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2. Sulfasalazine

Sulfasalazine

Pronunciation: *sul-faz-a-la-zine*

Generic name: sulfasalazine

Brand names: [Azulfidine](#), [Azulfidine EN-tabs](#)

Dosage form: oral tablet, oral delayed-release tablet

Drug classes: [5-aminosalicylates](#), [Antirheumatics](#)

Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Nov 24, 2024.

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What is sulfasalazine?

Sulfasalazine is used to treat ulcerative colitis, rheumatoid arthritis, and polyarticular-course juvenile rheumatoid arthritis, and works by lowering inflammation in the body, reducing pain and swelling. Sulfasalazine also limits the damage that rheumatoid arthritis causes to your joints, helping to prevent disease progression. It is a slow-acting disease-modifying anti-rheumatic drug (DMARD), that takes time to build up and start working.

Sulfasalazine's mechanism of action is not fully understood but is thought to involve reducing the activity of the immune system. Sulfasalazine consists of the anti-inflammatory agent 5-aminosalicylic acid (5-ASA, mesalamine, or mesalazine) and the antibiotic sulfapyridine, which are linked by a bond. Sulfasalazine is too big to be absorbed by your small intestine, but bacteria in your colon can break the bond between 5-ASA and sulfapyridine, which frees 5-ASA to work locally in your colon to help in ulcerative colitis. Sulfasalazine belongs to the drug class called disease-modifying anti-rheumatic drugs (DMARDs). It may also be called a 5-aminosalicylate or an antirheumatic.

Sulfasalazine has been used since the 1950s. Sulfasalazine is available as a generic and under the brand name Azulfidine (a standard tablet) and Azulfidine EN (an enteric-coated, delayed-release tablet). The delay-release, enteric-coated tablets are recommended for people who experience gastrointestinal side effects such as nausea and vomiting.

What is sulfasalazine used for?

Sulfasalazine is a prescription medication that is available as a standard tablet and as a delay-release, enteric-coated tablet.

Standard sulfasalazine tablets are used:

- to treat mild to moderate [ulcerative colitis](#).
- as an add-on (adjunctive) therapy in severe ulcerative colitis.
- to prolong periods of remission between acute attacks of ulcerative colitis.

Delay-release, enteric-coated sulfasalazine tablets are used:

- to treat mild to moderate ulcerative colitis, particularly in patients who cannot take standard, uncoated sulfasalazine tablets because of gastrointestinal side effects that are not caused by high blood levels of sulfapyridine and its metabolites. This includes patients who experience nausea and vomiting with the first few doses and patients who continue to have symptoms when their dose is reduced
- as an add-on (adjunctive) therapy in severe ulcerative colitis
- to prolong periods of remission between acute attacks of ulcerative colitis
- to treat **rheumatoid arthritis** in patients who have responded inadequately to salicylates or other nonsteroidal anti-inflammatory drugs (NSAIDs)
- to treat children with polyarticular-course juvenile rheumatoid arthritis who have responded inadequately to salicylates or other NSAIDs.

Because sulfasalazine does not produce an immediate response, other analgesics and/or NSAIDs may still be needed until sulfasalazine starts working.

Sulfasalazine is also used 'off-label' - for conditions it is not approved for, such as ankylosing spondylitis, Crohn's disease, and psoriatic arthritis.

It is not known if sulfasalazine is safe and effective in children below the age of 2 years old.

Sulfasalazine side effects

The **most common** side effects of sulfasalazine are:

- weight loss
- headache
- nausea
- vomiting
- gastric upset
- temporary low sperm count.

Less frequent side effects of sulfasalazine are:

- skin rash or hives
- itch
- fever
- changes in your blood cell counts
- blue hands and feet due to low oxygen levels (cyanosis).

Sulfasalazine may also produce an orange-yellow discoloration of the urine or skin.

Serious side effects and warnings

Sulfasalazine can cause the following serious side effects.

Liver, kidney, or blood toxicity. Treatment with sulfasalazine may cause allergic reactions, changes in blood cell counts, kidney and liver damage, and nervous system changes, some of which may be potentially fatal. Tell your doctor if you get a sore throat, fever, pallor, purpura, or jaundice while taking sulfasalazine. Your healthcare provider should monitor your blood cell counts and liver and kidney function during treatment.

Low sperm counts and infertility in men. Stopping sulfasalazine appears to reverse these effects.

Serious infections. Sulfasalazine may increase your risk for infection, including fatal sepsis and pneumonia. Tell your doctor right away if you develop signs of an infection, such as a fever, rash, sore throat, cough, and pain when urinating.

Hypersensitivity (allergic) and severe skin reactions. Sulfasalazine may cause severe hypersensitivity reactions, such as drug reactions with eosinophilia and systemic symptoms (DRESS), exfoliative dermatitis, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). Most events occur in the first month of therapy. Early signs of such a reaction include fever or swollen lymph nodes (lymphadenopathy) with or without a rash. Seek urgent medical attention.

These are not all the possible side effects of sulfasalazine. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Sulfasalazine side effects](#) (more detail)

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Who should not take sulfasalazine?

Do not take sulfasalazine if:

- you are allergic to sulfasalazine, its metabolites, sulfonamides or salicylates, or any of the other ingredients in sulfasalazine. See below for a complete list of ingredients.
- you have intestinal or urinary obstruction
- you have porphyria.

 [Sulfasalazine pregnancy and breastfeeding warnings](#) (more detail)

Before taking

Before taking sulfasalazine you should tell your healthcare provider about all your medical conditions, including if you:

- have a history of recurring or chronic infections
- have underlying conditions or take other drugs which may make you more susceptible to infections
- have severe allergy or bronchial asthma
- have glucose-6-phosphate dehydrogenase deficiency
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Pregnancy

It is not known if sulfasalazine harms an unborn baby. Neural tube defects have been reported in some infants born to mothers taking sulfasalazine during pregnancy. This may be linked to the drug's ability to inhibit the absorption and

metabolism of folic acid. Sulfasalazine and sulfapyridine pass through the placenta and you should discuss taking sulfasalazine during pregnancy with your healthcare provider before you start taking it.

Breastfeeding

Sulfasalazine and its metabolites pass into breast milk and can lead to a type of brain damage called kernicterus in newborns. Limited data also suggests it may cause infants to develop bloody stools or diarrhea. Talk to your doctor about the best way to feed your baby while on sulfasalazine.

How should I take sulfasalazine?

Take sulfasalazine exactly as your doctor tells you to.

- Sulfasalazine tablets are taken multiple times a day (usually 2 to 6 times a day).
- Take sulfasalazine tablets preferably after food and with a full glass of water.
- Swallow sulfasalazine delayed-release, enteric-coated tablets whole. Do not break, crush, or chew.
- Your doctor will order frequent tests while you are on sulfasalazine.

Sulfasalazine dosage

Your healthcare provider will adjust your dosage of sulfasalazine depending on your response and how well you tolerate it.

Ulcerative Colitis

Initial sulfasalazine dosage for ulcerative colitis in adults: sulfasalazine 3 to 4 g daily taken in evenly divided doses throughout the day with dosage intervals not exceeding eight hours.

- **Maintenance dose in adults:** sulfasalazine 2 g daily in divided doses.
- A lower starting dose of 1 to 2 g may also be used to reduce the risk of gastrointestinal side effects.

Initial sulfasalazine dosage for ulcerative colitis in children ≥ 6 years: sulfasalazine 40 to 60 mg per kg of body weight in each 24-hour period, divided into 3 to 6 doses.

- **Maintenance dose for children ≥ 6 years:** sulfasalazine 30 mg per kg of body weight in each 24-hour period, divided into 4 doses.

Rheumatoid arthritis

The recommended sulfasalazine dose for adults with rheumatoid arthritis is 2 g daily in 2 evenly divided doses.

- Initially, a lower dose of 0.5 to 1 g daily should be used to reduce the risk of gastrointestinal side effects. A suggested dosing schedule is given below.

Suggested Dosing Schedule for Adult Rheumatoid Arthritis:

Week of treatment	Morning No. of 500 mg tablets	Evening No. of 500 mg tablets
1	-	1
2	1	1
3	1	2
4	2	2

Juvenile Rheumatoid Arthritis (JRA) - polyarticular course

The recommended sulfasalazine maintenance dose for children ≥ 6 years with JRA is 30 to 50 mg/kg of body weight daily in 2 evenly divided doses.

- Typically, the maximum dose is 2 g per day.
- Initially, a dose of a quarter to a third of the planned maintenance dose should be used and increased weekly until the maintenance dose is reached at one month. This reduces the risk of gastrointestinal side effects.

See the full [sulfasalazine prescribing information](#) for further information about sulfasalazine dosing.

 [Detailed Sulfasalazine dosage information](#)

What happens if I miss a dose?

If you miss a dose of sulfasalazine take your next dose as soon as you remember. If it is nearly time for your next dose, just take the next dose at the right time. Do not take double the dose.

What happens if I overdose?

If you take too much sulfasalazine seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What other drugs will affect sulfasalazine?

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your doctor if you take medicines that contain digoxin or folic acid. Sulfasalazine may reduce your absorption of these drugs. Sulfasalazine used in combination with methotrexate may increase your risk of gastrointestinal adverse events, especially nausea.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

 [Sulfasalazine drug interactions](#) (more detail)

Does sulfasalazine interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

sulfasalazine

+

Enter a drug name

Add

Storage

Store sulfasalazine tablets at room temperature around 25°C (77°F).

Keep out of reach of children.

Sulfasalazine ingredients

Sulfasalazine is available in generic form and under the brand name Azulfidine.

Active ingredients: sulfasalazine

Inactive ingredients:

Azulfidine tablets: magnesium stearate, unspecified povidone, silicon dioxide, corn starch

Azulfidine EN-tabs (enteric coated, delayed-release tablets): white wax, carnauba wax, cellacefate, magnesium stearate, polyethylene glycol 20000, unspecified povidone, propylene glycol, glyceryl stearate SE, silicon dioxide, corn starch, talc

Generic versions of sulfasalazine may contain different inactive ingredients. Check the product label for your particular formulation of sulfasalazine for a complete list of ingredients.

Who makes sulfasalazine?

Pfizer Labs makes sulfasalazine under the brand names Azulfidine and Azulfidine EN-tabs.

Generic sulfasalazine is made by Actavis Pharma, Inc., Chartwell RX, LLC., Greenstone LLC, and many others.

Popular FAQ

How long does sulfasalazine take to work?



Does sulfasalazine cause cancer?



Does sulfasalazine suppress the immune system?



What are the long-term effects of taking sulfasalazine?



Does sulfasalazine cause weight gain?



Does sulfasalazine cause hair loss?



How long does sulfasalazine stay in your system?



Is sulfasalazine a steroid drug?



Does sulfasalazine cause high blood pressure?



References

1. [Sulfasalazine Delayed Release Tablets Package Insert](#)
2. [Sulfasalazine Tablets Package Insert](#)
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5. Choi J, Fenando A. Sulfasalazine. [Updated 2021 Jun 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-.

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Patient resources

- [Sulfasalazine Tablets patient information](#)

Other brands

[Azulfidine](#), [Sulfazine](#), [Azulfidine EN-tabs](#)

Professional resources

- [Sulfasalazine monograph](#)
- [Sulfasalazine \(FDA\)](#)
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- [Crohn's Disease, Maintenance](#)
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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation


 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

 Drug history at FDA



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