SAMTRIM TABLETS

Sulphamethoxazole & Trimethoprim

Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

SAMTRIM TABLETS 400MG/80MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains:

Sulphamethoxazole B.P	400mg
Trimethoprim B.P	80mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

White circular beveled tablets with both 'SAMTRIM'and break line marked on the same one side and plain on the other side.
Oral Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Samtrim is indicated in adults and children (>12 to <18 years old) and adults (>18 years old).
Respiratory tract infection: acute and chronic bronchitis, bronchiectasis, pneumonia, pharyngitis, tonsillitis sinusitis, otitis media.
Urinary Tract Infections: acute and chromic cystitis pyelonephritis, urethritis, prostatitis.
Gastrointestinal tract infections include typhoid and paratyphoid fever, typhoid carrier state and bacillary dysentry, cholera.
Skin and soft tissue infections, pyoderma, furuncles, absecesses and infected wounds

4.2 Posology and method of administration.

Oral Administration

The usal adult dose is two tablets of samtrim every 12 hours for 10 to 14 days for management of most infeections. Larger quantites have been given in special circumstances in patients with serious or life threatening disease.

The recommended daily dose for children for treatment of urinary tract infections and otitis media is 8mg/kg of trimethoprim and 40mg/kg of sulphamethoxazole every 12 hours for 10 days; the sam regimen is followed for 5 days to treat shigellosis

4.3 Contraindications

Samtrim is contraindicated in patients with marked liver parenchymal damage. It is also contraindicated in patients with severe renal insufficiency when repeated determinations of the plasma concentration cannot be made. Except in rare circumstances (Samtrim) should not be given to patients with serious hematlogical disorders. The combination has occasionally been administered to patients receiving cytotoxic agents for the trearment of leukemias, without evidence of any adverse effect on the bone marrow or peripheral blood.

Satrim should not be administered to patients with a history of hypersensitivity to salfonamides or trimethoprim.

If pregnancy cannot be excluded, possible risks should be balanced against the expected therapeutic effect.

4.4 Special warnings and precaution for use.

In patients with impaired renal function, the dosage should be reduced or the interval between doses prolonged in order to prevent accumulation in the blood. Determination of plasma drug concetrations is recommeded in such patients. Dosage recommendations for patients with impaired renal function are available or request.

Regular blood counts are advisable whenver samtrim is given for prolong periods. Especially in the elderly, there is a possibility of hematological changes indicative of folic acid deficiency; these ae reversible by folinic and therapy.

An adequate urinary output should be maintained at all time. Treatment must be discontinued immediately if a skin rash appears.

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

Trimethoprim may interfere with the estimation of serum/plasma creatinine when the alkaline picrate reaction is used. This may result in overestimation of serum/plasma creatinine of the order of 10%. The creatinine clearance is reduced: the renal tubular secretion of creatinine is decreased from 23% to 9% whilst the glomerular filtration remains unchanged.

4.6 Pregnancy and Lactation.

Pregnancy

Trimethoprim and sulphamethoxazole cross the placenta and their safety in pregnant women has not been established. Case-control studies have shown that there may be an association between exposure to folate antagonists and birth defects in humans.

Lactation

The components of Samtrim (trimethoprim and sulphamethoxazole) are excreted in breast milk. Administration of co-trimoxazole should be avoided in late pregnancy and in lactating mothers where the mother or infant has, or is at particular risk of developing, hyperbilirubinaemia. Additionally, administration of Samtrim should be avoided in infants younger than eight weeks in view of the predisposition of young infants to hyperbilirubinaemia

4.7 Effect on the ability to drive and use machine.

There have been no studies to investigate the effect of Samtrim on driving performance or the ability to operate machinery. Further a detrimental effect on such activities cannot be predicted from the pharmacology of the drug. Nevertheless the clinical status of the patient and the adverse events profile of co-trimoxazole should be borne in mind when considering the patients ability to operate machinery.

4.8 Undesirable effect.

As with any other drug, allergic reactions such as an itchy rash and hives may occur in patients with hypersensitivity to the components of the drug.

4.9 Overdose.

Nausea, vomiting, dizziness and confusion are likely signs of overdosage.
Therapeutic doses of upto 6gm daily may produce toxicity or fatalities. The aniline radical is largely responsible for the effect on the blood or hematoproietic system.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Samtrim is an antibacterial drug composed of two active principles, sulphamethoxazole and trimethoprim. Sulphamethoxazole is a competitive inhibitor of dihydropteroate synthetase enzyme. Sulphamethoxazole competitively inhibits the utilisation of para-aminobenzoic acid in the synthesis of dihydrofolate by the bacterial cell resulting in bacteriostasis. Trimethoprim reversibly inhibits bacterial dihydrofolate reductase, an enzyme active in the folate metabolic pathway converting dihydrofolate to tetrahydrofolate. Depending on the conditions the effect may be bactericidal. Thus trimethoprim and sulfamethoxazole block two consecutive steps in the biosynthesis of purines and therefore nucleic acids essential to many bacteria.

5.2 Pharmacokinetic properties.

The oral administration of trimethoprim and sulphamethoxazole are rapidly and nearly completely absorbed. The presence of food does not appear to delay absorption. Peak levels in the blood occur between one and four hours after ingestion and the level attained is dose related. Effective levels persist in the blood for up to 24 hours after a therapeutic dose. Steady state levels in adults are reached after dosing for 2-3 days. Neither component has an appreciable effect on the concentrations achieved in the blood by the other.

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

Unknown

6.3 Shelf-life

30 Months from the date of manufacture

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 350cc plastic securi-containers.

Samtrim is also packs in 10 x 10 blisters and put inside a printed carton white and blue folded box.

7 MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
2, WESTERN RESERVOIR ROAD,
ILORIN,
KWARA STATE, NIGERIA.
08057075266
sampharmaceuticalltd@gmail.com

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04 – 0277.

9 AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 2nd June 2016

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