

PACKAGE LEAFLET: INFORMATION FOR THE USER

DOKSICIKLIN HF

100 mg capsules, hard

DOXYCYCLINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What DOKSICIKLIN HF is and what it is used for
2. Before you take DOKSICIKLIN HF
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1. WHAT DOKSICIKLIN HF IS AND WHAT IT IS USED FOR

Doxycycline HF capsules contain the active ingredient doxycycline, of the class of medicines known as tetracycline antibiotics. It is also known as a broad-spectrum antibiotic and may be for the treatment of various types of infections caused by bacteria:

- upper and lower respiratory tract
- urinary tract
- sexually-transmitted diseases
- skin infections such as acne
- eye infections
- rickettsial infections such as Q fever or fever caused by the tick
- other infections such as malaria, cholera, brucellosis, leptospirosis, psittacosis and fevers caused by the tick.

Or for prevention of:

- traveler's diarrhea, typhus and leptospirosis.

2. BEFORE YOU TAKE DOKSICIKLIN HF

Do not take DOKSICIKLIN HF

- are allergic (hypersensitivity) to doxycycline, to any other related antibiotics (such as tetracycline or minocycline), or the other ingredients in the composition (see Section 6).
- A child has less than 12 years.

Warnings and Precautions

Take special care when taking medicine DOKSICIKLIN HF if:

- If you have liver disease or are taking medicines that can affect your liver
- If you have porphyria (a genetic blood disorder)
- suffer from myasthenia gravis, a condition characterized by muscle weakness, problems in chewing and swallowing and slurred speech
- You are sensitive to sunlight
- If you have systemic lupus erythematosus (SLE) condition characterized by a rash (especially on the face), hair loss, fever, weakness and pain in the joints.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

Tell your doctor if you are taking any of the following medications:

- Warfarin or other anticoagulants (to prevent clotting)
- penicillin or rifampicin (to treat infection)
- Medicines such as antacids containing aluminum, calcium or magnesium or other medicines containing iron, bismuth or zinc salt. These medicines should not be taken simultaneously with the medicine DOKSICIKLIN HF, because resorption of doxycycline can be decreased
- phenobarbital, carbamazepine, phenytoin or primidone (for epilepsy)
- Oral contraceptives (contraceptive pill)
- methoxyflurane (an anesthetic), if you need to go into surgery, you should tell your doctor or dentist that you are taking the medicine DOKSICIKLIN HF
- Cyclosporine (used after organ transplants).

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or breast-feeding consult your doctor or pharmacist before taking the medicine because Doxycycline can harm your baby.

3. HOW TO TAKE DOKSICIKLIN HF

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

You're not supposed to drink alcohol while taking DOKSICIKLIN HF capsules, contact your doctor if you have any questions.

Swallow the capsules whole with a full glass of water, if the capsule irritate your stomach, take it with food or milk. It is necessary to take the capsules while sitting or standing and much earlier before going to bed at night to prevent irritation or ulceration in your esophagus. It is important that after taking DOKSICIKLIN HF capsules you are not lying down during the next 30 minutes.

The usual dose is in the duration of treatment of 10 days if your doctor does not prescribe otherwise:

Adults, older people and children over 12 years:

- General infection: a single dose of 200 mg on the first day or two a 100 mg dose, and maintenance of the 100 mg daily. In severe infections and may be administered 200 mg daily during the treatment period.

Specific infections:

- Acne vulgaris - 50 mg daily with food or liquid for a period of 6-12 weeks.
- STIs - 100 mg twice daily for 7-10 days.
- Syphilis - 300 mg per day in split doses for 10 days.
- fever caused by the tick - single dose of 100 mg or 200 mg, depending on the severity of symptoms.
- Malaria - 200 mg daily for at least 7 days. Your doctor with Doxycycline HF can prescribe another medication such as quinine.
- prevention of typhoid infection (which is transmitted by mites) - single dose of 200 mg.
- Prevention of traveler's diarrhea (diarrhea) - 200 mg on the first day of travel, and then 100 mg per day during their stay in a particular area. Do not use this medicine for more than 3 weeks, if you have not received different instructions from your doctor.
- Prevention of infection leptospirosis - 200 mg once a week during their stay in infection infected area and 200 mg at the end of the trip. Do not use this medicine for more than 3 weeks, if you have not received different instructions from your doctor.

Children under 12 years

Medicine DOKSICKLIN HF is not recommended for use in children younger than 12 years since it may cause permanent discoloration of enamel and affect bone development.

If you take more DOKSICKLIN HF than you should

If you have taken more medicine than you should, talk to your doctor or pharmacist.

If you forget to take DOKSICKLIN HF

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

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DOKSICKLIN HF can cause side effects, although not everybody gets them.

Stop taking the medicine DOKSICKLIN HF and seek immediate medical advice if:

- Notice that your skin is very sensitive to light (there may be a skin rash, itching, redness or severe sunburn after sun exposure or tanning bed).

Immediately contact your doctor if you experience some of the following reactions:

- wheezing, difficulty breathing, fever, sudden swelling of the face, lips, throat, tongue, hands, or feet, increased heart rate, low blood pressure, rash or itching (encompassing the entire body), pericarditis (inflammation of the lining of the heart).
- swollen tongue, watery diarrhea, fever and cramps (pseudomembranous colitis), pain and itching in the rectal area and / or in the genital area, inflammation of the region around the vagina or thrush infection of the vagina or mouth
- The worsening of systemic lupus erythematosus.

Tell your doctor if you notice some of the following side effects or any other side effects not listed:

- Blood: change in the number of certain blood cells, you may notice that you bruise easily, have a nosebleed, or suffer from infections and sore throat, porphyria (sensitivity to sunlight, inflammation of the nerves and stomach pains).
- Glands and Hormones: discoloration of tissue of the thyroid gland (does not affect the function of the thyroid gland).
- Central nervous system: headache, increased pressure in the head (severe headache, blurred and / or double vision, blind spots), permanent loss of vision, saliency fontanelle (soft spot on the head) in infants.
- Ears: Tinnitus (ringing and ringing in the ears)
- gastrointestinal tract: abdominal pain, loss of appetite, feeling sick or nausea, heartburn, diarrhea, difficulty in swallowing, sensitive and sore tongue or mouth, inflammation and / or ulcers in the esophagus, discolouration or underdevelopment of teeth.
- Liver: changes in tests of liver function, inflammation of the liver (hepatitis), jaundice (yellowing of the skin and whites of the eyes), liver failure and inflammation of the pancreas (pancreatitis).
- Skin: severe skin reactions such as. erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (rash with flushing, fever, blisters or ulcers), toxic epidermal necrolysis (redness, scaling and swelling of the skin as in burns), separation of the nail from the nail plate.
- Muscles and bones: aching muscles and joints.
- Kidneys: increased urea in the blood.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE DOKSICIKLIN HF

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use DOKSICIKLIN HF after the expiry date which is stated on the label.

Shelf life: 4 years.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What DOKSICIKLIN HF contains

The active substances are:

Doxycycline 100 mg, capsules, hard:

1 capsule contains: 100 mg of doxycycline (as doxycycline hyclate)

The other ingredients are:

Doxycycline 100 mg, capsules, hard:

Lactose monohydrate; Corn starch; Magnesium stearate; Silica, colloidal anhydrous; Sodium lauryl sulphate.

Hard gelatine capsules

The color of the capsule:

Head capsules - dark green: Titanium dioxide (E 171 C.I. 77891); Quinoline Yellow (E 104 C.I. 19140);

Sunset Yellow (E 110 C.I. 15985); Patent Blue (E131 V C.I. 42051); Brilliant Black (E 151 C.I. 28440).

The body of of the capsule - dark green: titanium dioxide (E 171 C.I. 77891); Quinoline Yellow (E 104 C.I. 19140); Sunset Yellow (E 110 C.I. 15985); Patent Blue (E131 V C.I. 42051); Brilliant Black (E 151 C.I. 28440).

What DOKSICIKLIN HF looks like and contents of the pack

Doxycycline 100 mg, capsules, hard:

Hard gelatin capsules dark green color, filled with dust light yellow color.

Blister (Al / PVC). The package contains one blister with 5 capsules.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka

Novakovići bb, Banja Luka, Bosnia and Herzegovina