PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

FENAMIN-500

Each film coated tablet contains 500mg of mefenamic acid.

Contains sugar: Lactose monohydrate 143 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

FENAMIN-500 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FENAMIN-500 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FENAMIN-500 with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What FENAMIN-500 is and what it is used for

A 2.7 Antipyretic and anti-inflammatory analgesics

FENAMIN-500 is used for the relief of period pain.

2. What you need to know before you take FENAMIN-500

Do not take FENAMIN-500

- If you are hypersensitive (allergic) to or have had an allergic reaction to mefenamic acid or any other ingredient in FENAMIN-500, aspirin or other related painkillers (see What FENAMIN-500 contains).
- 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 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-500:

- If you are asthmatic or suffer from 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).

- If you are an elderly with has an increased frequency of side effects to NSAIDs such as FENAMIN-500, especially gastrointestinal bleeding and perforation (PUBs), which may be fatal.
- If you suffer from a bleeding disorder.
- If you are dehydrated.
- 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.
- If you 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).

Other medicines and FENAMIN-500

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

In particular, FENAMIN-500 can affect the following medicines:

- Some medicines that are anticoagulants (i.e., thins blood/ prevent clotting e.g., aspirin/acetylsalicylic acid, warfarin, ticlodipine) may affect or be affected by treatment with FENAMIN-500;
- Antiplatelet medicines, used to prevent blood clots and serotonin reuptake inhibitors (SSRIs), used for the treatment of depression;
- Lithium;
- Corticosteroids;
- NSAIDs.

FENAMIN-500 with food and drink

FENAMIN-500 must be taken with food.

Pregnancy and breastfeeding and fertility

Always tell your healthcare provider if you are taking any other medicine. 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-500.

Driving and using machinery

FENAMIN-500 may make you feel dizzy or drowsy. If FENAMIN-500 affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

FENAMIN-500 contains:

croscarmellose sodium, iron oxide yellow (C.I. 77492), lactose monohydrate, macrogol, magnesium stearate, polyvinyl alcohol, povidone K25, purified talc, titanium dioxide (C.I. 77891).

FENAMIN-500 contains lactose, 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-500.

3. How to take FENAMIN-500

Do not share medicines prescribed for you with any other person.

Always take FENAMIN-500 exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual adult dose is:

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

FENAMIN-500 should not be given for longer than 3 days.

If you have the impression that the effect of FENAMIN-500 is too strong or too weak, tell your doctor or pharmacist.

If you take more FENAMIN-500 than you should

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

If you forget to take FENAMIN-500

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-500 can have side effects.

Not all side effects reported for FENAMIN-500 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FENAMIN-500, please consult your healthcare provider for advice.

If any of the following happens, stop taking FENAMIN-500 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-500. You may need urgent medical attention or hospitalization.

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-500 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-500;
- FENAMIN-500 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 frequently side effects:

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

- constipation, flatulence (wind).

Frequency unknown:

- Indigestion, heartburn;
- blurred or disturbed vision.

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 or nurse. 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-500.

May also report to Adcock Ingram Limited 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-500

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-500 contains

- The active substance is mefenamic acid
- The other ingredients are croscarmellose sodium, iron oxide yellow (C.I. 77492), lactose monohydrate, macrogol, magnesium stearate, polyvinyl alcohol, povidone K25, purified talc, titanium dioxide (C.I. 77891)
- Contains sugar: Lactose monohydrate 143 mg

What FENAMIN-500 looks like and contents of the pack

A pale yellow, round, film-coated, bevelled edge biconvex tablet.

9 tablets are packed in a white, polypropylene container and sealed with a white low-density polyethylene cap together with a white foam insert and rayon. The container is packed with a leaflet.

9 tablets are packed in a white, polypropylene container and sealed with a white low- density polyethylene cap. The container is packed with a leaflet.

9 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing.

One or more blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

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