SCHEDULING STATUS

S3

ADCO MEFENAMIC ACID 50 mg/5 mL, suspension
Mefenamic acid
Sugar free.

Read all of this leaflet carefully before you start taking ADCO MEFENAMIC ACID 50 mg/5 mL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADCO MEFENAMIC ACID 50 mg/5 mL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ADCO MEFENAMIC ACID 50 mg/5 mL is and what it is used for
2. What you need to know before you take ADCO MEFENAMIC ACID 50 mg/5 mL
3. How to take ADCO MEFENAMIC ACID 50 mg/5 mL
4. Possible side effects
5. How to store ADCO MEFENAMIC ACID 50 mg/5 mL
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1. What ADCO MEFENAMIC ACID 50 mg/5 mL is and what it is used for

ADCO MEFENAMIC ACID 50 mg/5 mL 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 fever (antipyretic).
ADCO MEFENAMIC ACID 50 mg/5 mL is used for the treatment of mild to moderate pain, such as pain from injury, arthritis, or muscle pain. It is also used for painful periods (dysmenorrhoea), headaches, tooth pain and fever.
ADCO MEFENAMIC ACID 50 mg/5 mL will decrease the amount of blood that is lost during your period where there is usually heavy or prolonged bleeding (menorrhagia).

2. What you need to know before you take ADCO MEFENAMIC ACID 50 mg/5 mL

Do not take ADCO MEFENAMIC ACID 50 mg/5 mL

- If you are hypersensitive (allergic) to mefenamic acid, aspirin or any other NSAIDs or component of ADCO MEFENAMIC ACID 50 mg/5 mL (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 health care professional because these medicines may cause problems in your unborn baby.

- If you are breastfeeding.
- 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 50 mg/5 mL.

Take special care with ADCO MEFENAMIC ACID 50 mg/5 mL:

- 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 50 mg/5 mL 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 50 mg/5 mL 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 50 mg/5 mL 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, gastroesophageal reflux disease (GERD) or angiodysplasia as ADCO MEFENAMIC ACID 50 mg/5 mL may exacerbate these conditions.
- 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).
- This medicine contains 750 mg sorbitol in each 5 mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 300 mg propylene glycol in each 5 mL. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

- If you are pregnant or breast feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- This medicine contains 25 mg sodium benzoate per 5 mL of suspension.
- 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 health care 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 specific data is available for children.

Other medicines and ADCO MEFENAMIC ACID 50 mg/5 mL
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 50 mg/5 mL, 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 50 mg/5 mL 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 50 mg/5 mL, 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 50 mg/5 mL, 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 health care provider for advice before taking ADCO MEFENAMIC ACID 50 mg/5 mL.
Safety in pregnancy and breastfeeding has not been established.

Driving and using machines
It is not always possible to predict to what extent ADCO MEFENAMIC ACID 50 mg/5 mL 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 50 mg/5 mL affects them.

3. How to take ADCO MEFENAMIC ACID 50 mg/5 mL

Do not share medicines prescribed for you with any other person.
Always take ADCO MEFENAMIC ACID 50 mg/5 mL 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 50 mg/5 mL is for oral use.
The usual dose of ADCO MEFENAMIC ACID 50 mg/5 mL is as follows:

Children 6 months to 1 year	:5 mL three times per day
Children 2 to 4 years	:10 mL three times per day
Children 5 to 8 years	:10 mL four times per day
Children 9 to 12 years	:15 mL four times per day

ADCO MEFENAMIC ACID 50 mg/5 mL may be taken with meals to lower stomach irritation.

ADCO MEFENAMIC ACID 50 mg/5 mL should not be used for longer than seven days at a time. Use the lowest effective dose for the shortest possible duration of treatment.

If you take more ADCO MEFENAMIC ACID 50 mg/5 mL 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 50 mg/5 mL 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 50 mg/5 mL

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 50 mg/5 mL

No information available.

4. Possible side effects

ADCO MEFENAMIC ACID 50 mg/5 mL can have side effects.
Not all side effects reported for ADCO MEFENAMIC ACID 50 mg/5 mL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO MEFENAMIC ACID 50 mg/5 mL, 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), perforation or gastrointestinal bleeding (bleeding in the bowels).
- Nausea.
- Vomiting.
- Flatulence.
- Constipation.
- Abdominal pain.
- Melaena (dark sticky faeces with or without blood).
- Haematemesis (vomiting of blood).
- Ulcerative stomatitis (painful swelling and sores inside the mouth).
- Worsening of colitis (inflammation in your colon) and Crohn's disease (a chronic inflammatory bowel disease that affects the lining of the digestive tract).
- Gastritis (inflammation of the lining of your stomach).

Less frequent side effects:

- Headache, drowsiness, dizziness, and nervousness.
- Visual disturbances.
- Diarrhoea.
- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS).

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 50 mg/5 mL.

5. How to store ADCO MEFENAMIC ACID 50 mg/5 mL
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 label or carton.
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 50 mg/5 mL contains
The active substance is mefenamic acid.
Each 5 mL contains 50 mg mefenamic acid.

The other ingredients are:
Citric acid, Fresh mint flavour, Kaolin light, Parekh pharma flavour, Polysorbate 20, Polysorbate 80, Povidone, Propylene glycol, Purified water, Sodium benzoate, Sodium cyclamate, Sodium saccharin, Sorbitol 70 %, and Xantham gum.

What ADCO MEFENAMIC ACID 50 mg/5 mL looks like and contents of the pack
ADCO MEFENAMIC ACID 50 mg/5 mL is a smooth, off-white, opaque suspension with a fruity odour and sweet with bitter after taste. It is packed in amber glass bottles of 100 mL and 200 mL with a white polypropylene cap with liner.

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