylene liner and a translucent polyethylene tamper evident band.

100 or 200 ml are packed into a round, amber polyvinyl chloride bottle and sealed with a white, low density polyethylene snap cap.

Not all packs and pack sizes are necessarily marketed.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens

Midrand, 1685

Customer care: 0860 ADCOCK/232625

This leaflet was revised in

18 August 2023.

REGISTRATION NUMBER

27/2.7/0283

Access to the corresponding professional information

For the Professional Information for FENAMIN SUSPENSION scan the QR code.

The same information is available at www.adcock.com/products/productinformation .