Patient Information Leaflet

SCHEDULING STATUS

S2

ADCO-MEFENAMIC ACID 250 mg, hard gelatine capsules

Mefenamic acid

Sugar free.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ADCO-MEFENAMIC ACID 250 mg 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 ADCO-MEFENAMIC ACID 250 mg is and what it is used for
2. What you need to know before you take ADCO-MEFENAMIC ACID 250 mg
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1. What ADCO-MEFENAMIC ACID 250 mg is and what it is used for

ADCO-MEFENAMIC ACID 250 mg contains mefenamic acid. It belongs to the group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Mefenamic acid can be used for pain

(analgesic) and inflammation (anti-inflammatory).

ADCO-MEFENAMIC ACID 250 mg is indicated to treat pain, swelling and inflammation as well as for cramping pain in the lower abdomen occurring just before or during menstruation (primary dysmenorrhoea).

2. What you need to know before you take ADCO-MEFENAMIC ACID 250 mg

Do not take ADCO-MEFENAMIC ACID 250 mg

- If you are hypersensitive (allergic) to mefenamic acid, aspirin or any other NSAIDs or component of ADCO-MEFENAMIC ACID 250 mg (listed in section 6).
- If you have or have had a stomach ulcer or have a history of inflammation and bleeding in the bowels.
- If you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy unless specifically advised to do so by your healthcare professional because these medicines may cause problems in your unborn baby.
- If you have epilepsy (fits).
- If you have liver problems.
- If you have heart failure.

Warnings and precautions

Talk to your doctor or health care provider before taking ADCO-MEFENAMIC ACID 250 mg.

Take special care with ADCO-MEFENAMIC ACID 250 mg:

- If you have or have had any allergies or allergic reactions (including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing) which required hospital treatment.
- Therapy should be discontinued if diarrhoea or skin rash occur.
- If you are using anti-coagulants (blood thinners). ADCO-MEFENAMIC ACID 250 mg may enhance the effects of these medicines, affect your blood and cause conditions such as haemolytic anaemia (low red blood cells), agranulocytosis (low white blood cells), pancytopenia (low levels of red blood cells, white blood cells and platelets),

thrombocytopenia (low levels of platelets) or thrombocytopenia purpura (decrease of platelets) and bone marrow suppression. Your doctor might want to monitor you if you use ADCO-MEFENAMIC ACID 250 mg for long periods.

- If you are asthmatic and suffer from bronchoconstriction (coughing, wheezing, and shortness of breath) when taking aspirin.
- If you have heart problems such as high blood pressure (hypertension) and/or heart failure as ADCO-MEFENAMIC ACID 250 mg may cause fluid retention and swelling.
- If you have high cholesterol (hyperlipidaemia), high blood sugar (diabetes) or if you are a smoker.
- The elderly and patients with a history of stomach ulcers are more susceptible to develop side-effects affecting the bowels when using NSAIDs. Therefore, they should be carefully monitored for stomach ulcers and bleeding as it may be fatal.
- If you have a history of gastrointestinal disease such as ulcerative colitis, Crohn's disease, hiatus hernia, GERD or angiodysplasia as ADCO-MEFENAMIC ACID 250 mg may exacerbate these conditions

Tell your doctor or healthcare 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 ADCO-MEFENAMIC ACID 250 mg

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Some medicines may increase or decrease the effects of ADCO-MEFENAMIC ACID 250 mg, and your doctor may wish to monitor you carefully if you are taking these medicines.

- Anti-inflammatory medicines such as NSAIDs (e.g., aspirin, ibuprofen, etc.): if taken with ADCO-MEFENAMIC ACID 250 mg it may increase your side-effects.
- Corticosteroids (cortisones): May increase the risk of developing stomach ulcers or it may cause existing ulcers to bleed.
- Anticoagulant medicines which thin the blood (e.g., warfarin): if taken with ADCO-MEFENAMIC ACID 250 mg, you may be at an increased risk of bleeding, therefore your doctor is likely to monitor you more closely.
- Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs) used for depression: if taken with ADCO-MEFENAMIC ACID 250 mg, you may be at an increased risk of bleeding if you suffer from stomach ulcers.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking ADCO-MEFENAMIC ACID 250 mg.

Driving and using machines

It is not always possible to predict to what extent ADCO-MEFENAMIC ACID 250 mg may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADCO-MEFENAMIC ACID 250 mg affects them.

3. How to take ADCO-MEFENAMIC ACID 250 mg

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

Always take ADCO-MEFENAMIC ACID 250 mg exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

ADCO-MEFENAMIC ACID 250 mg is for oral use.

The usual adult dose of ADCO-MEFENAMIC ACID 250 mg is 500 mg (two 250 mg hard gelatine capsules) three times per day (every eight hours) with food. The dose may be reduced to 250 mg (one hard gelatine capsule) three times per day.

ADCO-MEFENAMIC ACID 250 mg should not be used for longer than five days at a time.
Use the lowest effective dose for the shortest possible duration of treatment.

If you take more ADCO-MEFENAMIC ACID 250 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
If you have taken more than you should, ADCO-MEFENAMIC ACID 250 mg may cause epileptic fits (convulsions) and gastrointestinal bleeding (bleeding in the bowels). Treatment is symptomatic and supportive.

If you forget to take / missed a dose of ADCO-MEFENAMIC ACID 250 mg

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ADCO-MEFENAMIC ACID 250 mg

No information available.

4. Possible side effects

ADCO-MEFENAMIC ACID 250 mg can have side effects.
Not all side effects reported for ADCO-MEFENAMIC ACID 250 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-MEFENAMIC ACID 250 mg, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Indigestion (dyspepsia), upper gastrointestinal discomfort as well as peptic ulceration (stomach ulcers) and gastrointestinal bleeding (bleeding in the bowels).

Less frequent side effects:

- Headache, drowsiness, dizziness, and nervousness.
- Visual disturbances.
- Diarrhoea.

Side effects of an unknown frequency:

- Prothrombin (protein made by the liver for blood clotting) concentration may decrease and enhance the effect of blood thinners.
- Haemolytic anaemia (low levels of red blood cells), agranulocytosis (low white blood cells levels), pancytopenia (low levels of red blood cells, white blood cells and platelets), thrombocytopenia (low levels of platelets) or thrombocytopenia purpura (decrease of platelets) and bone marrow suppression.
- Oedema (swelling due to fluid build-up/retention), high blood pressure, and heart failure.
- Bronchoconstriction (coughing, wheezing, and shortness of breath) in asthmatic patients with aspirin sensitivity.
- Skin rash may be a sensitivity reaction and hives (urticaria).
- Fluid filled blisters due to allergic skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis.
- Allergic glomerulonephritis (kidney inflammation).

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. This includes any possible side effects not listed in this leaflet. 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 ADCO-MEFENAMIC ACID 250 mg.

5. How to store ADCO-MEFENAMIC ACID 250 mg

Store all medicines out of reach of children.

Store at or below 25 °C in the original packaging.

Do not use after the expiry date stated on the container, carton or blister.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ADCO-MEFENAMIC ACID 250 mg contains

The active substance is mefenamic acid.

Each hard gelatine capsule contains 250 mg mefenamic acid.

The other ingredients are:

Contents of the hard gelatine capsules

Colloidal silicon dioxide, magnesium stearate, polyvinylpyrrolidone, sodium lauryl sulphate, sodium starch glycolate, starch.

Hard gelatine capsules:

Gelatine, indigo carmine (cap), quinoline yellow (body), titanium dioxide.

What ADCO-MEFENAMIC ACID 250 mg looks like and contents of the pack

ADCO-MEFENAMIC ACID 250 mg capsules are size '1' hard gelatine capsules with opaque, yellow body and opaque, blue cap containing a white powder.

18 capsules are packed into either LDPE, white securitainers with a white lid, or an amber, round glass bottle with a white, polypropylene cap, or blister packs with transparent PVC/PVDC film on aluminium foil.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

www.adcock.com

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