

Sulfatyle 500 Tablet

Sulfasalazine (500mg) Tablet

Category: Anti-inflammatory / Disease-modifying antirheumatic drug (DMARD)

Dosage Form: Oral Tablet

Description:

Sulfasalazine (500mg) is an anti-inflammatory and disease-modifying antirheumatic drug (DMARD) commonly used to treat inflammatory bowel diseases such as ulcerative colitis and Crohn's disease, as well as rheumatoid arthritis. Sulfasalazine works by reducing inflammation in the intestines and joints, providing relief from symptoms such as pain, swelling, and discomfort. The drug is a prodrug that is metabolized into two active components: 5-aminosalicylic acid (5-ASA) and sulfapyridine. These components help to reduce inflammation and modify the course of disease in autoimmune conditions.

Sulfasalazine is also used to treat ankylosing spondylitis, juvenile idiopathic arthritis, and other chronic inflammatory conditions.

Composition (Per Tablet):

- Sulfasalazine: 500mg

Indications:

Sulfasalazine 500mg is indicated for the treatment of:

1. Ulcerative Colitis:

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

2. Rheumatoid Arthritis:

- As a disease-modifying antirheumatic drug (DMARD), it reduces joint inflammation, pain, and stiffness, helping to slow the progression of rheumatoid arthritis.

3. Crohn's Disease:

- To manage symptoms of Crohn's disease, particularly during flare-ups and to maintain remission.

4. Ankylosing Spondylitis:

- For the management of symptoms and inflammation associated with ankylosing spondylitis.

5. Juvenile Idiopathic Arthritis:

- Used to treat juvenile idiopathic arthritis in children when prescribed.

Dosage and Administration:

• For Ulcerative Colitis:

- Starting dose: 500mg to 1000mg once or twice daily, gradually increased based on individual response and tolerance, up to a daily dose of 4000mg.
- Maintenance dose: 2000mg to 4000mg daily, taken in divided doses.

• For Rheumatoid Arthritis:

- Starting dose: 500mg to 1000mg daily, with gradual increases to 2000mg to 3000mg daily, based on response.

• For Crohn's Disease:

- Initially, 1000mg daily, gradually increased depending on the response.
- For Ankylosing Spondylitis:
 - 500mg to 1000mg daily, with a possible increase to higher doses as needed.
- Administration:
 - Take the tablet orally, usually with food to help reduce gastrointestinal side effects such as nausea.
 - Swallow whole, do not chew or crush the tablet.
- Adjustments for Special Populations:
 - In patients with liver or kidney dysfunction, or the elderly, dose adjustments may be necessary, and treatment should be closely monitored.

Mechanism of Action:

Sulfasalazine is a prodrug, which is metabolized in the body by intestinal bacteria to produce two active compounds:

- **5-aminosalicylic acid (5-ASA):** This component works in the intestines to reduce inflammation by inhibiting the production of pro-inflammatory cytokines and other inflammatory mediators, helping manage conditions like ulcerative colitis and Crohn's disease.
- **Sulfapyridine:** This component is primarily responsible for the anti-inflammatory effects in rheumatoid arthritis, acting on immune cells to reduce inflammation in joints.

By modulating immune function and reducing the inflammatory processes in the body, sulfasalazine helps to alleviate symptoms,

prevent disease progression, and maintain remission in various autoimmune conditions.

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 such as bone marrow suppression, agranulocytosis, or megaloblastic anemia.

Caution: In patients with g6pd deficiency, asthma, or sulfa drug allergies due to a higher risk of adverse effects.

Warnings and Precautions:

1. **Blood Dyscrasias:**
 - Regular blood tests are necessary as sulfasalazine can cause bone marrow suppression, leading to conditions like anemia, leukopenia, or thrombocytopenia.
2. **Liver and Kidney Function:**
 - Liver toxicity is a potential risk. Renal function should also be monitored, particularly in patients with pre-existing kidney issues.
3. **Gastrointestinal Disturbances:**
 - Sulfasalazine can cause nausea, vomiting, diarrhea, or abdominal pain, particularly when starting therapy or increasing the dose.
4. **Photosensitivity:**

- Patients should use sun protection as sulfasalazine may increase sensitivity to sunlight, leading to an increased risk of sunburn.

5. Fertility Concerns:

- Sulfasalazine may lower sperm count in men, and patients planning to conceive should discuss treatment options with their healthcare provider.

6. Pregnancy and Lactation:

- Sulfasalazine is generally considered safe during pregnancy (Category B) but should only be used if necessary. It is also excreted in breast milk, so consult a doctor before using during breastfeeding.

Adverse Effects:

Common Side Effects:

- Gastrointestinal issues such as nausea, vomiting, diarrhea, abdominal pain, or loss of appetite.
- Headache or dizziness.
- Rash and itching.
- Fatigue or tiredness.

Serious Side Effects:

- Severe allergic reactions (e.g., anaphylaxis, hives, swelling of the throat).
 - Blood disorders, including anemia, leukopenia, and thrombocytopenia.
 - Liver damage (e.g., hepatitis, jaundice).
 - Pancreatitis (inflammation of the pancreas).
 - Interstitial lung disease (a rare but serious side effect).
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Drug Interactions:

- **Methotrexate:**
 - Co-administration with methotrexate may increase the risk of bone marrow toxicity and should be done with caution.
 - **Warfarin:**
 - Sulfasalazine may interact with warfarin, increasing the risk of bleeding. Monitor INR closely.
 - **Iron Supplements:**
 - Sulfasalazine may decrease the absorption of iron, so it should be taken at a different time of day from iron supplements.
 - **Other DMARDs or Immunosuppressants:**
 - Combining with other DMARDs or immunosuppressants may increase the risk of infections or bone marrow suppression.
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Storage Instructions:

- Store at room temperature (15°C – 30°C).
 - Keep in the original packaging to protect from moisture and light.
 - Keep out of reach of children.
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Key Points for Use:

- Sulfasalazine is effective in managing ulcerative colitis, rheumatoid arthritis, Crohn's disease, and other inflammatory conditions.
- Regular blood tests are required to monitor for potential side effects like bone marrow suppression.
- Take with food to minimize gastrointestinal side effects.

- **Use sun protection to avoid increased photosensitivity.**
- **Monitor liver and kidney function during long-term treatment.**

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