Scheduling Status **S2**

FENAMIN 250, 250 mg capsules

Mefenamic Acid

Contains sugar:

Lactose monohydrate 55 mg

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

FENAMIN 250 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FENAMIN 250 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FENAMIN 250 with any other person.
- Ask your health care provider or pharmacist 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 250** is and what it is used for

2. What you need to know before you take **FENAMIN 250**

3. How to take **FENAMIN 250**

4. Possible side effects

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6. Contents of the pack and other information

1. WHAT FENAMIN 250 IS AND WHAT IT IS USED FOR

FENAMIN 250 contains mefenamic acid. Mefenamic acid is a non-steroidal anti-inflammatory medicine (NSAID) with antipyretic (helps against fever) and analgesic (pain-killing) properties. It is used for the relief of mild to moderate pain and relief of swelling and inflammation.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FENAMIN 250

Do not take FENAMIN 250

- 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 250 (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 are being treated for pain after coronary artery bypass graft (CABG) surgery
- If you are pregnant or breastfeeding.
- 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.

Warnings and precautions

Special care should be taken with FENAMIN 250:

- If you are asthmatic or suffer from kidney, liver or bowel problems, or any allergic reactions e.g., hay fever.
- If you 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 250, especially gastrointestinal bleeding and perforation (PUBs), which may be fatal.
- Suffer from a bleeding disorder
- If you are dehydrated.
- 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.

Children

No information available.

Other medicines and FENAMIN 250

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

The use of FENAMIN 250 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 250.
- Antiplatelet medicines, used to prevent blood clots and serotonin reuptake inhibitors (SSRIs), used for the treatment of depression.
- Lithium.
- Any other anti-inflammatory pain killer, including aspirin.

FENAMIN 250 with food and drink

FENAMIN 250 must be taken with food.

Pregnancy and breastfeeding

You should not take FENAMIN 250 if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking FENAMIN 250.

Driving and using machines

FENAMIN 250 may make you feel dizzy or drowsy. If FENAMIN 250 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 predict to what extent FENAMIN 250 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 250 affects them.

FENAMIN 250 contains lactose monohydrate

FENAMIN 250 contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take FENAMIN 250

3. How to take FENAMIN 250

Do not share medicines prescribed for you with any other person. Always take FENAMIN 250 exactly as describe in this leaflet or as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

FENAMIN 250 should not be given for longer than 5 days.

If you take more FENAMIN 250 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 250

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 250 can have side effects.

Not all side effects reported for FENAMIN 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FENAMIN 250, please consult your healthcare provider for advice.

If any of the following happens, stop taking FENAMIN 250 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 250. 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 250 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 250;
- FENAMIN 250 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 250.

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 250

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

Protect from light.

Do not store 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 250 contains

The active substance is mefenamic acid.

Each capsule contains 250 mg of mefenamic acid.

The other ingredients are:

Brilliant blue (C.I. 42090) (E133), croscarmellose sodium, gelatin (E441), lactose monohydrate, magnesium stearate, povidone K25, quinoline yellow (C.I. 47005) (E104), sodium lauryl sulphate, titanium dioxide (C.I. 77891) (E171)

Contains sugar:

Lactose monohydrate 55 mg

What FENAMIN 250 looks like and contents of the pack

An off-white, free-flowing powder encapsulated within a no. 1 capsule with a turquoise cap and a pale-yellow body.

30 capsules are packed in a white polypropylene container with a white low-density polyethylene cap and temper evident seal. The container is packed into an outer cardboard carton together with a leaflet.

30 capsules are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. There are 10 capsules per blister strip and three blister strips are packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK/232625

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Access to the corresponding professional information

The professional information for this medicine is available on www.fenamin.com