

# Sulfatyle 1000 Tablet

## Sulfasalazine (1000mg) Tablet

**Category:** Anti-inflammatory / Disease-modifying antirheumatic drug (DMARD)  
**Dosage Form:** Oral Tablet

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### Description:

Sulfasalazine (1000mg) is a sulfonamide and anti-inflammatory drug used to treat inflammatory bowel diseases like ulcerative colitis and Crohn's disease, as well as rheumatoid arthritis. It works by reducing inflammation in the intestines and joints, which helps to relieve symptoms such as pain, swelling, and discomfort. Sulfasalazine is also a disease-modifying antirheumatic drug (DMARD), which helps to control and slow the progression of rheumatoid arthritis.

The drug is metabolized in the body to sulfapyridine (which has anti-inflammatory properties) and 5-aminosalicylic acid (5-ASA), which primarily works in the intestines to reduce inflammation. It helps to prevent flare-ups and reduces symptoms of conditions like ulcerative colitis and rheumatoid arthritis.

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### Composition (Per Tablet):

- Sulfasalazine: 1000mg
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### Indications:

Sulfasalazine 1000mg is indicated for the treatment of:

#### 1. Ulcerative Colitis:

- To reduce inflammation and manage flare-ups in patients with mild to moderate ulcerative colitis.

#### 2. Rheumatoid Arthritis:

- As a DMARD, it is used to reduce joint inflammation, pain, and stiffness, helping to slow the progression of rheumatoid arthritis.

#### 3. Crohn's Disease:

- To manage symptoms of Crohn's disease (a type of inflammatory bowel disease), particularly during flare-ups.

#### 4. Other Autoimmune Conditions:

- Occasionally used in other autoimmune diseases as prescribed by a healthcare provider.
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### Dosage and Administration:

#### • For Ulcerative Colitis:

- The starting dose is typically 500mg to 1000mg once or twice daily, gradually increasing up to 4000mg per day based on individual response and tolerance.
- Maintenance dose: 2000mg to 4000mg daily, in divided doses.

#### • For Rheumatoid Arthritis:

- Starting dose is generally 500mg to 1000mg per day, with gradual increases to a daily dose of 2000mg to 3000mg, depending on the patient's response.

#### • For Crohn's Disease:

- A similar dosing regimen is used, with an initial dose starting at 1000mg daily, which can be

increased based on clinical response.

- **Administration:**
  - Sulfasalazine tablets should be taken orally, usually with food to reduce gastrointestinal irritation.
  - Tablets should be swallowed whole. Do not chew, crush, or split the tablets.
- **Adjustments for Special Populations:**
  - In patients with liver or kidney impairment, or those who are elderly, dose adjustments may be required, and treatment should be closely monitored.

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### Mechanism of Action:

Sulfasalazine is a prodrug, meaning it is metabolized in the body into active components. It is broken down by bacteria in the colon into 5-aminosalicylic acid (5-ASA) and sulfapyridine.

- 5-ASA has anti-inflammatory properties and works directly in the intestines to reduce the inflammation associated with inflammatory bowel diseases like ulcerative colitis and Crohn's disease.
- Sulfapyridine, a component of sulfasalazine, is primarily responsible for its anti-rheumatic effects, helping to reduce joint inflammation in rheumatoid arthritis.

By reducing the production of inflammatory mediators, sulfasalazine effectively controls symptoms such as pain, swelling, and redness in both the gastrointestinal and musculoskeletal systems.

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### Contraindications:

Sulfasalazine should not be used in patients with:

- Hypersensitivity to sulfasalazine, sulfonamides, or salicylates.
- Intestinal or urinary tract obstructions.
- Severe liver disease (e.g., cirrhosis, hepatitis).
- Severe renal impairment (creatinine clearance < 30 mL/min).
- Porphyria (a rare inherited disorder).
- Blood disorders (e.g., bone marrow suppression, agranulocytosis, or megaloblastic anemia).

**Caution:** In patients with g6pd deficiency (a genetic enzyme deficiency), asthma, or sulfa drug allergies, as the risk of adverse effects may be higher.

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### Warnings and Precautions:

1. **Blood Dyscrasias:**
  - Regular monitoring of blood counts is required during treatment as sulfasalazine can cause bone marrow suppression. Any signs of anemia, leukopenia, or thrombocytopenia should be monitored.
2. **Liver and Kidney Function:**
  - Sulfasalazine may cause liver toxicity and should be used cautiously in patients with liver disorders. Renal function should be monitored, especially in patients with pre-existing kidney issues.
3. **Gastrointestinal Reactions:**
  - Sulfasalazine can cause gastrointestinal discomfort such as nausea, vomiting, diarrhea, or abdominal pain, especially at higher doses.
4. **Skin Reactions:**

- Can cause skin rashes and may be associated with photosensitivity (sensitivity to sunlight).

#### **5. Fertility:**

- Use with caution in men as it may affect sperm count and fertility. It is generally advised to stop sulfasalazine before planning pregnancy, especially if fertility concerns arise.

#### **6. Pregnancy and Lactation:**

- It is categorized as Category B by the FDA for pregnancy, indicating that it is generally considered safe during pregnancy but should be used only if absolutely necessary. Breastfeeding is not contraindicated, but sulfasalazine and its metabolites can be excreted in breast milk.

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#### **Adverse Effects:**

#### **Common Side Effects:**

- Nausea, vomiting, and loss of appetite
- Gastrointestinal disturbances (e.g., diarrhea, abdominal pain)
- Headache
- Rash
- Fatigue
- Dizziness

#### **Serious Side Effects:**

- Severe allergic reactions (e.g., anaphylaxis, hives, swelling of the throat)
- Blood disorders (e.g., leukopenia, anemia, thrombocytopenia)
- Liver damage (e.g., hepatitis, jaundice)
- Interstitial lung disease (rare, but serious)
- Kidney damage (e.g., nephritis, glomerulonephritis)

- Pancreatitis

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#### **Drug Interactions:**

- Other DMARDs and Immunosuppressants:
  - Caution when using in combination with other disease-modifying antirheumatic drugs (DMARDs) or immunosuppressants, as this may increase the risk of infections or bone marrow suppression.
- Methotrexate:
  - Concomitant use with methotrexate can increase the risk of bone marrow toxicity. Close monitoring is required.
- Warfarin:
  - Sulfasalazine may interfere with the metabolism of warfarin, increasing the risk of bleeding. Monitor INR closely.
- Iron Supplements:
  - Sulfasalazine can interfere with the absorption of iron, so it should be taken at a different time of day from iron supplements.

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#### **Storage Instructions:**

- Store at room temperature (15°C – 30°C).
- Protect from moisture and heat. Keep the bottle tightly closed.
- Keep out of reach of children.

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#### **Key Points for Use:**

- Sulfasalazine is effective in treating ulcerative colitis, rheumatoid arthritis,

**and Crohn's disease by reducing inflammation.**

- **Monitor blood counts and liver/kidney function regularly during treatment.**
- **Take with food to reduce gastrointestinal side effects.**
- **Avoid sun exposure due to the potential for photosensitivity.**
- **Be cautious in patients with pre-existing kidney, liver, or blood disorders.**

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