RIDAURA® (auranofin) contains gold and, like other gold-containing drugs, can cause gold toxicity, signs of which include: fall in hemoglobin, leukopenia below 4,000 WBC/cu mm, granulocytes below 1,500/cu mm, decrease in platelets below 150,000/cu mm, proteinuria, hematuria, pruritus, rash, stomatitis or persistent diarrhea. Therefore, the results of recommended laboratory work (See PRECAUTIONS) should be reviewed before writing each RIDAURA® prescription. Like other gold preparations, RIDAURA® is only indicated for use in selected patients with active rheumatoid arthritis. Physicians planning to use RIDAURA® should be experienced with chrysotherapy and should thoroughly familiarize themselves with the toxicity and benefits of RIDAURA®.

In addition, the following precautions should be routinely employed:
1. The possibility of adverse reactions should be explained to patients before starting therapy.
2. Patients should be advised to report promptly any symptoms suggesting toxicity. (See PRECAUTIONS – Information for Patients.)
Why Ridaura® (auranofin)?
Managing everyday life can be a challenge for your patients with rheumatoid arthritis (RA). Ridaura® is indicated in the management of adults with active classical or definite rheumatoid arthritis (ARA criteria) who:
• Have had an insufficient therapeutic response to, or
• Are intolerant of
an adequate trial of full doses of one or more NSAIDs. Ridaura® should be added to a comprehensive baseline program, including nondrug therapies.

What is Ridaura®?
Ridaura® is an established prescription medicine. It is available in oral form as capsules containing 3 mg auranofin. Auranofin contains 29% gold.

Important Safety Information
Contraindications
Ridaura® is contraindicated in patients with a history of any of the following gold-induced disorders: anaphylactic reactions, necrotizing enterocolitis, pulmonary fibrosis, exfoliative dermatitis, bone marrow aplasia or other severe hematologic disorders.

Potential Benefits vs Risks
The potential benefits of using Ridaura® in patients with progressive renal disease, significant hepatocellular disease, inflammatory bowel disease, skin rash or history of bone marrow depression should be weighed against 1) the potential risks of gold toxicity on organ systems previously compromised or with decreased reserve, and 2) the difficulty in quickly detecting and correctly attributing the toxic effect.

Use With Other Agents
The safety of concomitant use of Ridaura® with injectable gold, hydroxychloroquine, penicillamine, immunosuppressive agents or high doses of corticosteroids has not been established.

Recommended Monitoring and Potential Adverse Events
Blood dyscrasias should be constantly watched for through regular monitoring (at least monthly) of the formed elements of the blood throughout treatment.

A precipitous decline in platelets or a platelet count less than 100,000/cu mm or signs and symptoms suggestive of thrombocytopenia indicates a need to immediately suspend Ridaura® and other therapies with the potential to cause thrombocytopenia until the thrombocytopenia resolves and further studies show it was not due to gold therapy.

It is important to perform urinalysis regularly and to discontinue treatment promptly if proteinuria or hematuria develops.

The most common reaction to Ridaura® is diarrhea/loose stools reported in approximately 50% of patients. Ulcerative colitis is a rare serious gold reaction. Therefore, patients with gastrointestinal symptoms should be monitored for the appearance of gastrointestinal bleeding.

Use in Specific Populations
Use of Ridaura® by pregnant women is not recommended. Women of childbearing potential should be warned of the potential risks of Ridaura® therapy during pregnancy. Nursing during Ridaura® therapy is not recommended.

Ridaura® is not recommended for use in pediatric patients because its safety and effectiveness have not been established in this population.

Please see accompanying full Prescribing Information, including Boxed Warning, for Ridaura®
What is gold therapy and how does it work?
Gold therapy is one of the original medications developed specifically to treat RA and has been used since 1929. Ridaura® contains 29% gold. Although it is not clear how gold works, it is believed gold may affect the immune response involved in triggering RA. In patients with adult RA, Ridaura® may modify disease activity as manifested by synovitis and associated symptoms and reflected by laboratory parameters such as ESR. There is no substantial evidence, however, that gold-containing compounds induce remission of RA.

How soon can your patient expect to see improvements in their RA symptoms?
It can take a while to see any improvement after treatment with gold therapy. Your adult patients may see an effect after three to four months. However, six months of treatment with Ridaura® and/or dose increase may be necessary.

Can Ridaura® be taken with other medications?
It is not known whether Ridaura® is safe for use with injectable gold, hydroxychloroquine, penicillamine, immunosuppressive agents (e.g., cyclophosphamide, azathioprine, or methotrexate) or high doses of corticosteroids. Ridaura® may interact with other drugs, so it is important to consider all of the prescription drugs, over-the-counter medications, vitamins and herbal products your patients are taking.

Patients should be advised not to start, stop or change the dosage of any of their medications without your approval.

What should your patients know about Ridaura® side effects?
Patients should be advised that Ridaura® contains gold and, like other gold-containing drugs, can cause gold toxicity and other serious side effects. The most common reaction to Ridaura® is diarrhea/loose stools reported in approximately 50% of patients. Ulcerative colitis is a rare serious gold reaction. Therefore, patients with gastrointestinal symptoms should be monitored for the appearance of gastrointestinal bleeding. The possibility of adverse reactions should be explained to patients before starting therapy. Patients should be advised to promptly report any symptoms suggesting toxicity.

Please see attached full prescribing information for a comprehensive list of Ridaura® side effects.

Who should not take Ridaura®?
Your adult RA patients should not take Ridaura® if they are allergic to auranofin, gold, any heavy metal compound or any of the ingredients in Ridaura®. Ridaura® is contraindicated in patients with a history of any of the following gold-induced disorders: anaphylactic reactions, necrotizing enterocolitis, pulmonary fibrosis, exfoliative dermatitis, bone marrow aplasia or other severe hematologic disorders.

ıp Discover more at Ridaura.com

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