Package leaflet: Information for the user

Sulfasalazin-Heyl®

500 mg enteric coated film tablets
Active substance: 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-Heyl is and what it is used for

Sulfasalazin-Heyl is an anti-inflammatory drug (non-steroidal anti-inflammatory drug).

Therapeutic indications of Sulfasalazin-Heyl:

- Sulfasalazin-Heyl is used to treat adults with active rheumatoid arthritis.
  Active rheumatoid arthritis is a chronic collagen disease characterised by inflammation of the synovial membrane (synovium). This membrane produces a fluid that acts as a lubricant for many of the joints. The inflammation leads to a thickening of this membrane and a swelling of the joint.
- Treatment of active juvenile idiopathic oligoarthritis (enthesitis associated arthritis) from the age of 6, who responded insufficiently to non-steroidal anti-inflammatory drugs (NSAIDs) and/or local glucocorticoid injections.
- Treatment of active juvenile idiopathic polyarthritis and spondyloarthropathy with peripheral arthritis from the age of 6 (enthesitis associated arthritis), who responded insufficiently to non-steroidal anti-inflammatory drugs (NSAIDs).

2. What you need to know before you take Sulfasalazin-Heyl

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

Do not take Sulfasalazin-Heyl

- if you are hypersensitive (allergic) to sulfasalazine, one of its degradation products or any of the other ingredients of this medicine listed in section 6;
- if you are hypersensitive (allergic) to sulfonamides or salicylates;
- in case of diseases of the blood-forming organs;

- in case of disturbance of red blood pigment formation (acute intermittent porphyria);
- if your liver or kidney function is severely impaired;
- in patients with glucose 6 phosphate dehydrogenase deficiency (risk of occurrence of haemolytic anaemia);
- in case of preexisting blood count changes such as a decrease in white blood cells and blood platelets;
- in case of bowel obstruction;
- in case of target rash (erythema exsudativum multiforme, also in the anamnesis).

Simultaneous therapy with methenamine is contraindicated.

Sulfasalazin-Heyl is not suitable for treating systemic juvenile idiopathic arthritis (JIA).

Sulfasalazin-Heyl must not be given to children under 6 years of age.

The following describes when you should use Sulfasalazin-Heyl with special caution only under certain conditions (i.e. at greater intervals or at reduced doses and under medical supervision). Please consult your doctor. This also applies if this information was previously true for you.

Warnings and precautions
Severe myelosuppression-associated infections have been reported, including blood poisoning (sepsis) and pneumonia. If you develop a new infection during treatment with the medicine, your doctor will monitor you closely. If you develop a severe infection, your doctor will stop treatment. Caution is advised if you have a history of recurrent or chronic infections or underlying conditions that make you susceptible to infection.

Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis) that may be life-threatening have been reported in connection with the use of Sulfasalazin-Heyl. These initially appear as reddish, disc-shaped or circular patches (often with a bladder in the middle) on the trunk. The skin rash can lead to large blistering or detachment of the skin. Additional symptoms that should be considered are open, sore spots (ulcers) in the mouth, throat, nose and genital area as well as reddened and swollen eyes (conjunctivitis). These potentially life-threatening skin reactions are often accompanied by flu-like symptoms (headache, fever and aching limbs). The highest risk of these severe skin reactions occurs during the first weeks of treatment. If you have had Stevens-Johnson syndrome or toxic epidermal necrolysis associated with the use of Sulfasalazin-Heyl, you should never be treated with Sulfasalazin-Heyl again.

If you develop a skin rash or the other symptoms mentioned above, stop using Sulfasalazin-Heyl and seek medical attention immediately. Tell him or her that you are taking Sulfasalazin-Heyl.

Special care should be taken when taking Sulfasalazin-Heyl

- in case of patients with a disposition to hypersensitivity reactions (allergy disposition) or bronchial asthma;
- in case of patients with restricted liver or kidney functions (slight liver or kidney insufficiency);
- in case of known hypersensitivity to sulphonyl ureas;
- in case of male patients wanting to have children. Sulfasalazin-Heyl should be temporarily discontinued here after consultation with the doctor, as semen production may decrease. On average, semen production normalizes within 2 to 3 months after discontinuation of therapy. To date, no damage associated with this temporary infertility has been reported in newborns. The reduction of sperm cells does not influence sexual potency.

A complete blood count, including differential leukocyte count and liver function tests, should be performed before starting treatment with sulfasalazine and then every 2 weeks during the first 3 therapy months. The same checks should be performed once a month for the next 3 months of therapy, and then every 3 months and if clinically indicated thereafter. Kidney function controls (including urine analysis) should be performed on all patients at the start of treatment and at least monthly during the first 3 months of treatment. After that, further monitoring should be performed according to clinical need.

If symptoms such as sore throat, fever, paleness, purpura or jaundice occur during therapy with sulfasalazine, this may indicate myelosuppression, hemolysis or hepatotoxicity. In such cases, sulfasalazine therapy should be discontinued until the results of blood tests are available.

Immunoglobulins may drop off during therapy with sulfasalazine and an increase in antinuclear antibodies (ANA) may occur. These changes may be due to disease. Their significance for therapy is unclear. As a precaution, the control of immunoglobulins and ANA is recommended at the beginning of treatment and at regular intervals.

Severe hypersensitivity reactions may also affect internal organs such as liver inflammation (hepatitis), kidney inflammation (nephritis), heart muscle inflammation (myocarditis), mononucleosis-like syndrome (i.e. pseudomonucleosis), haematopoietic changes (haematological abnormalities including haematophagic histiocytosis) and/or pneumonitis including eosinophilic infiltrates.

Severe, life-threatening, systemic hypersensitivity reactions such as drug rash with eosinophilia and systemic symptoms (DRESS) were reported in patients taking various drugs including sulfasalazine. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may also be present although there is apparently no skin rash. If such symptoms are present, the patient should be examined immediately. If no alternative etiology can be found for these symptoms, sulfasalazine should be discontinued.

Treatment with Sulfasalazin-Heyl should only be performed under medical supervision.

There should be a sufficient intake of fluids during treatment with Sulfasalazin-Heyl.

In patients who can only degrade the active substance at a slower rate, so-called slow acetylators, the active substance (sulfapyridine) level can reach very high (toxic) concentrations. Therefore, it is recommended to determine the acetylating phenotype at the beginning of treatment with sulfasalazine in case of side effects. If several substances given in parallel have to be degraded (acetylated) and if rheumatoid arthritis is combined with a Sjögren syndrome and/or other overlap syndromes, this determination is just as useful as before the therapy of high-risk patients (age, body weight, concomitant diseases).

Children
Treatment with Sulfasalazin-Heyl in children should only be initiated and monitored by specialists with sufficient experience in the diagnosis and treatment of the rheumatic disease in question.

Sulfasalazin-Heyl should not be given to children under 6 years of age.

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

Taking Sulfasalazin-Heyl with other medicines may lead to interactions with the active substance itself or with its main metabolites. The most important interactions occur when antibiotics, iron, calcium, folic acid and drugs with strong protein binding are taken at the same time.

Folic acid
During therapy with Sulfasalazin-Heyl, reduced folic acid levels may occur, presumably due to inhibition of uptake. This can lead to a folic acid deficiency or increase a folic acid deficiency already caused by the underlying disease or pregnancy.

Iron
Sulfasalazin and iron form chelates. This leads to inhibition of absorption of Sulfasalazin-Heyl.

Calcium
With simultaneous calcium gluconate therapy, it was described that Sulfasalazin-Heyl was absorbed with a delay.

Digoxin
In individual cases it was reported that the intake of digoxin was inhibited when Sulfasalazin-Heyl and digoxin were taken at the same time.

Antibiotics
The effect of Sulfasalazin-Heyl can be reduced by taking antibiotics at the same time (proven for ampicillin, neomycin, rifampicin, ethambutol). The reason for this is the inhibition of partial bacterial degradation due to damage to the intestinal flora.

Anion exchange resins
Anion exchange resins such as colestipol or colestyramine bind both sulfasalazine and its degradation products in the intestine. This may reduce the effect of Sulfasalazin-Heyl.

Anticoagulants
The degradation of oral anticoagulants such as phenprocoumon or dicumarol via the liver can be impaired. Special care and regular monitoring of the coagulation status are necessary when taking them at the same time.

Medication with high protein binding
Taking methotrexate, phenylbutazone, sulfinpyrazone, or other protein-bound drugs with Sulfasalazin-Heyl at the same time can enhance the effect of these drugs.

Medication with haemotoxic effect
Reduction of white blood cells (leukopenia), anaemia and/or thrombocytopenia can occur more frequently and intensively under therapy with Sulfasalazin-Heyl. If Sulfasalazin-Heyl is taken simultaneously with other possibly blood-damaging drugs, a close monitoring must be carried out.

Ciclosporin
Combined use can lead to reduced levels of ciclosporin. Control and adjustment of the dosage may be necessary.

Live typhoid vaccine
A reduced immune reaction after administration of live typhoid vaccine is possible. A minimum interval of 24 hours between the intake of Sulfasalazin-Heyl and the application of a live typhoid vaccine is recommended.

Hepatotoxic drugs
If the simultaneous intake of Sulfasalazin-Heyl with hepatotoxic agents is unavoidable, liver function must be carefully monitored.

Sulfonylureas (certain blood sugar reducing agents)
When administered simultaneously with sulfonylureas, their blood sugar-lowering effect can be enhanced.

Methenamine
Sulfasalazin-Heyl must not be used together with preparations containing methenamine because of the possible formation of crystalluria (see " Do not take Sulfasalazin-Heyl").
Taking the drug may possibly lead to false positive results in the determination of normetanephrine in urine by liquid chromatography. Your doctor will take this into account.

Sulfasalazin-Heyl with food and drink
While taking Sulfasalazin-Heyl you should preferably not drink alcohol.

Pregnancy and breast-feeding
Pregnancy
Your doctor will only decide to prescribe Sulfasalazin-Heyl if there is a clear need and with caution. Mothers who received sulfasalazine during pregnancy have reported infants with nervous system disorders, although the role of sulfasalazine in these disorders has not been studied. Since the intake of sulfasalazine can lead to folic acid deficiency, a supplementary administration of folic acid during the use of Sulfasalazin-Heyl is recommended for women of childbearing age and in the first 3 months of pregnancy.

Breast-feeding
Ask your doctor or pharmacist for advice before using medicines. Sulfasalazine and its degradation products are found in low concentrations in breast milk. Therefore, caution is advised, especially when breastfeeding premature infants and those with reduced metabolic activity (slow acetylator, glucose-6-phosphate dehydrogenase deficiency). There have been reports of blood stool or diar-

rhoea in infants breastfed by mothers treated with sulfasalazine. In cases where the outcome of such events has also been reported, blood stool and diarrhoea in the children decreased after discontinuing sulfasalazine in the mother. Therefore, Sulfasalazin-Heyl should be prescribed to nursing mothers with caution.

Driving and using machines
The ability of some patients to react may be limited. Patients who suffer from dizziness or central nervous disorders during therapy with sulfasalazine should not drive vehicles, operate potentially dangerous machinery, or perform other activities that may be dangerous due to impaired responsiveness. This applies to an increased extent in combination with alcohol.

3. How to take Sulfasalazin-Heyl

Always take Sulfasalazin-Heyl exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Active rheumatoid arthritis in adults
Sulfasalazin-Heyl is taken daily. The therapy is started with small doses and is increased gradually to the ideal dose.

Week	**1**	**2**	**3**	**4 and every further week**
morning	----	1 enteric coated tablet (500 mg sulfasalazine)	1 enteric coated tablet (500 mg sulfasalazine)	2 enteric coated tablets (1,000 mg sulfasalazine)
evening	1 enteric coated tablet (500 mg sulfasalazine)	1 enteric coated tablet (500 mg sulfasalazine)	2 enteric coated tablets (1,000 mg sulfasalazine)	2 enteric coated tablets (1,000 mg sulfasalazine)

The daily dosage can be increased to three times 2 enteric-coated tablets of Sulfasalazin-Heyl (corresponding to three times 1,000 mg sulfasalazine) after 3 months if your doctor decides that two times 2 enteric-coated tablets of Sulfasalazin-Heyl (corresponding to two times 1,000 mg sulfasalazine) are not sufficient for you. A maximum daily dose of 8 enteric-coated tablets of Sulfasalazin-Heyl (corresponding to 4,000 mg sulfasalazine) should not be exceeded.

Active juvenile idiopathic arthritis (children 6 years and older)
The daily dose should be 50 mg/kg body weight, divided into 2 single doses. The maximum daily dose is 2 g sulfasalazine. If no satisfactory effect is observed after 3 months, the daily dose can be increased to 75 mg/kg body weight, maximum 3 g sulfasalazine per day.
In order to reduce possible gastrointestinal intolerances, a creeping therapy (starting with a quarter or a third of the maintenance dose) is recommended, in which the maintenance dose is reached after 4 weeks by weekly dose increases.

Method of administration
Sulfasalazin-Heyl should be taken daily at least 1 hour before a meal with plenty of liquid. The enteric-coated tablets should not be broken or crushed but swallowed whole.

Duration of use
Experience shows that clinical efficacy sets in after 1 to 3 months of treatment. Additional treatment with analgesics or anti-inflammatory agents may be necessary.

The treatment and the additional treatment are carried out on medical prescription and under medical supervision. It should not be discontinued without consulting your doctor, as the symptoms may return.

Sulfasalazin-Heyl is generally used for long-term treatment. If it is effective and well tolerated, it can be taken for years.

If you take more Sulfasalazin-Heyl than you should
Take Sulfasalazin-Heyl according to your doctor's instructions or according to the dosage instructions given in the package leaflet. If you feel that your symptoms are not sufficiently relieved, do not increase the dose yourself, but consult your doctor.

Nausea, vomiting, stomach upset and stomach/abdominal pain may be symptoms of overdose. In more advanced cases symptoms of the central nervous system may occur, such as drowsiness and cramps. Contact your doctor or hospital immediately to decide on necessary action.
In case of severe poisoning, Sulfasalazin-Heyl should be discontinued immediately.

If you forget to take Sulfasalazin-Heyl
Do not take a double dose to make up for a forgotten dose but continue with the indicated dose. Ask your doctor for advice and continue taking the dose prescribed by your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following side effects, please talk to your doctor, who will determine how to proceed.
Many side effects are dose-dependent and can be mitigated or avoided by reducing the dose.

The following categories are used as a basis for the frequency of side effects:

Very common:	may effect more than 1 in 10 people
Common:	may effect more than 1 in 100 people
Uncommon:	may effect more than 1 in 1000 people
Rare:	may effect more than 1 in 10000 people
Very rare:	affecting less than 1 in 10000 people
Not known:	cannot be estimated from the available data

Significant side effects or signs that you should watch for and action if your are affected:
The potentially life-threatening agranulocytosis (massive reduction of certain white blood cells) manifests itself in severe general feeling of illness, associated with fever, chills, palpitations, sore throat and swallowing difficulty, as well as painful inflammation of the mucous membranes in the mouth, nose and throat area, as well as in the anal and genital area. In these cases, Sulfasalazin-Heyl must be discontinued **immediately** and the doctor consulted. Self-treatment with painkillers and antipyretic agents should be avoided.
After the symptoms have subsided, Sulfasalazin-Heyl should not be taken again.

The side effects can generally be divided into 2 groups:
The 1st group is dose-dependent, depends on the individually different metabolic activity (acetylator phenotype) and is largely predictable. This group includes side effects such as nausea and vomiting, headaches, anaemia due to the breakdown of red blood cells (haemolytic anaemia) and an increased concentration of methaemoglobin (methaemoglobinaemia).
In the case of dose-dependent side effects, Sulfasalazin-Heyl can be given again in small doses after an interruption of 1 week. These doses should be increased slowly, but preferably under clinical observation.

The 2nd group consists of hypersensitivity reactions, which are not predictable and usually occur at the beginning of treatment. This group includes side effects such as skin rash, anaemia due to blood formation disorders (aplastic anaemia), disorders of liver and lung function and autoimmune haemolysis (decomposition of red blood cells by antibodies directed against them).

In case of hypersensitivity reactions, Sulfasalazin-Heyl should be discontinued immediately.

Possible side effects

Infections and infestations

Rare:	Mucosal inflammation of the small and large intestine after non-inflammatory disease of the intestinal mucosa or antibiotic therapy (pseudomembranous colitis)

Blood and lymphatic system disorders

Common:	Anaemia caused by folic acid deficiency (folic acid deficiency anaemia), frequent occurrence of large blood cells (megaloblastosis and macrocytosis), reduced number of white blood cells (leukopenia)
Uncommon:	Reduction of red and white blood cells and platelets (pancytopenia), decay of red blood cells (haemolytic anaemia), inability of the red blood pigment to bind oxygen (methaemoglobinaemia), reduced number of platelets (thrombocytopaenia)
Rare:	Severe reduction of certain white blood cells (agranulocytosis), anaemia as a result of blood formation disorders (aplastic anaemia), bone marrow hypofunction (myelosuppression), reproduction of plasma cells (plasmocytosis), increased number of certain white blood cells (eosinophilia)
Very rare:	Bone marrow disorders (myelodysplastic syndrome)
Not known:	Pseudomononucleosis

Immune system disorders

Uncommon:	Formation of antibodies against body tissues, reduced amount of antibodies (hypogammaglobulinaemia), disease including the occurrence of butterfly-shaped reddening of the face (systemic lupus erythematosus)
Rare:	Skin reaction with change in blood count (eosinophilia) and signs of disease that can affect organs of the entire organism, sometimes reactions similar to Pfeiffer's glandular fever or serum sickness (DRESS syndrome), acute pathological reaction of the immune system (anaphylaxis)

Metabolism and nutrition disorders

Common:	Loss of appetite
Not known:	Folate deficiency

Psychiatric disorders

Uncommon:	Depression
Very rare:	Psychosis

Nervous system disorders

Very common:	Headaches
Common:	Dizziness, disturbances of the sense of taste
Uncommon:	Abnormal sensations (paresthesias), disturbances of the sense of smell, nerve disorders in arms and legs
Rare:	Metallic taste
Very rare:	Diseases of the nerves (central and peripheral neuropathy), inflammation of the spinal cord (transverse myelitis), certain meningitis (aseptic meningitis)
Not known:	Pathological brain change (encephalopathy)

Eye disorders

Uncommon:	Allergic conjunctivitis
Rare:	Yellow coloration of the eyes
Very rare:	Yellow coloration of contact lenses

Ear and labyrinth disorders

Uncommon:	Tinnitus

Cardiac disorders

Uncommon:	Palpitations, increased heart rate (tachycardia)
Very rare:	Inflammation of the pericardium (pericarditis), inflammation of the heart muscle (myocarditis)

Vascular disorders

Uncommon:	Elevated blood pressure
Very rare:	Circulatory disorders of the hands and feet (Raynaud-Syndrom)
Not known:	Paleness

Respiratory, thoracic and mediastinal disorders

Common:	Cough
Uncommon:	Bronchial asthma, dyspnoea
Rare:	Inflammation of the alveoli (fibrosing alveolitis), allergic lung disease (eosinophilic pneumonia)
Very rare:	Inflammation of the bronchioles (bronchiolitis obliterans)
Not known:	Disease of the connective tissue of the lung (interstitial lung disease), eosinophilic infiltration, pain in the mouth pharynx

Gastrointestinal disorders

Very common:	Nausea, abdominal pain, loss of appetite, digestive disorders (dyspepsia), stomach complaints
Common:	Vomiting, diarrhoea, abdominal pain
Uncommon:	Flatulence
Rare:	Inflammation of the pancreas (pancreatitis), inflammation of the mucous membrane of the mouth (stomatitis)
Very rare:	Exacerbation of an existing inflammatory bowel disease (colitis ulcerosa)

Hepatobiliary disorders

Common:	Elevated liver enzymes
Uncommon:	Jaundice (icterus)
Rare:	Hepatitis
Very rare:	Severe form of liver inflammation, possibly fatal (fulminant hepatitis)
Not known:	Liver failure, inflammation of the liver with bile flow stoppage (cholestatic hepatitis), bile flow stoppage (cholestasis)

Skin and subcutaneous tissue disorders

Common:	Itching (pruritus), skin rash (exanthema), small spots of bleeding in the skin or mucous membrane (purpura)
Uncommon:	Hives (urticaria), tissue swelling, especially in the face (quincke's edema), sensitivity to light (photosensitivity), rash in the area of the mucous membranes (enanthema), hair loss (alopecia)
Rare:	Blue-red discoloration of the skin and mucous membranes due to insufficient oxygen saturation of the blood (cyanosis), yellow-orange discoloration of the skin, inflammatory skin disease (exfoliative dermatitis)
Very rare:	Severe and potentially life-threatening skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis)
Not known:	acute generalising pustular exanthema, inflammatory skin redness (erythema), skin disease with blistering (Lichen ruber planus)

Musculoskeletal and connective tissue disorders

Common:	Joint pain (arthralgia)
Uncommon:	Muscle weakness
Rare:	Muscle pain
Not known:	Severe autoimmune disease (Sjögrens syndrome)

Renal and urinary disorders

Common:	Protein in urine (proteinuria)
Rare:	Blood in the urine (haematuria), crystal excretions in the urine, yellow-orange discoloration of the urine
Very rare:	pathological changes in the kidneys (acute interstitial nephritis, nephrotic syndrome)
Not known:	Kidney stone disease (nephrolithiasis)

Reproductive system and breast disorders

Very common:	Insufficient number of sperm cells in men (oligospermia) with temporarily reduced fertility

Congenital, familial and genetic disorders

Rare:	Disturbances in the formation of the red blood pigment (acute porphyria attacks).

General disorders and administration site conditions

Very common:	Tiredness
Common:	Fever, drowsiness, dizziness, poor concentration, insomnia
Uncommon:	Facial edema, general weakness
Not known:	Yellow coloration of body fluids

Investigations

Rare:	Increase in antinuclear antibodies (ANA)

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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sulfasalazin-Heyl

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

Do not use this medicine after the expiry date which is stated on the label and on the carton after "Verwendbar bis". The expiry date refers to the last day of that month.

Do not store above 25 ºC.

Do not throw away any medicine via wastewater (e.g. not via the toilet or the washbasin). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Further information can be found at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Sulfasalazin-Heyl contains

The active substance is sulfasalazine.
1 enteric coated filmtablet contains 500 mg sulfasalazine.

The other ingredients are: Carmellose sodium; crospovidone, macrogol 6000; magnesium stearate; sodium citrate 2 H_2O; methacrylic acid-ethyl acrylate copolymer (1:1); povidone; propylene glycol; silica, colloidal anhydrous; stearic acid; talc; titanium dioxide; water, purified.

What Sulfasalazin-Heyl looks like and contents of the pack

Sulfasalazin-Heyl are white, silky-matt, oval film tablets of 15.4 to 16 mm in length.
Sulfasalazin-Heyl is available in bottles with 100 and 300 enteric coated tablets.

Marketing Authorisation Holder:
Heyl Chem.-pharm. Fabrik
GmbH & Co. KG
Kurfürstendamm 178-179
10707 Berlin
Germany
Phone: +49 30 81696-0 Email: info@heyl-berlin.de
Fax: +49 30 81696-33 Website: www.heyl-berlin.de

Manufacturer:
Dragenopharm
Apotheker Püschl GmbH
Göllstraße 1
84529 Tittmoning
Germany

This medical product is authorized in the Member States of the EEA under the following names:
Federal Republic of Germany: Sulfasalazin-Heyl®
Republic of Malta: Sulfasalazin-Heyl®

This leaflet was last approved in July 2019.

Properties
Sulfasalazine is a disease-modifying drug for the treatment of rheumatoid arthritis (chronic polyarthritis). Although its clinical efficacy has been demonstrated, there are still uncertainties about the actual mechanism of action. An essential factor in the action of sulfasalazine appears to be its influence on the leukotriene synthesis, arachidonic acid metabolism and lipooxygenation at the site of the inflammatory event. The contribution of antimicrobial action to efficacy is uncertain. An immunomodulating effect has also been suggested.