SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

ADCO MEFENAMIC ACID 50 mg/5 mL, suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains 50 mg mefenamic acid.

Excipients with known effect:

- Contains preservative (Sodium benzoate): 0,5 % *m/v*
- Contains sweetener (Sodium saccharin): 5 mg/5 mL
- Contains sweetener (Sodium cyclamate): 20 mg/5 mL
- Contains sorbitol 70 %: 750 mg/5 mL
- Contains propylene glycol: 300 mg/5 mL

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.

Smooth, off-white, opaque suspension with a fruity odour and sweet with bitter after taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ADCO MEFENAMIC ACID 50 mg/5 mL is used for the relief of mild to moderate pain in acute and chronic conditions including pain of traumatic, arthritic, or muscular origin; dysmenorrhoea; headache and dental pain. Mefenamic acid reduces blood loss in menorrhagia where menorrhagia is due to ovulatory dysfunctional bleeding. Uterine and other pathology should first be excluded before prescribing ADCO MEFENAMIC ACID 50 mg/5 mL for this indication. ADCO MEFENAMIC ACID 50 mg/5 mL is also indicated as an antipyretic in febrile conditions.

4.2 Posology and method of administration

Posology

Children

6 months to 1 year :5 mL three times per day

2 to 4 years :10 mL three times per day

5 to 8 years :10 mL four times per day
9 to 12 years :15 mL four times per day

Gastric irritation may be reduced by taking medication during meals.
Mefenamic acid should not be used, continuously, for longer than seven days at a time.
Use the lowest effective dose for the shortest possible duration of treatment.

Special populations
No information available.

Paediatric population
Refer to posology in children above.

Method of administration
For oral administration.
Shake the bottle before use.

4.3 Contraindications

- Hypersensitivity to mefenamic acid or to any of the inactive ingredients (excipients) of ADCO MEFENAMIC ACID 50 mg/5 mL (see section 6.1).
- ADCO MEFENAMIC ACID 50 mg/5 mL is contraindicated in patients who respond to aspirin and aspirin like medicines with sensitivity reactions like bronchoconstriction, skin rashes and urticaria.
- ADCO MEFENAMIC ACID 50 mg/5 mL is contraindicated in patients with a history of gastrointestinal perforation, ulceration or bleeding (PUBs) and/or inflammatory bowel disease, related to previous non-steroidal anti-inflammatory agents (NSAIDs), including ADCO MEFENAMIC ACID 50 mg/5 mL.
- Active or history of recurrent ulcer/haemorrhage/perforations.
- Safety in pregnancy and lactation has not been established.
- Avoid use of NSAIDs in women around 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/foetal renal dysfunction and premature closure of the foetal ductus arteriosus (see section 4.4 and 4.6).
- Do not use in epileptic patients or in patients with impaired hepatic function.
- ADCO MEFENAMIC ACID 50 mg/5 mL is contraindicated in heart failure.

4.4 Special warnings and precautions for use

ADCO MEFENAMIC ACID 50 mg/5 mL may enhance the effects of the coumarin anticoagulants.
Therapy should be discontinued if diarrhoea or skin rash occur.
Reported haematological effects include haemolytic anaemia, agranulocytosis, pancytopenia, thrombocytopenia or thrombocytopenia purpura and bone marrow aplasia. Allergic glomerulonephritis has occurred as well as abnormalities of hepatic and renal function. Therefore, blood counts and monitoring of hepatic and renal function are advised during prolonged therapy with mefenamic acid.

Bronchoconstriction may occur in asthmatic patients with aspirin sensitivity. ADCO MEFENAMIC ACID 50 mg/5 mL affects platelet function and it may enhance the effect of anticoagulant therapy.

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with ADCO MEFENAMIC ACID 50 mg/5 mL therapy. In view of ADCO MEFENAMIC ACID 50 mg/5 mL's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Caution is required in patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) and should only be treated with diclofenac after careful consideration.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs including ADCO MEFENAMIC ACID 50 mg/5 mL especially gastrointestinal perforation, ulceration, and bleeding (PUBs) which may be fatal.

The risk of gastrointestinal perforation, ulceration, or bleeding (PUBs) is higher with increasing doses of ADCO MEFENAMIC ACID 50 mg/5 mL in patients with a history of ulcers, and the elderly.

When gastrointestinal bleeding or ulceration occurs in patients receiving ADCO MEFENAMIC ACID 50 mg/5 mL treatment with ADCO MEFENAMIC ACID 50 mg/5 mL should be stopped.

ADCO MEFENAMIC ACID 50 mg/5 mL should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. ADCO MEFENAMIC ACID 50 mg/5 mL should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Foetal Toxicity:

Regular use of NSAIDs such as ADCO MEFENAMIC ACID 50 mg/5 mL during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus *in utero*, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed, and its duration increased.

Limit use of NSAIDs, including ADCO MEFENAMIC ACID 50 mg/5 mL, between 20 and 30 weeks of pregnancy due to the risk of oligohydramnios/foetal renal dysfunction. Avoid use of NSAIDs in women around 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/foetal renal dysfunction and premature closure of the foetal ductus arteriosus.

If NSAID treatment is necessary between 20 weeks and 30 weeks gestation, limit ADCO MEFENAMIC ACID 50 mg/5 mL use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if ADCO MEFENAMIC ACID 50 mg/5 mL treatment extends beyond 48 hours. Discontinue ADCO MEFENAMIC ACID 50 mg/5 mL if oligohydramnios occurs and follow up according to clinical practice (see section 4.3 and 4.6).

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):

DRESS has been reported in patients taking NSAIDs such as ADCO MEFENAMIC ACID 50 mg/5 ml. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue ADCO MEFENAMIC ACID 50 mg/5 ml and evaluate the patient immediately.

Sorbitol

ADCO MEFENAMIC ACID 50 mg/5 mL contains sorbitol. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit[1], that is to say essentially 'sodium-free'.

[1]Calculated based on posology of children 9 to 12 years (higher dosage unit).

Propylene glycol

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.

Sodium benzoate

This medicine contains 25 mg sodium benzoate per 5 mL of suspension.

4.5 Interactions with other medicines and other forms of interaction

Non-Steroidal Anti-inflammatories (NSAIDs):

The use of two or more NSAIDs concomitantly could result in an increase in side-effects.

Corticosteroids:

Increased risk of gastrointestinal perforation, ulceration, or bleeding (PUBs).

Anti-coagulants:

ADCO MEFENAMIC ACID 50 mg/5 mL may enhance the effects of anti-coagulants such as warfarin.

Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs):

Increased risk of gastrointestinal bleeding.

Paediatric population

No information available.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Use of NSAIDs, including ADCO MEFENAMIC ACID 50 mg/5 mL, can cause premature closure of the foetal ductus arteriosus and foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, the use of ADCO MEFENAMIC ACID 50 mg/5 mL dose and duration between 20 and 30 weeks of gestation should be limited and avoided at around 30 weeks of gestation and later in pregnancy (see section 4.3 and 4.4).

Breastfeeding

Safety in lactation has not been established.

Fertility

No information available.

4.7 Effects on ability to drive and use machines

No information available.

Refer to section 4.8.

4.8 Undesirable effects

a. Summary of the safety profile

The most frequently reported side effects are gastrointestinal disturbances and include dyspepsia, upper gastrointestinal discomfort as well as peptic ulceration and gastrointestinal bleeding.

b. Tabulated summary of adverse reactions

Adverse reactions are listed by system organ class.

SYSTEM ORGAN CLASS	**FREQUENCY**	**ADVERSE REACTIONS**

Blood and lymphatic system disorders	Frequency unknown	Prothrombin concentration may decrease and enhance the effect of anticoagulant therapy, haemolytic anaemia, agranulocytosis, pancytopenia, thrombocytopenia or thrombocytopenia purpura and bone marrow aplasia.
Nervous system disorders	Less frequent	Headache, drowsiness, dizziness, nervousness.
Eye disorders	Less frequent	Visual disturbances.
Cardiac disorders	Frequency unknown	Oedema, hypertension, and cardiac failure.
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Bronchoconstriction in asthmatic patients with aspirin sensitivity.
Gastrointestinal Disorders[1]	Frequent	Dyspepsia, upper gastrointestinal discomfort as well as peptic ulceration and gastrointestinal bleeding.
	Less frequent	Diarrhoea.
Skin and subcutaneous tissue disorders	Less frequent	Drug reaction with Eosinophilia and Systemic Symptoms (DRESS) (see section 4.4).
	Frequency unknown	Skin rash may be a sensitivity reaction and urticaria. Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.
Renal and urinary disorders	Frequency unknown	Allergic glomerulonephritis

Post marketing experience

No information available.

c. Description of selected adverse reactions

[1]Gastrointestinal system disorders: The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation, or gastrointestinal bleeding, sometimes fatal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain,

melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

Mefenamic acid has a marked tendency to induce tonic-clonic (grand mal) convulsions in over dosage. Acute erosion or ulceration of the gastrointestinal mucosa may be a delayed manifestation.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.

Mechanism of action

Mefenamic acid has analgesic, anti-inflammatory and antipyretic properties. It inhibits the synthesis of prostaglandins. Mefenamic acid shows central and peripheral action, and it owes these properties to its capacity to inhibit cyclooxygenase.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid (anhydrous)

Fresh mint flavour (LR11196)

Kaolin light

Parekh pharma flavour (LR 14996)

Polysorbate 20
Polysorbate 80
Povidone (Kollidon 90)
Propylene glycol
Purified water
Sodium benzoate
Sodium cyclamate
Sodium saccharin
Sorbitol 70 % Non-crystalising
Xantham gum (Keltrol TF)

6.2 Incompatibilities

No data available.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Amber glass bottles of 100 mL and 200 mL suspension with a white polypropylene cap with liner.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)

28/2.7/0220

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 21 January 2000

10. DATE OF REVISION OF THE TEXT

01 May 2023

Namibia: NS2 04/2.7/1562

Zimbabwe: 100 ml: 2002/2.1/4077 P

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