Trimac®

Co-trimoxazole

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Dual -action chemotherapeutic agent with bactericidal properties.

Composition:

The active ingredients of **Trimac®** are trimethoprim [2,4-diamino-5-(3,4,5-trimethoxybenxyl)-pyrimidine] and sulfamethoxazole (5-methyl-3-sulfanilamido-isoxazole).

Form	Trimethoprim B.P.	Sulfamethoxazole B.P.
1 Forte tablet	160 mg	800 mg
1 teaspoonful (5 ml) pediatric syrup	40 mg	200 mg

Properties:

The antibacterial effect of **Trimac®** covers a wide range of gram-positive and gram-negative organisms such as *Streptococci, Staphylococci, Pneumococci, Haemophilus influenzae, Neisseria, E. coli, Proteus mirabilis, Proteus vulgaris, Bordetella, Salmonella, Klebsiella-Aerobacter, Shigella, Vibrio cholerae, Brucella, Pseudomonas pseudomallei, Pseudomonas cepacia, Pneumocystis carinii, Serratia marcescens*, *Yersinia* and *Norcardia.*

Indications:

- Respiratory tract infections: Acute and chronic bronchitis, pneumonia, *Pneumocystis carinii* pneumonitis, pharyngitis, tonsilitis (in infections due to group A β-hemolytic streptococci the rate of eradication is not fully satisfactory), sinusitis and otitis media.
- Urinary tract infections: Acute and chronic cystitis, pyelonephritis, and urethritis, prostatitis.
- Genital infections in both sexes, including gonococcal urethritis.
- Gastrointestinal tract infections, Including typhoid and paratyphoid fever, typhoid carrier state and bacillary dysentery; cholera (as an adjunct to fluid and electrolyte replacement).
- Skin and soft tissue infections: pyoderma, furuncles, abscesses and infected wounds.
- Other bacterial infections: Acute and chronic osteomyelitis, acute brucellosis, septicemia due to sensitive organisms. Nocardiosis, mycetoma (except when caused by the true fungi), South American blastomycosis.

Dosage and administration:

(a) For adults and children over 12 years of age	Forte tablets	
	Morning	evening
Standard dosage	1	1
Minimum dosage and dosage For long term therapy (longer than 14 days)	½	½
High dosage (for particularly Severe cases)	1½	1½
Dose for uncomplicated gonorrhea (Limited to 1 day)	2½	2½
(b) For children, according to age	**1 teaspoonful (5ml) pediatric syrup**	
	Morning	**Evening**
6 weeks to 5 months	½	½
6 months to 5 years	1	1
6 years to 12 years	2	2

PREPARATION FOR USE:
(A) Forte tablets.
Oral Use;
Swallow the tablet with a drink of water.
(B) Pediatric Suspension.
Oral route;
Shake the bottle well before use.

The above dosage schedule for children corresponds approximately to an average dose of 6 mg trimethoprim plus 30 mg sulfamethoxazole per kg bodyweight per day. For severe infections the dosage shown for children may be increased by 50%.
In acute infections **Trimac®** should be given for at least five days or until, the patient has been symptom-free for two days.

Symptoms of overdose:
If you suspect a significant overdose of **Trimac®**, if you have nausea or vomiting, stomach pain, dizziness, drowsiness, confusion, depression, blood in the urine and loss of consciousness, consult your doctor who may decide to prescribe medication.

Side effects:
At the recommended dosage **Trimac®** is usually well tolerated. Of the reported adverse effects most are mild and comprise nausea (with or without vomiting) and drug rashes. As with a great variety of other drugs, **Trimac®** has in isolated cases been associated with the Stevens-Johnson and Lyell's syndromes. Hematological changes have been reported, the majority being mild, asymptomatic, and reversible on withdrawal of the drug. The changes mainly took the form of leukopenia, neutropenia and thrombocytopenia. Rare cases of tinnitus have been reported. Very rarely, agranulocytosis, megaloblastic anemia and purpura occurred. Although trimethoprim and sulfamethoxazole are excreted in breast milk, administration of **Trimac®** to nursing mothers represents a negligible risk to the infant.

Precautions:
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 concentrations is recommended in such patients. Dosage recommendations for patients with impaired renal function are available on request. Regular blood counts are advisable whenever **Trimac®** is given for prolonged periods. Especially in the elderly, there is a possibility of hematological changes indicative of folic acid deficiency; these are reversible by folinic acid therapy.
An adequate urinary output should be maintained at all times. Treatment must be discontinued immediately if a skin rash appears.

Contraindications:
Trimac® 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, **Trimac®** should not be given to patients with serious hematological disorders. The combination has occasionally been administered to patients receiving cytotoxic agents for the treatment of leukemia, without evidence of any adverse effect on the bone marrow or peripheral blood.
Trimac® should not be administered to patients with a history of hypersensitivity to sulfonamides or trimethoprim. For safety reasons **Trimac®** is contraindicated during pregnancy. If pregnancy cannot be excluded, possible risks should be balanced against the expected therapeutic effect.
Trimac® should not be given to premature and newborn infants during the first few weeks of life.

Drug interactions:
Trimac® may enhance the effect of concurrently administered oral anticoagulants (e.g. Marcoumar (Trade Mark) or warfarin) and phenytoin. It may also affect the dose of hypoglycemic drugs required.
Occasional reports suggest that patients receiving Pyrimethamine as malarial prophylaxis in doses exceeding 25 mg weekly may develop megaloblastic anemia if **Trimac®** is prescribed concurrently.

Packs:

Forte tablets	10X10
Pediatric Suspension	50ml

Storage:
Tablets and suspension should be stored below 30^{o}C. Bottles of suspension already in use can be stored at room temperature or under refrigeration.

KEEP OUT OF THE REACH OF CHILDREN: Parents and caregivers are advised to oversee treatment in children

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Manufactured by:
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