

**TETRAMED®**  
**500 mg capsules**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about TETRAMED**

Each capsule of TETRAMED contains 500 mg tetracycline hydrochloride.

TETRAMED capsules are for oral use.

Tetracycline is a broad-spectrum antibiotic with an antimicrobial spectrum of activity against a wide range of gram-positive and gram-negative organisms. Tetracycline exerts its antimicrobial effect by inhibition of protein synthesis.

TETRAMED is indicated for the treatment of adults with infections caused by susceptible strains of microorganisms in the conditions listed below:

- Rickettsial infections (including typhus fever and the typhus group, Q fever, rickettsialpox, and tick fevers)
- Chlamydial infections (including psittacosis, lymphogranuloma venereum, trachoma, non-gonococcal urethritis, endocervicitis, rectitis and conjunctivitis)
- Ear, nose, throat and bronchopulmonary infections
- Urinary tract infections
- Acne and rosacea
- Mycoplasmal infections (especially pneumonia caused by *Mycoplasma pneumoniae*)
- Part of regimens for pelvic inflammatory disease
- Cholera, relapsing fever, Lyme disease, chancroid, trench fever
- Mouth infections, especially in destructive forms of periodontal disease
- Brucellosis, plague, tularemia
- As an alternative treatment of actinomycosis, infected animal bites, anthrax, chronic bronchitis, gas gangrene, gastro-enteritis (due to *Campylobacter* or *Yersinia enterocolitica*), granuloma inguinale, leptospirosis, syphilis, listeriosis, gonorrhoea, streptococcal infections
- With quinine to treat falciparum malaria
- Adjunct to amebicides in acute intestinal amebiasis
- Malabsorption syndromes such as tropical sprue
- As part of triple therapy to eradicate *Helicobacter pylori* in patients with peptic ulcer disease

**The way to take TETRAMED**

Take TETRAMED as directed. TETRAMED should be taken with plenty of fluid while sitting or standing, well before going to bed and preferably 1 hour before or 2 hours after meals

Dosage and duration of treatment are individualized on the basis of the condition under treatment.

The usual adult daily dose is 1-2 g/day divided in 2 to 4 equal doses depending on the severity of the infection.

The usual adult dosage of TETRAMED is 1 or 2 capsules of 500 mg every 12 hours or 1 capsule every 6 hours.

Higher doses, up to 4 g daily, have occasionally been given to adults with severe infection.

Dosage should be reduced in case of impaired renal or hepatic function.

Special dosage recommendations for adults:

<b>Indication</b>	<b>Dosage</b>
Brucellosis	1 capsule of 500 mg, every 6 hours for 3 weeks, accompanied by 1 g streptomycin intramuscularly twice/day the first week, and once daily the second week
Syphilis	A total of 30 to 40 g in equally divided doses over 10 to

	15 days (500 mg every 6 hours for 15 days); close follow up and laboratory tests must be performed
Gonorrhea in patients sensitive to beta-lactamins	Initial oral dose 1.5 g followed by 500 mg every 6 hours for 4 days
Acne (long-term therapy)	500 mg every 12 hours
With quinine to treat falciparum malaria	3 to 7 day course of quinine given with 7 days tetracycline 500 mg every 12 hours
As part of triple therapy to eradicate <i>Helicobacter pylori</i> in patients with peptic ulcer disease	The usual dose of tetracycline in these regimens is 500 mg every 6 hours for 2 weeks

*For children over 8 years old:*

The usual recommended dose is 25 to 50 mg/kg daily by mouth in 4 divided doses.

#### **Duration of treatment**

The duration of treatment is determined according to the disease process. Do not discontinue the treatment without consulting your doctor; otherwise the success of the treatment is not sure.

Therapy should be continued for at least 24 to 48 hours after symptoms and fever have subsided.

When used in streptococcal infections, therapy should be continued for at least 10 days.

In the treatment of acne, maximum improvement is said to occur after 3 to 6 months, but treatment may need to continue for 2 or more years.

#### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

#### **In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

#### **Contraindications**

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

#### **Precautions**

- The use of drugs of the tetracycline class during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth. Tetracycline drugs, therefore, should not be used in this age group unless other drugs are not likely to be effective or are contraindicated.
- This drug should be used with caution in case of renal or hepatic impairment.
- Avoid prolonged exposure to sunlight during treatment with this medication, if this occurs and skin eruption develops, treatment should be discontinued. Sunscreen should be considered.
- Drink fluid liberally along with the treatment.
- In long-term therapy, periodic laboratory evaluation of organ systems, including hematopoietic, renal and hepatic studies should be performed.
- This medication should not be used during pregnancy or lactation.

#### **Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant use with systemic retinoids is not recommended.

The absorption of this drug is impaired when taking bismuth subsalicylate, colestipol, colestyramine, antacids containing aluminum, calcium or magnesium and iron-containing preparations. If antacids or iron salts should be used, take at least 2 hours before or after this drug.

Use with caution with oral anticoagulants, penicillins, methoxyflurane, and oral contraceptives.

**Adverse reactions**

The most reported adverse reactions include anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, vaginal candidiasis, oral candidiasis and photosensitivity reactions. Hematologic disorders, increases in liver enzymes, and allergic reactions have been rarely reported.

Benign intracranial hypertension has been associated with the use of tetracyclines. The usual clinical manifestations are headache and blurred vision.

Inform your doctor if any adverse effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

TETRAMED, tetracycline hydrochloride 500 mg, pack of 12 capsules

**Revision date: 03/2008**

TERC5/003