

Package leaflet: information for the user

Tetracycline HCl CF 250 mg, hard capsules

tetracycline hydrochloride

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Tetracycline HCl CF 250 mg and what is it used for?

Tetracycline belongs to the group of antibacterial medicines that inhibit the growth of certain types of bacteria.

Tetracycline HCl CF 250 mg is used for inflammations caused by bacteria sensitive to tetracycline such as:

- inflammation of the respiratory tract
- inflammation of the urinary tract
- skin inflammation
- throat, nose, and ear inflammation
- eye inflammation
- inflammation of the intestines
- inflammation of the genital organs

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

You are pregnant.

You are breastfeeding.

You suffer from a combined severely reduced kidney and liver function.

You have severe liver dysfunction.

You have severe kidney dysfunction.

In children under 8 years, because the risk of tooth discoloration is high.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

In case of severe diarrhea with fever during treatment. One should consider inflammation of the colon mucosa or staphylococcal infection of the small intestine.

The treatment should be stopped immediately.

In case of blood clotting disorders. Tetracycline can affect blood clotting and therefore this medication should be used with caution.

In case of mild to moderate renal impairment, the medication should only be used under the supervision of a doctor.

When used together with other substances harmful to the liver.

In case of impaired liver function (use only under the supervision of a doctor).

Upon exposure to direct sunlight or ultraviolet light, one should be prepared to stop the treatment immediately at the first signs of a skin rash.

As with other antibiotics, infections by non-sensitive microorganisms may occur.

Are you using any other medications?

Are you using any other medications besides Tetracycline HCl CF 250 mg, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist.

The effect of tetracycline is weakened by the simultaneous intake of antacids, dairy products, or iron preparations. Simultaneous intake with these substances should therefore be avoided.

Activated charcoal and ion exchangers reduce the absorption of tetracycline into the blood.

The effect of anticoagulants is enhanced by tetracycline; adjustment of the dosage of anticoagulants may be necessary.

Tetracycline can counteract the effect of bactericidal agents such as penicillins, therefore these agents should not be used simultaneously.

What should you pay attention to with food and drink?

The capsules should not be taken with dairy products. Take the capsules whole, in a sitting or standing position, 1 hour before or 2 hours after a meal with a glass of water. In case of gastrointestinal complaints, it is advised to take the capsules during the meal. See "3. How do you use this medicine?", under "Method of administration".

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

Observations in humans have shown that tetracyclines are harmful to the fetus because they delay bone formation; as a result, the bones become more brittle and tooth development is adversely affected, and liver damage may also occur in the mother. Do not use during pregnancy.

Breastfeeding

Tetracycline passes into breast milk.

Do not use during breastfeeding.

Driving ability and the use of machines

So far, no data is known regarding the influence of tetracycline on driving ability and reaction time. In cases where dizziness, blurred vision, or double vision occur, operating vehicles and machines is discouraged.

Tetracycline HCl CF 250 mg contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Adults

The recommended dosage is: 250 mg every six hours, up to a maximum of 2 g per day.

For uncomplicated gonorrhoea: 500 mg every six hours for 5 days.

For urinary tract infections caused by bacteria other than gonococci: 500 mg every six hours for 7 days.

Use in children from 8 years

The recommended dosage is: 20 - 40 mg/kg body weight per day in 4 doses.

Symptoms usually disappear within a few days, nevertheless complete the course.

A streptococcal infection should be treated for at least 10 days. Using doses greater than 500 mg is not useful.

Elderly

In the elderly, a lower dosage should be used.

In case of reduced kidney or liver function

In case of reduced kidney or liver function, a lower dosage should be used.

Method of administration

To prevent capsules from getting stuck in the esophagus, which can lead to irritation or even esophageal damage, the capsules should be taken whole, 1 hour before or 2 hours after a meal, with a glass of water in a sitting or standing position.

Do not lie down immediately after taking the capsules. In case of gastrointestinal complaints, it is advised to take the capsules during a meal.

The capsules should not be taken with dairy products. Spread the intake evenly throughout the day.

If you notice or think that tetracycline is working too strongly, or not enough, consult your doctor or pharmacist.

Have you used too much of this medicine?

If you have taken too much Tetracycline HCl CF 250 mg, contact your doctor or pharmacist immediately.

The most noticeable symptoms of overdose are: vomiting, fever attacks, jaundice, bruising, black stools, prolonged blood clotting time. If you suspect or notice an overdose, you should warn a doctor as soon as possible. Show him the packaging or the patient leaflet. He can then treat you further in the correct way.

Have you forgotten to use this medicine?

If you forgot to take your capsule and the time is not too long past, you should still take the capsule. If the time has already passed by several hours, it is better to wait until the next time you need to take a capsule and then continue the course as prescribed.

Do not take a double dose to make up for a forgotten dose.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone experiences them. The frequency of the side effects mentioned below is not known (cannot be determined with the available data).

Blood and lymphatic system disorders:

A shortage of platelets accompanied by bruising and a tendency to bleed (thrombocytopenia), a shortage of white blood cells accompanied by increased susceptibility to infections (neutropenia).

Immune system disorders:

Allergic reactions have been reported with possible symptoms of sudden fluid accumulation in the skin and mucous membranes, breathing difficulties and/or itching and rash, and bruising.

Nervous system disorders:

Headache, nausea, tinnitus, dizziness, and blurred or double vision due to increased pressure in the skull have been observed in rare cases in older children and adults.

Cardiac disorders:

Inflammation of the pericardium (pericarditis).

Gastrointestinal disorders:

Gastrointestinal complaints (e.g., loss of appetite, nausea, vomiting, diarrhea); inflammation of the tongue; inflammation of the oral mucosa; itching of the anus; a certain swallowing disorder (dysphagia); inflammation of the mucosa of the small and large intestine (enterocolitis); a certain inflammation of the large intestine (pseudomembranous colitis); inflammatory lesions around the anus and/or genitals; and black tongue.

Inflammation of the esophagus and esophageal ulcers have been reported after oral administration of tetracycline, when the medication is taken lying down and/or with insufficient fluid.

Hepatobiliary disorders:

Liver damage, sometimes accompanied by pancreatitis with severe pain in the upper abdomen radiating to the back, nausea, and vomiting, during prolonged use or in cases of impaired liver or kidney function.

Skin and subcutaneous tissue disorders:

Rash; hypersensitivity of the skin to sunlight and UV light; rash with severe itching and formation of welts (urticaria), a certain skin inflammation with scaling and/or hair loss (exfoliative dermatitis), skin lesion caused by hypersensitivity to a certain medication characterized by a sharply defined, thickened, red spot, sometimes with blistering (fixed-drug eruption).

Musculoskeletal and connective tissue disorders and bone abnormalities:

Growing bone and tooth development are adversely affected (bones become more brittle and teeth discolor).

Renal and urinary disorders:

Increase in blood urea levels and nitrogen compounds in the blood in patients with impaired kidney function, with possible symptoms including general body weakness, lethargy, malaise, and nausea.

General disorders and administration site conditions:

A vitamin B deficiency may occur during prolonged treatment.

5. Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

How should you store this medicine?

Store in the original packaging, below 25 °C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging after "Do not use after:" or "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal ensures they are destroyed correctly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is tetracycline hydrochloride. Each capsule contains 250 mg of tetracycline hydrochloride.

The other substances in this medicine are sodium carboxymethyl starch, magnesium stearate (E572), gelatin (E441), quinoline yellow (E104), erythrosine (E127), titanium dioxide (E171).

What does Tetracycline HCl CF 250 mg look like and what is in a package? The capsules are yellow and filled with a yellow powder.

Tetracycline HCl CF 250 mg is available in packages with 1 or more blister strips of 10 capsules and in containers with 30, 50, 100, 150, 200, 250, 500, 1000, 1500, 2000, or 2500 capsules.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder:

Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Netherlands

Manufacturer:

Centrafarm Services B.V.
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