

RETADOX®
100 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 RETADOX

Each capsule of RETADOX contains 100 mg doxycycline (as doxycycline hyclate). RETADOX capsules are for oral use.

Doxycycline is a broad-spectrum antibiotic synthetically derived from oxytetracycline. RETADOX has an antimicrobial spectrum of activity against a wide range of gram-positive and gram-negative organisms. Doxycycline exerts its antimicrobial effect by inhibition of protein synthesis.

RETADOX is indicated for the treatment of the following infections:

- Brucellosis; pasteurellosis; rocky mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsialpox, and tick fevers caused by Rickettsiae; psittacosis; relapsing fever; chancroid; plague; tularemia; cholera; *Campylobacter fetus* infections; bartonellosis; uncomplicated gonorrhoea; syphilis; yaws; listeriosis; Vincent's infection; actinomycosis; nongonococcal urethritis; granuloma inguinale and infections caused by *Clostridium* species
- Lymphogranuloma venereum, trachoma, inclusion conjunctivitis and uncomplicated urethral, endocervical or rectal infections in adults caused by *Chlamydia trachomatis*
- Moderate to severe acne vulgaris and rosacea
- Chronic periodontitis
- Respiratory tract infections: Ear, nose, throat and bronchopulmonary infections, particularly acute exacerbations of chronic bronchitis
- Urinary tract infections
- Anthrax including inhalational anthrax (post-exposure)
- Adjunct to amebicides in acute intestinal amebiasis
- Prophylaxis of malaria due to *Plasmodium falciparum*

The way to take RETADOX

Take RETADOX as directed by your physician.

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

The absorption of doxycycline is not influenced by simultaneous ingestion of food or milk. Take the capsules during meals with a full glass of water, at least one hour before bedtime.

- The usual dose for adults is 200 mg on the first day of treatment, administered as 100 mg every 12 hours (1 capsule of 100 mg every 12 hours) followed by a maintenance dose of 100 mg once daily (1 capsule once daily).
- In the management of more severe infections (particularly chronic infections of the urinary tract), 1 capsule of 100 mg every 12 hours is recommended.
- Children above eight years of age weighing 45 kg or less may be given 4 mg/kg/day divided into 2 doses on the first day of treatment, followed by 2 mg/kg/day, as a single daily dose or divided into two doses on subsequent days. In severe infections, the initial dosage is maintained throughout the course of treatment.
- For children weighing more than 45 kg, the usual adult dose should be used.

Special dosage recommendations:

Indication	Dosage
Acne	100 mg/day (1 capsule/day) for at least 3 months
Uncomplicated gonococcal infections in adults	- 200 mg/day (1 capsule of 100 mg every 12 hours) for 7 days or - 300 mg (3 capsules of 100 mg) as a single

	dose followed in one hour by a second 300 mg dose (3 capsules of 100 mg)
Uncomplicated urethral, endocervical, or rectal infection in adults caused by <i>Chlamydia trachomatis</i>	100 mg (1 capsule) every 12 hours for 7 to 10 days
Nongonococcal urethritis	100 mg (1 capsule) every 12 hours for 7 days
Syphilis (early)	100 mg (1 capsule) every 12 hours for 2 weeks
Syphilis of more than one year duration	100 mg (1 capsule) every 12 hours for 4 weeks
Acute epididymo-orchitis	100 mg (1 capsule) every 12 hours for at least 10 days
Prophylaxis of malaria	- Adults: 100 mg/day (1 capsule/day) - Children over 8 years of age: 2 mg/kg/day once daily up to the adult dose Prophylaxis should begin 1-2 days before travel to the malarious area and should be continued during the travel and for 4 weeks after the traveler leaves the malarious area.
Inhalational anthrax (post-exposure)	Adults and children weighing 45 kg or more: 100 mg (1 capsule) every 12 hours for 60 days Children weighing less than 45 kg: 2.2 mg/kg twice a day for 60 days

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.

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

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.
- 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.
- It is recommended not to use this medication 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, 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, penicillin, barbiturates, carbamazepine, phenytoin, methoxyflurane and oral contraceptives.

Adverse reactions

The most reported adverse reactions include anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, vaginal candidiasis, and photosensitivity reactions.

Hematologic disorders and allergic reactions have been rarely reported.

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

Storage

Store at controlled room temperature (up to 30°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

RETADOX, doxycycline 100 mg (as doxycycline hyclate), pack of 10 capsules

Revision date: 10/2007

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