SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

TIEMPE/Trimethoprim 200mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Trimethoprim BP 200 mg.

3 PHARMACEUTICAL FORM

Tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of susceptible infections caused by Trimethoprim sensitive organisms, including most Gram-positive and Gram-negative aerobic organisms, including Haemophilus influenzae, Streptococcus pneumoniae, Klebsiella pneumoniae, Staphylococcus aureus, E. Coli, Enterobacter, Proteus and Streptococcus faecalis.

Exceptions include anaerobic bacteria. Mycobacterium tuberculosis, Neisseria gonorrhoea, Pseudomonas auruginosa and Treponema pallidum.

Prophylaxis of recurrent urinary tract infections.

4.2 Posology and method of administration

Adults: Treatment of urinary tract infections and all other susceptible infections: 200 mg twice daily.
Long term prophylaxis of recurrent urinary tract infections: 100 mg at night before bedtime.

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

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

Elderly: Treat as adults.

Advised dosage schedule where there is reduced kidney function:

eGFR (ml/min)	Dosage advised
Over 30	Normal
15- 30	Normal for 3 days then half dose
Under 15	Half the normal dose

Monitoring of renal function and serum electrolytes should be considered particularly with longer term use, in patients with impaired renal function. Trimethoprim should only be initiated and used in dialysis patients under close supervision from specialists in both infectious disease and renal medicine. Trimethoprim is removed by dialysis.
Monitoring trimethoprim plasma concentration may be considered with long term therapy but the value of this in individual cases should first be discussed with specialists in infectious disease and renal medicine.

Route of Administration: Oral.

4.3 Contraindications

Severe hepatic insufficiency. Megaloblastic anaemia and other blood dyscrasias. Trimethoprim should not be administered to premature infants or children under 4 months of age. Pregnancy - Trimethoprim should not be administered to pregnant women.
First trimester of pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

Severe cutaneous adverse reactions (SCARs)

Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported in association with trimethoprim treatment (see section 4.8).

Patients should be advised of the signs and symptoms and monitored closely for skin reactions.

If signs and symptoms suggestive of these reactions appear, trimethoprim should be withdrawn immediately and an alternative treatment considered (as appropriate).

If the patient has developed a serious reaction such as SJS, TEN or DRESS with the use of trimethoprim, the treatment must not be restarted in this patient at any time.

Patients with marked impairment of renal function; care should be taken to avoid accumulation and resulting adverse hepatological effects.

Monitoring of renal function and serum electrolytes should be considered particularly with longer term use.

Trimethoprim should only be initiated and used in dialysis patients under close supervision from specialists in both infectious disease and renal medicine.

Regular haematological tests should be undertaken in patients receiving long-term treatment and those pre-disposed to folate deficiency. The elderly may be more susceptible to folate deficiency and a lower dose may be advisable.

Patients and their carers should be told how to recognise signs of blood disorders and advised to seek immediate medical attention if symptoms such as fever, sore throat, rash, mouth ulcers, purpura, bruising or bleeding develop.Particular care should be exercised in the haematological monitoring of children on long-term therapy. Porphyria.

Elevations in serum potassium have been observed in some patients treated with trimethoprim. Patients at risk for the development of hyperkalaemia include those with renal insufficiency, poorly controlled diabetes mellitus, or those using concomitant potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, renin angiotensin system inhibitors (eg: ACE inhibitors or renin angiotensin receptor blockers), or those patients taking other drugs associated with increases in serum potassium (e.g. heparin). If concomitant use of the above-mentioned agents is deemed appropriate, monitoring of serum potassium is recommended (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

The plasma concentration of procainamide is increased with concomitant use of trimethoprim. The plasma concentration of digoxin is also possibly increased.
Antiepileptics: plasma concentration and antifolate effect of phenytoin increased.
Antimalarials: Increased risk of antifolate effect with pyrimethamine.
Ciclosporin may increase the nephrotoxicity of trimethoprim.
Cytotoxics: Increased risk of haematological toxicity with azathioprine and mercaptopurine. Avoid concomitant use with methotrexate.
Trimethoprim may potentiate the anticoagulant effect of warfarin.

Concomitant use of drugs that may increase serum potassium levels may lead to a significant increase in serum potassium. Potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, renin-angiotensin system inhibitors (eg: ACE inhibitors or renin angiotensin receptor blockers) and other potassium increasing substances (eg: heparin). Monitoring of potassium should be undertaken as appropriate (see section 4.4).

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4.6 Fertility, pregnancy and lactation

The usual caution in prescribing any drug for women of child-bearing age should be exercised with Trimethoprim.

Trimethoprim is contraindicated during the first trimester of pregnancy (see section 4.3). Studies in animals have shown a teratogenic effect.

Epidemiological studies have shown an increased risk of spontaneous abortion and congenital malformations, in particular neural tube defects, oral clefts and cardiovascular defects, in children of mothers treated with trimethoprim during the first trimester of pregnancy. The presumed mechanism of action is thought to be interference with folates.

In the second and third trimesters, use should be avoided, unless clinically necessary.

Trimethoprim is not contra-indicated 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

Does not affect.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders
Not Known: Drug reaction with eosinophilia and systemic symptoms (DRESS)

Psychiatric disorders
Very rare: Hallucinations

Nausea, vomiting, gastro-intestinal disturbance, headache, skin rashes and pruritus. All these are rare.
Cases of Megaloblastic anaemia during prolonged therapy with Trimethoprim in doses higher then those recommended rarely occur but are reversible with discontinuation of therapy and administration of folinic acid.

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 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
Crospovidone
Sodium starch glycollate
Magnesium stearate
Industrial methylated spirit
Purified water

6.2 Incompatibilities

There are no major incompatibilities.

6.3 Shelf life

36 months all pack sizes.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Polypropylene or high density polystyrene with polythene closures and polyurethane wads or polythene inserts.
Pack sizes: 50, 100, 500, 1000, 5000

250 micron PVC glass-clear/bluish rigid PVC (Pharmaceutical grade). 20 micron hard-tempered aluminium foil coated on the dull side with 6-7 gsm heat seal lacquer and printed on the bright side.

Pack sizes: 28

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
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3rd floor, 1060 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0118

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10 DATE OF REVISION OF THE TEXT

08/01/2026