

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Trimethoprim Tablets 200mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Trimethoprim 200.00mg
For excipients, see 6.1

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of susceptible infections caused by trimethoprim sensitive organisms including urinary and respiratory tract infections and for the prophylaxis of recurrent urinary tract infections. It is effective against most Gram-positive and Gram-negative aerobic organisms, including *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Klebsiella pneumoniae*, *Staphylococcus aureus*, *Escherichia coli*, *Enterobacter*, *Proteus* and *Streptococcus faecalis*.

Exceptions include anaerobic bacteria. *Mycobacterium tuberculosis*, *Neisseria gonorrhoeae*, *Pseudomonas aeruginosa* and *Treponema pallidum*.

Route of administration: oral

4.2 Posology and method of administration

Adults: treatment of urinary tract infections and all other susceptible infections: 200mg twice daily.

Long-term prophylaxis of recurrent urinary tract infections: 100mg at night before bed-time.

Children: 4 months to 12 years of age:- treatment of urinary tract infections and all other susceptible infections: 6mg/kg bodyweight daily, sub-divided into 2 equal doses.

Long-term prophylaxis of recurrent urinary tract infections: 2.5mg/kg body weight daily given as a single dose before bedtime.

Elderly: treat as for adults.

4.3 Contraindications

Hypersensitivity to Trimethoprim or to any other components of the formulation. Severe hepatic insufficiency. Severe renal insufficiency. Megaloblastic anaemia and other blood dyscrasias. Trimethoprim should not be administered to premature infants or children under 4 months of age.

4.4 Special warnings and precautions for use

Patients with marked impairment of renal function; care should be taken to avoid accumulation and resulting adverse hepatological effects. Regular haematological effects. Regular haematological tests should be undertaken in patients receiving long-term treatment and those pre-disposed to folate deficiency. Particular care should be exercised in the haematological monitoring of children on long-term therapy.

4.5 Interaction with other medicinal products and other forms of interaction

Trimethoprim may potentiate the anticoagulant effect of warfarin.

4.6 Pregnancy and lactation

Trimethoprim should not be administered to pregnant women. Trimethoprim is not contraindicated for short-term use in lactating mothers, although the drug is excreted in breast milk.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Nausea, vomiting, gastro-intestinal disturbance and headache. All these are rare. Cases of megaloblastic anaemia during prolonged therapy with trimethoprim in doses higher than those recommended rarely occur but are reversible with discontinuation of therapy and administration of folic acid. Aseptic meningitis has been reported. Skin rashes, pruritus and urticaria have been reported occasionally. More severe skin sensitivity reactions such as erythema multiforme, Stevens Johnson syndrome and epidermal necrolysis have been reported rarely.

Anaphylactic reactions, anaphylactoid reactions and angioedema rarely have been reported.

4.9 Overdose

Treat symptomatically, gastric lavage and forced diuresis can be used. Depression of haematopoiesis by trimethoprim can be counteracted by intramuscular injections of calcium folinate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Trimethoprim has potent anti-microbial activity through its selective inhibition of bacterial dihydrofolate reductase. It is effective against most gram-positive and gram-negative aerobic organisms.

5.2 Pharmacokinetic properties

Absorption is by the oral route. Peak plasma levels are reached in about one hour but significant plasma levels are obtained within half-an-hour.

Excretion is mainly in the urine in the form of the unchanged drug.

Trimethoprim may cause an apparent rise in serum creatinine levels due to competition in the tubular secretory mechanisms.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Povidone 25cps
Crospovidone
Sodium starch glycollate
Magnesium stearate
Industrial methylated spirit
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36m for all

6.4 Special precautions for storage

Store in a well closed container. Store in a dry place below 25°C

6.5 Nature and contents of container

High density polystyrene with polythene lids and/or polypropylene containers with polythene lids and polyurethane or polythene inserts

Blister pack - 25 micron PVC glass-clear/bluish rigid PVC (pharmaceutical grade) 20 micron hard-tempered aluminium foil coated on the pull side with 6-7gsm heat seal lacquer and printed on the bright side.

Pack sizes: 50,100, 500, 1000, 5000, 28 (blister pack)

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Limited

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8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0430

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

N/A

10 DATE OF REVISION OF THE TEXT

May 2009

