

MECOLZINE 500MG

GASTRO RESISTANT TABLET

Mesalazine 500mg

What is in this leaflet?

1. What MECOLZINE is used for
2. How MECOLZINE works
3. Before you use MECOLZINE
4. How to use MECOLZINE
5. While you are using it
6. Side Effects
7. Storage and Disposal of MECOLZINE
8. Product Description
9. Manufacturer
10. Product Registration Holder

1. What MECOLZINE is used for

MECOLZINE contains Mesalazine which belongs to a group of drugs called intestinal anti-inflammatory drugs. It is indicated in the treatment of ulcerative colitis, an inflammatory bowel disease.

2. How MECOLZINE works

MECOLZINE acts on cells lining the intestine and is believed to decrease the production of prostaglandin, a substance in the body that regulates inflammation, and modulate the inflammatory response derived from the cyclooxygenase and lipoxygenase pathways.

3. Before you use MECOLZINE

When you must not use it:

Do not take MECOLZINE:

- if you are allergic to Mesalazine or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to aspirin or any other salicylate.
- if you have a medical condition that can make you prone to bleeding.

- if you have severe kidney and/or liver failure.

Before you start to use it:

Before starting treatment with MECOLZINE, tell your doctor:

- if you are or want to become pregnant
- if you are breast-feeding
- if you have liver or kidney problems
- if you suffer from any lung disease, for example, asthma
- if you have ever had an allergy to sulfasalazine
- if you have an ulcer in your stomach or small intestine
- if you had previously had inflammation of the heart (which could be a result of an infection in the heart).
- if you have ever developed a severe skin rash or skin peeling, blistering or mouth sores after using Mesalazine.

If you experience any allergic reaction (e.g. skin rash, itching) or cramps, abdominal pain, severe headache and fever during the course of treatment, do not take any more tablets and tell your doctor immediately.

Before and during treatment, your doctor may want to perform blood and urine tests on a regular basis to check the function of your liver, kidneys, blood and lungs.

Kidney stones may develop with use of Mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with Mesalazine.

Mesalazine may produce red-brown urine discoloration after contact with sodium

hypochlorite bleach in the toilet water. It concerns a chemical reaction between Mesalazine and bleach and is harmless.

Severe skin rashes including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been observed with Mesalazine treatment. Stop taking Mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 6.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is limited experience with the use of Mesalazine during pregnancy and breast-feeding. The newborn may develop allergic reactions after breast-feeding, e.g. diarrhoea. If the newborn develops diarrhoea, breast-feeding should be discontinued.

It is not recommended to use MECOLZINE during pregnancy or breast-feeding unless your doctor tells you otherwise.

Taking other medicines:

In general, you can continue treatment with other medicines while taking MECOLZINE. However, tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines, including medicines

MECOLZINE 500MG

GASTRO RESISTANT TABLET

Mesalazine 500mg

obtained without a prescription.

MECOLZINE can interact with some medications if they are given at the same time.

In particular:

- medicines to lower blood sugar (antidiabetics)
- medicines to lower blood pressure (antihypertensives/diuretics)
- medications for the treatment or prevention of gout attacks
- medicines that help the bowel movement (laxatives containing lactulose)
- medicines to prevent blood clotting (anticoagulants)
- medicines to reduce the activity of the immune system (eg. azathioprine or 6-mercaptopurine or thioguanine)
- medicines to treat pain and inflammation (anti-inflammatories)

MECOLZINE contains sodium (under the form of anhydrous sodium carbonate and croscarmellose sodium).

This medicine contains 49 mg of sodium (the main component of table/cooking salt) in each gastro-resistant tablet. This is equivalent to 2.5% of the maximum daily sodium intake for adults.

Talk to your doctor or pharmacist if you need 8 or more gastro-resistant tablets daily for a prolonged period, especially if you have been advised to follow a low-salt (sodium) diet.

4. How to use MECOLZINE

How much to use:

Always take this medicine exactly as your doctor or pharmacist has told you. Check

with your doctor or pharmacist if you are not sure.

The recommended dose for adults is:

- **To treat an acute episode of colitis**, your doctor will normally prescribe a dose of between 1.5 grams (3 gastro-resistant tablets) and 4 grams (8 gastro-resistant tablets) of Mesalazine a day, which can be administered in one or more doses.

- **To help prevent further episodes of colitis**, your doctor may prescribe a dose of between 1.5 grams (3 gastro-resistant tablets) and 3 grams (6 gastro-resistant tablets) of Mesalazine a day, which may be administered in one or more doses.

When to use it:

It is important that you take MECOLZINE tablets every day, even when you do not have symptoms of ulcerative colitis. Always finish the treatment you have been prescribed.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

How long to use it:

Your doctor will tell you how long you need to take this medicine. Do not stop your treatment, even though you may feel better, as your symptoms may appear again if you stop your treatment too early.

If you forget to use it:

Do not take a double dose to make up for a forgotten dose. Consult your doctor or pharmacist if you have any further questions on the use of this medicine.

If you use too much (overdose):

If you take more MECOLZINE than your recommended dose, notify your doctor. In case of overdose or accidental intake, notify your doctor or pharmacist immediately. It is recommendable to show the healthcare professional the leaflet and the package.

5. While you are using it

Things you must do:

MECOLZINE tablets should be orally taken.

The tablets should be swallowed whole, with liquid and before meals.

Follow your doctor's instructions carefully regarding how to use this medicine, during both acute inflammatory stages and maintenance treatment.

Blood tests (blood differential; liver function tests such as ALT and serum creatinine) should be determined before and during treatment, according to the decision of the treating doctor.

Things you must not do:

Do not take a double dose to make up for a forgotten dose.

Do not take MECOLZINE concomitantly with laxatives such as lactulose or similar.

Things to be careful of:

The use of MECOLZINE in elderly patients should be done with caution and always limited to those patients with normal renal function.

Women who are pregnant or breast-feeding should not take MECOLZINE unless advised otherwise by their doctor.

MECOLZINE 500MG

GASTRO RESISTANT TABLET

Mesalazine 500mg

MECOLZINE is not recommended to be given to children under 18 years of age due to lack of data on safety and efficacy. Do not administer to children under 5 years.

6. Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although severe allergic reactions are very rare. If you have any of these symptoms after using this medicine, stop using this medicine and contact your doctor immediately:

- Allergic skin rash;
- fever;
- difficulty breathing.

If you experience fever or irritation of the throat or mouth, stop using this medicine and contact your doctor immediately. These symptoms may, very rarely, be due to a decrease in the number of white blood cells (a condition called agranulocytosis).

Serious side effects

Stop using Mesalazine and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged lymph nodes. These serious skin rashes can be preceded by fever and flu-like symptoms.

The following side effects have also been reported in patients using Mesalazine:

Rare side effects (may affect up to 1 in 1,000 people)

- abdominal pain, diarrhoea, flatulence, nausea and vomiting;
- headache, dizziness;
- chest pain, difficulty breathing or swollen limbs due to an effect on the heart;
- greater sensitivity of the skin to sunlight and ultraviolet light (photosensitivity).

Very rare side effects (may affect up to 1 in 10,000 people)

- problems with kidney function, sometimes involving swelling of the limbs or flank pain;
- severe abdominal pain due to acute inflammation of the pancreas;
- worsening of the symptoms of colitis;
- fever, sore throat or nausea due to changes in the blood count;
- difficulty breathing, cough, wheezing, marks on chest x-ray due to allergic and/or inflammatory conditions in the lungs;
- diarrhoea and severe abdominal pain due to an intestinal allergic reaction to the medicine;
- skin rash or inflammation;
- muscle and joint pain;
- jaundice or abdominal pain due liver or bile flow disorders;
- hair loss and development of baldness;
- erythema multiforme;
- numbness and tingling of the fingers and toes (peripheral neuropathy);

- reversible reduction in sperm production;
- blood count disorders.

Side effects of unknown frequency (cannot be estimated from the available data).

- kidney stones and associated kidney pain.

Photosensitivity

More severe reactions have been reported in patients with pre-existing skin conditions such as atopic dermatitis and atopic eczema.

Notify your doctor if these symptoms continue or worsen.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of MECOLZINE

Storage:

Keep this medicine out of the sight and reach of children.

Store below 30 °C

Do not use this medicine after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

Disposal:

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer use. These measures will help protect the environment.

MECOLZINE 500MG GASTRO RESISTANT TABLET

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8. Product Description

What it looks like:

MECOLZINE comes in oblong orange tablet.

MECOLZINE is supplied in aluminium-aluminium heat-sealed blister containing 10 tablets per strip, in packs of 30, 50, 100 or 200 tablets per cardboard box.

Not all pack sizes may be marketed.

Ingredients:

MECOLZINE tablet contains
Active ingredient: Mesalazine 500mg

The other ingredients (excipients):

Core:

Anhydrous sodium carbonate,
Glycine, Povidone,
Microcrystalline cellulose,
Croscarmellose sodium,
Anhydrous colloidal silica,
Calcium stearate.

Coating:

Methacrylic acid-ethyl acrylate copolymer (1:1), Methacrylic acid-methyl methacrylate copolymer (1:1), Methacrylic acid-methyl methacrylate copolymer (1:2), Dibutyl sebacate, Povidone K30, Talc, Titanium dioxide, Macrogol 6000, Yellow iron oxide, Red iron oxide.

9. Manufacturer

FAES FARMA, S.A.
Máximo Aguirre, 14,
48940 Lamiaco-Lejona
(Vizcaya) Spain.

10. Product Registration Holder

Eurodrug Laboratories (M) Sdn. Bhd.

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MAL number

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