Package leaflet: Information for the user

Sulfasalazin medac, 500 mg gastro-resistant tablets

Sulfasalazine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sulfasalazin medac is and what it is used for
2. What you need to know before you take Sulfasalazin medac
3. How to take Sulfasalazin medac
4. Possible side effects
5. How to store Sulfasalazin medac
6. Contents of the pack and other information

1. What Sulfasalazin medac is and what it is used for

Sulfasalazin medac is used in the treatment of
- active rheumatoid arthritis in adults.
- active juvenile idiopathic arthritis in children from the age of 6, where standard treatment was not sufficiently effective.

Rheumatoid arthritis is a chronic collagen disease characterised by inflammation of the synovial membrane. This membrane is situated on the inside of the joint capsules and produces a fluid acting as lubricant for many joints. The inflammation leads to thickening of the membrane and swelling of the joint.

Juvenile arthritis concerns children and adolescents younger than 16 years. Oligoarthritic forms are indicated if 4 or fewer joints are affected within the first 6 months of the disease. Polyarthritic forms are indicated if 5 or more joints are affected within the first 6 months of the disease.

Sulfasalazin medac helps to prevent damage to joints and slowly reduces the swelling and stiffness of joints.

Your doctor may have prescribed a different use. Please always follow your doctor's instructions.

2. What you need to know before you take Sulfasalazin medac

Do not take Sulfasalazin medac
- if you are **allergic** to sulfasalazine or its breakdown products, sulfonamides (e.g. sulfonamide antibiotics) or salicylates (e.g. acetylicsalicylic acid) or any of the other ingredients of this medicine (listed in section 6).
- if you have or ever have had an **acute skin reaction showing redness and ring-like eruptions** (erythema exsudativum multiforme).
- if you suffer from a **rare blood disease** called porphyria.
- if you suffer from **blood count disorders** like decrease in white blood cells or platelets.

- if you suffer from **bowel obstruction**.
- if your **liver or kidney function** is strongly impaired.
- in case you suffer from **glucose-6-phosphate dehydrogenase deficiency** (rare enzyme disorder).
- if you are being treated with **methenamine** (used for prevention of urinary tract infections).

Sulfasalazin medac must not be used for the treatment of systemic forms of juvenile idiopathic arthritis (JIA).

Children under the age of 6 should not use Sulfasalazin medac.

Warnings and precautions
Talk to your doctor or pharmacist before taking Sulfasalazin medac.

Potentially life-threatening skin rashes
Potentially life-threatening skin rashes (**Stevens-Johnson syndrome, toxic epidermal necrolysis**) have been reported with the use of Sulfasalazin medac. First signs of these reactions include **reddish target-like spots** or **circular patches,** often with central blisters on the trunk.
Additional signs to look for include **ulcers in the mouth, throat, nose, genitals and red and swollen eyes** (conjunctivitis).
These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin. You are most at risk of developing these serious skin reactions within the first weeks of your treatment with Sulfasalazin medac.
If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Sulfasalazin medac, you must not be re-started on Sulfasalazin medac at any time.
If you develop a rash or any of these skin symptoms, talk to your doctor immediately and tell him/her that you are taking Sulfasalazin medac.

Take special care with Sulfasalazin medac
- if you have an **allergic disposition** or **bronchial asthma**
- if you are **allergic** to **sulfonyl urea**
- if your **liver** or **kidney function** is impaired

Your doctor will be supervising you during your treatment with Sulfasalazin medac. Before and during your treatment with Sulfasalazin medac your **blood-cell count** (including platelets and differential blood count) as well as the way your liver and kidney works will be **checked regularly** by your doctor. These checks should be carried out every two weeks during the first three months of your therapy and once a month from the fourth to the sixth month of your treatment. Thereafter, your doctor will check you for the occurrence of side effects every three months.

If you are a **man** and would like to become a father, you should stop taking Sulfasalazin medac after consulting your doctor as **your sperm production may decrease**. There have been no reports of birth defects in new-born babies that could be traced back to this decreased production of sperm.

You should make sure to **drink adequately** during treatment with Sulfasalazin medac to prevent the development of kidney stones.

Your **skin** and **secretions** may turn **a yellow colour** and if you wear soft contact lenses, these may discolour as well.

Talk to your doctor if you experience a **sore throat, fever, pale skin, bleeding under the skin** (purpura) or **yellow skin and eyes** (jaundice) during your treatment.

Tell your doctor if you are taking or have recently taken Sulfasalazin medac, or any other sulfasalazine containing products, because they may **affect results of blood and urine tests**.

If you know that you are a so called slow acetylator (NAT2 polymorphism), you might suffer from increased side effects and your dosage might be adjusted by your doctor.

Children
Treatment with Sulfasalazin medac in children should only be initiated and supervised by medical specialists with sufficient experience in diagnosis and treatment of juvenile idiopathic arthritis.

Other medicines and Sulfasalazin medac
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This applies in particular to:
- Antibiotics.
- Iron.
- Calcium.
- Folic acid (vitamin used for supplement therapy in pregnancy or to reduce methotrexate side effects).
- Medicines which highly bind to blood proteins like methotrexate (used to treat autoimmune disease or cancer), phenylbutazone (used to treat arthritis and pain) or sulfinpyrazone (used to treat gout).
- Methenamine (used to prevent urinary tract infection) should not be administered at the same time as Sulfasalazin medac (see **Do not take Sulfasalazin medac**).

Further medicines which also affect Sulfasalazin medac or which are affected by it are:
- Digoxin (used in the treatment of heart failure).
- Anion exchange resins (used in the treatment of increased blood lipids).
- Anticoagulants (used to prevent blood clotting).
- Bone marrow depressants (medicines which can decrease the blood cell production in the bone marrow).
- Cyclosporine (used to suppress the immune system in autoimmune diseases or organ transplantation).
- Live typhoid vaccine.
- Hepatotoxic agents (medicines which cause liver damage).
- Sulfonyl ureas (used to treat diabetes).
- Azathioprine (used to suppress the immune system in autoimmune diseases or organ transplantation).

Sulfasalazin medac with food, drink and alcohol
Take your tablets at least 1 hour before a meal with plenty of water and swallow them whole.

Pregnancy, breast-feeding and fertility
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.

<u>Pregnancy</u>
Discuss with your doctor if you are pregnant or become pregnant during treatment.
Your doctor will prescribe sulfasalazine with caution if you are pregnant. Available data have not shown that treatment with sulfasalazine during pregnancy presents a risk to the unborn and new-born child or the pregnancy. Therapy with sulfasalazine may lead to folic acid deficiency which can cause birth defects. Therefore pregnant women during the first three months of pregnancy as well as women of childbearing age should take folic acid supplements while taking sulfasalazine.

Breast-feeding
Ask your doctor for advice before taking your medicine. Sulfasalazine and its breakdown products are excreted in human milk. Caution is advised when breast-feeding premature babies or newborns with jaundice.

Driving and using machines
The ability to react might be impaired in some patients. If you experience dizziness or other central nervous system disturbances such as drowsiness or reduced concentration while taking sulfasalazine do not drive, use machines or do anything else that could be dangerous because of your decreased alertness.

Sulfasalazin medac contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Sulfasalazin medac

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dose
Your doctor will advise you on the dose. Usually you will start with a low dose, e.g. 500 mg (one tablet daily), and your doctor will tell you how to increase the dose gradually. This is usually over a period of around 4 weeks:

	1st week	2nd week	3rd week	4th and each following week
morning / daily dose	---------	1 tablet	1 tablet	2 tablets
evening / daily dose	1 tablet	1 tablet	2 tablets	2 tablets

After 3 months the daily dose may be increased to 3 x 2 tablets if your doctor decides that 2 x 2 tablets are not sufficient for you. Do not take more than 8 tablets a day.

In children from the age of 6 years the recommended daily dose is 50 mg/kg body weight in two evenly divided doses. The maximum daily dose should not exceed 2 g. To reduce possible gastrointestinal side effects, treatment should be started with a quarter to a third of the planned maintenance dose and increased weekly until reaching the maintenance dose after four weeks.

How to take
Take your tablets at least 1 hour before a meal with plenty of fluid. Do not crush, break or chew the tablets, but swallow them whole.

Sulfasalazine treatment usually shows results within 1 – 3 months. Additional therapy with pain-killing or anti-inflammatory medicines may be necessary, at least until Sulfasalazin medac starts being effective.

In general, Sulfasalazin medac is used for long-term treatment. It may be taken for years if it works well and is well-tolerated.

If you take more Sulfasalazin medac than you should
Nausea, vomiting, gastric disorder and abdominal pain can be symptoms of an overdose. In more serious cases you may experience central nervous system symptoms such as drowsiness or fits (convulsions). If you experience any of the above symptoms contact your doctor or a hospital immediately. They will decide which necessary precautions need to be taken.

If you forget to take Sulfasalazin medac
Do not take a double dose to make up for a forgotten dose. Inform your doctor and continue to take the dose prescribed by your doctor.

If you stop taking Sulfasalazin medac
The treatment as well as additional therapy is carried out on medical prescription and under supervision by your doctor. Do not stop without consulting your doctor as the symptoms may return.

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

4. Possible side effects

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

Many side effects are dose-dependent and may be diminished by decreasing the dose.

If you experience severe toxic or hypersensitivity reactions (e.g. severe skin reactions, shortness of breath) **stop taking Sulfasalazin medac immediately and talk to your doctor**.

In the case of dose-related side effects Sulfasalazin medac must be stopped for 1 week. If your doctor decides to continue the treatment Sulfasalazin medac may be administered again in small doses which are to be increased slowly, preferably under clinical supervision.

Very common (may affect more than 1 in 10 people)
- Headache
- Nausea, vomiting, abdominal pain
- Itching, skin eruption
- Loss of appetite
- Loss of strength, exhaustion
- Reduced sperm production in men, reversible impaired fertility

Common (may affect up to 1 in 10 people)
- Decrease in red blood cells caused by folic acid deficiency with occurrence of big blood cells; decrease in white blood count; increased liver enzymes
- Drowsiness, dizziness, reduced concentration, inability to sleep
- Hives, increased sensitivity to light
- Fever

Uncommon (may affect up to 1 in 100 people)
- Feeling your heartbeat (palpitations), increased heart rate
- Strong decrease of the white blood cell count, decrease of all blood cells, reduction in red blood cells caused by breakdown of the cells, reduced ability of the red blood pigment to carry oxygen, decreased number of platelets, reaction similar to viral infection with fever, sore throat, swollen glands and feeling tired (mononucleosis-like reaction)
- Disorder of the nerves of the peripheral nervous system which may cause changes of sensation, pain or muscle weakness, sensation of tingling, pricking or numbness of skin, disorder of smell and taste
- Red, irritated eyes
- Ringing in the ears (tinnitus)
- Allergic inflammation of the lung, cough, asthma, breathlessness
- Excess gas in the bowel, diarrhoea, inflammation of the pancreas
- Bluish skin, rapid swelling of face and throat
- Muscular weakening, joint pain, autoimmune reaction with joint pain, sore muscles, fever and red facial rash (lupus erythematosus syndrome)

- Increased blood pressure
- Reaction with fever, rash and joint pain (serum sickness like disorder)
- Decreased liver function; decreased number of antibodies, occurrence of antibodies against the body's own cells, tissues, or organs
- Depression

Rare (may affect up to 1 in 1,000 people)
- Reduction of blood cell production in the bone marrow, excess of certain immune cells in the blood (plasmocytosis), severe reduction in blood cells due to blood formation disorders
- Metallic taste
- In one singular case a yellow tint of soft contact lenses was reported
- Inflammation of air sacs and scarring of the connective tissue between the lungs (fibrosing alveolitis)
- Inflammation of the mucosa of the mouth (stomatitis)
- Blood in urine, crystals in urine, yellow-orange discolouration of urine
- Inflammatory skin reaction, yellow-orange discolouration of the skin, loss of hair
- Muscle pain
- Acute attacks of porphyria (disorder of haemoglobin formation)
- Skin reaction with abnormal white blood count (eosinophilia), fever and involvement of internal organs (DRESS syndrome), severe allergic reaction
- Inflammation of the liver

Very rare (may affect up to 1 in 10,000 people)
- Inflammation of the heart muscle, inflammation of the heart sac
- Inflammation of the protective membranes covering the brain and spinal cord, brain disorder leading to altered mental state (encephalopathy), spinal cord inflammation
- Inflammation of the small airways (bronchioles) in your lungs
- Worsening of remittent inflammatory bowel disease
- Kidney inflammation, kidney disorder that causes water retention in the body (nephrotic syndrome), proteins in urine
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell´s syndrome), see section 2
- Disordered blood formation due to bone marrow disease (myelodysplastic syndrome)
- Blood circulation disorder in toes and fingers
- Severe inflammation of the liver (potentially fatal)
- Psychosis

Not known (frequency cannot be estimated from the available data)
- Lung complications with breathlessness (so called interstitial lung disease)
- Prolonged, often severely itchy skin disease with small angular flat nodules. Often eruptions in the oral mucosa. In rarer cases, it can get to the scalp, which can cause scarring with hairless spots (lichen planus)

Reporting of side effects
If you get any 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 directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sulfasalazin medac

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 carton. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Sulfasalazin medac contains

- The active substance is sulfasalazine. Each tablet contains 500 mg.
- The other ingredients are crospovidone, stearic acid, povidone, anhydrous colloidal silicon dioxide, purified water, magnesium stearate, titanium dioxide, talc, sodium carmellose, sodium citrate, macrogol, propylene glycol, methacrylic acid-ethyl-acrylate copolymer (1 : 1) dispersion 30 per cent.

What Sulfasalazin medac looks like and contents of the pack
Sulfasalazin medac are white, coated, oval tablets. The gastro-resistant coat prevents the tablets from disintegrating in the stomach. Therefore, the active substance is not released until it reaches the intestine.

Pack sizes: 100 /300 tablets in a white plastic bottle sealed with a white plastic screw cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer:
medac
Gesellschaft für klinische Spezialpräparate mbH
Theaterstr. 6
22880 Wedel
Germany
Tel.: +49 4103 8006-0
Fax: +49 4103 8006-100

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Sulfasalazin “medac”, 500 mg enterotabletter
Germany:	Sulfasalazin medac 500 mg magensaftresistente Filmtabletten
Sweden:	Sulfasalazin medac 500 mg enterotabletter

This leaflet was last revisedin June 2022..