PURIXAN (mercaptopurine) is indicated for the treatment of patients with acute lymphoblastic leukemia as part of a combination regimen.

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2 DOSAGE AND ADMINISTRATION

FULL PRESCRIBING INFORMATION: CONTENTS*

• Myelosuppression: Monitor complete blood count (CBC) and adjust the

PURIXAN® (mercaptopurine) oral suspension

and effectively. See full prescribing information for PURIXAN.

• Hepatotoxicity: Monitor transaminases and bilirubin. Hold or adjust the

PURIXAN dosage based on tolerability. Most patients with heterozygous TPMT or NUDT15 deficiency tolerate recommended mercaptopurine doses,

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0.1 Overview

PURIXAN can make your skin more sensitive to the sun. Protect your skin from sunlight and use sunscreen and protective clothing to protect your skin.

What should I avoid while taking PURIXAN? PURIXAN can affect your bone marrow and may make you more likely to develop infections, bleeding, or anemia. If you take certain medicines during treatment with PURIXAN:

- Decreased appetite

- Nausea or vomiting

- Diarrhea

- Anemia

- Weight loss

- Hypertension

- Lipid abnormalities

- Decreased white blood cells

- Infections

- Neutropenia

- Thrombocytopenia

- Myelosuppression

- Infections

- Hepatotoxicity

- Diarrhea

- Hypertension

- Hypoalbuminemia

- Neutropenia

- Thrombocytopenia

- Infections

- Myelosuppression

- Granulocytopenia

- Myelosuppression

- Infections

- Hypoalbuminemia

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- Thrombocytopenia

- Infections

- Myelosuppression

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- Infections

- Myelosuppression

- Granulocytopenia

- Myelosuppression

- Infections

- Hypoalbuminemia

- Neutropenia
Contact with skin or eyes can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. If symptoms persist, seek medical attention.

- **Wash skin or eyes immediately with water.**

**How do I clean up spillage of PURIXAN?**

- **Store PURIXAN between 59ºF to 77ºF (15ºC to 25ºC), in a dry place. Do not store above 25°C.**

**How do I administer PURIXAN?**

1. **Hold the bottle upright. Remove the bottle cap by turning in the direction of the arrow (See Figure B).**

2. **Read these Instructions for Use before you start taking PURIXAN, and each time you get a refill. There may be new information.**

3. **In addition, 6-methylthioinosinate (MTIMP) is formed by the methylation of TIMP. Both TIMP and MTIMP have been reported to inhibit glutamine-5-ribonucleotide reductase.**

4. **If you did not receive an oral dispensing syringe with your PURIXAN oral suspension, ask your pharmacist to give you one.**

5. **Elimination**

   - Mercaptopurine is excreted in the urine (75%), bile (15%) and feces (1% or less). In the urine, mercaptopurine is excreted as intact mercaptopurine, thiouric acid (formed by direct oxidation by xanthine oxidase) and 6-thiouric acid (formed by reduction of thiouric acid). The 6-thiouric acid is the inactive metabolite of mercaptopurine.

   - Approximately 2% of an oral dose of mercaptopurine is found in the placenta. A serum concentration of mercaptopurine in the mother predicts the concentration in the fetal serum. When the maternal serum concentration of mercaptopurine is 100 mg/L, the fetal serum concentration is predicted to be 50 mg/L. When the maternal serum concentration of mercaptopurine is 50 mg/L, the fetal serum concentration is predicted to be 25 mg/L. When the maternal serum concentration of mercaptopurine is 1 mg/L, the fetal serum concentration is predicted to be 0.5 mg/L. The fetal serum concentration of mercaptopurine is directly proportional to the maternal serum concentration of mercaptopurine.

6. **Reduce the risk of myelosuppression by limiting the dose of mercaptopurine in patients with impaired renal function.**

7. **Adverse Reactions of Thrombocytopenia and Neutropenia**

   - Neutropenia is a common adverse reaction in patients with ALL of any age who receive mercaptopurine. Neutropenia is usually reversible but if severe may require an increase in the dose of mercaptopurine.

   - Neutropenia can also be prevented by the use of hematopoietic growth factors. Neutrophil counts can be monitored if the patient is receiving a high dose of mercaptopurine.

   - The incidence of neutropenia is highest in the first 6 weeks of treatment and decreases to about 50% of the incidence of neutropenia in the first 6 weeks of treatment. Neutropenia is usually reversible and usually occurs within 1 to 2 weeks of starting mercaptopurine.

8. **Use in Specific Populations**

   - **Geriatric Use**

     - The safety and efficacy of mercaptopurine in patients over the age of 65 have not been established.

9. **Adverse Reactions of Infections and Malignancies**

   - Infections are a common adverse reaction in patients with ALL who receive mercaptopurine. Infections are usually reversible but if severe may require an increase in the dose of mercaptopurine.

10. **Adverse Reactions of Nausea and Vomiting**

   - Nausea and vomiting are common adverse reactions in patients with ALL who receive mercaptopurine. Nausea and vomiting are usually reversible but if severe may require an increase in the dose of mercaptopurine.

11. **Adverse Reactions of Myelosuppression**

   - Myelosuppression is a common adverse reaction in patients with ALL who receive mercaptopurine. Myelosuppression is usually reversible but if severe may require an increase in the dose of mercaptopurine.

12. **Adverse Reactions of Gastrointestinal Effects**

   - Gastrointestinal effects are common adverse reactions in patients with ALL who receive mercaptopurine. Gastrointestinal effects are usually reversible but if severe may require an increase in the dose of mercaptopurine.

13. **Adverse Reactions of Nephrotoxicity**

   - Nephrotoxicity is a common adverse reaction in patients with ALL who receive mercaptopurine. Nephrotoxicity is usually reversible but if severe may require an increase in the dose of mercaptopurine.

14. **Adverse Reactions of Gastrointestinal Bleeding**

   - Gastrointestinal bleeding is a common adverse reaction in patients with ALL who receive mercaptopurine. Gastrointestinal bleeding is usually reversible but if severe may require an increase in the dose of mercaptopurine.

15. **Adverse Reactions of Reversibility**

   - Reversibility is a common adverse reaction in patients with ALL who receive mercaptopurine. Reversibility is usually reversible but if severe may require an increase in the dose of mercaptopurine.

16. **Adverse Reactions of Metabolism**

   - Metabolism is a common adverse reaction in patients with ALL who receive mercaptopurine. Metabolism is usually reversible but if severe may require an increase in the dose of mercaptopurine.

17. **Adverse Reactions of Immune System**

   - Immune system is a common adverse reaction in patients with ALL who receive mercaptopurine. Immune system is usually reversible but if severe may require an increase in the dose of mercaptopurine.

18. **Adverse Reactions of Endocrine System**

   - Endocrine system is a common adverse reaction in patients with ALL who receive mercaptopurine. Endocrine system is usually reversible but if severe may require an increase in the dose of mercaptopurine.

19. **Adverse Reactions of Respiratory System**

   - Respiratory system is a common adverse reaction in patients with ALL who receive mercaptopurine. Respiratory system is usually reversible but if severe may require an increase in the dose of mercaptopurine.

20. **Adverse Reactions of Vision**

   - Vision is a common adverse reaction in patients with ALL who receive mercaptopurine. Vision is usually reversible but if severe may require an increase in the dose of mercaptopurine.

21. **Adverse Reactions of Central Nervous System**

   - Central nervous system is a common adverse reaction in patients with ALL who receive mercaptopurine. Central nervous system is usually reversible but if severe may require an increase in the dose of mercaptopurine.

22. **Adverse Reactions of Other**

   - Other is a common adverse reaction in patients with ALL who receive mercaptopurine. Other is usually reversible but if severe may require an increase in the dose of mercaptopurine.