SAMIDINE TABLETS

Sulphadimidine B. P.

Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

SAMIDINE TABLETS 500MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains 500mg of Suphadimidine

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

White circular tablets with 'SAMIDINE' marked one side and the reverse face is plain.

Oral Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Suphadimidine is used in the treatment of acute, uncomplicated urinary tract infections.

4.2 Posology and method of administration.

Oral Administration only

Children: Single doses of 2.5gm followed by 1.0g to 1.25gm for 12 to 16 years; every 6 hours
Single doses of 2.0gm followed by 0.75g to 1.0gm for 8 to 12 years; every 6 hours
Single doses of 1.50gm followed by 0.75g for 4 to 8 years; every 6 hours
Single doses of 0.5gm followed by 0.25g for 4 to 8 years; every 6 hours

Adults: initial dose of 3gm with subsequent dosage of 1.0 to 1.5g every 6 hours. The initial and maintenance doses for adults and children may be increased by one third in very severe infections.

4.3 Contraindications

Samidine is contraindicated in patients with severe renal or hepatic failure or with blood disorders. It should not be given to patients with a history of hypersensitivity to the drug. Samidine should not given to infants within 1 to 2 months of birth because of the risk of producing kernic terus; and also to women prior to delivery or in nursing mother because of the same reason.

4.4 Special warnings and precaution for use.

Before using Sulphadimidine Tablet, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are Pregnant, planning to get pregnant or breastfeeding.

Keep out of reach of children.

4.5 Interaction with other medicinal product and other forms of interaction.

If used with other drugs or over the counter products at the same time, the effects of sulphadimidine tablet may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs.

4.6 Pregnancy and Lactation.

Pregnancy

There are no adequate data from the use of Sulphadimidine in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essentially by a physician.

Lactation

Sulphadimidine may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

4.7 Effect on the ability to drive and use machine.

If experience drowsiness, dizziness, hypotension or a headache as side-effects when using sulphadimidine tablets then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively.

4.8 Undesirable effect.

Samidine may cause nausea, vomiting and diarrhoea. Hypersensitivity reactions may occur; those involving the skin include rashes, photosensitivity reactions exfoliative dermatitis and toxic epidermal necrlysis (Lyell's syndrome).

4.9 Overdose.

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If suspect that anyone has overdosed of Sulphadimidine Tablet, please go to the emergency department of the closest hospital.

Please consult your physician or pharmacist for more information.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Sulphadimidine is rapidly absorbed and rapidly eliminated sulfonamide with excellent anitbaterial activity. Since its high solublity eliminates much of the renal toxicity inherent the use older sulfonamides, it has essentially replaced the less soluble agents. It is employed for both systemic and urinary tract infections.

It is a bateriostatic agent.

Sulphadimidine competitively inhibit bacterial synthesis of folic acid from para-aminobezoic acid.

5.2 Pharmacokinetic properties.

Sulphadimidine is well absorbed from the gastro-intestinal tract and over half is bound to plasma proteins particularly to albumin

Sulphadimidine is distributed throughout all tissues of the body. The time (about 4 hours) at which equallibrium with plasma is reached varies with the tissues.

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Purified Talc.

Magnesium Stearate

Gelatine

Methyl Paraben

Propyl Paraben

6.2 Incompatibilities

None known

6.3 Shelf-life

30 Months

6.4 Special precautions for storage

Protect from heat and light and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Bulk pack tablet whose quality has been approved by the quality control department in polythene bags in 1000's by weight. Seal the bags and place them in previously cleaned 1000cc plastic securi-containers.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

04 – 0272.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 2nd June 2016

10. DATE OF REVISION OF THE TEXT

17th August 2025