

PACKAGE LEAFLET: INFORMATION FOR THE USER

Minocycline Eurogenerics 50 mg filmomhulde tabletten Minocycline

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. See section 4.

What is in this leaflet

1. What Minocycline Eurogenerics is and what it is used for
2. What you need to know before you take Minocycline Eurogenerics
3. How to take Minocycline Eurogenerics
4. Possible side effects
5. How to store Minocycline Eurogenerics
6. Contents of the pack and other information

1. What Minocycline Eurogenerics is and what it is used for

Minocycline is an antibiotic that is effective against a number of bacteria types and belongs to the so-called tetracyclines group.

Minocycline Eurogenerics 50 mg is used for the treatment of severe acne with infections (a skin condition).

2. What you need to know before you take Minocycline Eurogenerics

Do not take Minocycline Eurogenerics if you:

- are allergic to minocycline, to other tetracyclines or any of the other ingredients of this medicine (listed in section 6)
- are pregnant or breast-feeding
- suffer from severe liver function disorders
- suffer from severe kidney disorders

Minocycline must not be administered to children under the age of 8 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Minocycline Eurogenerics if you:

- have reduced liver or kidney function
- are sensitive to sunlight or artificial light (e.g. sunbeds)
- suffer from a disease called Ménière.

During the treatment with Minocycline Eurogenerics, talk to your doctor if any of the following occurs:

- you develop severe diarrhoea or high fever (signs of another infection)
- you suffer from increased pressure in the skull (intercranial hypertension). Bulging of the skull can occur in infants. See section 4.
- develop headache, hallucinations, dizziness or visual problems including blurred vision or seeing spots (scotoma)

- you have systemic lupus erythematosus (SLE) and it becomes worse or you develop the disease. SLE is a condition characterized by a rash (especially on the face), hair loss, fever, a feeling of general discomfort and illness and joint pain

Taking Minocycline Eurogenerics may cause reduced levels of vitamin B, ascorbic and folic acid and may influence laboratory tests.

Other medicines and Minocycline Eurogenerics

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Like other medicines in the same group, Minocycline Eurogenerics 50 mg can cause interactions with many other medicines.

An interaction means that medicines or substances can influence each other's effect(s) and/or side effect(s) when used simultaneously.

An interaction can occur when minocycline is used simultaneously with:

- Iron preparations and antacids (medicines for heartburn); these substances reduce the absorption of minocycline and thus reduce its effectiveness.
- Activated charcoal and ion-exchangers (e.g. colestyramine); the absorption and activity of minocycline is reduced.
- Anti-coagulants (blood-thinning substances); minocycline increases the activity of these substances.
- So-called beta-lactam antibiotics; tetracyclines can reduce the effectiveness of these antibiotics. The combination with other antibiotics is not recommended.
- Methoxyflurane (used for anaesthesia); in combination with this substance, minocycline can cause kidney damage.
- Carbamazepine (medicine used to treat epilepsy); the combination with minocycline can lead to lower blood levels and therefore reduced efficacy of minocycline.
- Medicines that inhibit the intestinal peristaltic (used for diarrhoea); there is an increased risk of intestinal infection if minocycline is taken in combination with such medicines.
- Hepatotoxic medicines (medicines that have a toxic effect on the liver); in combination with such medicines, minocycline can lead to liver poisoning.
- Isotretinoin (another medication used for acne): it is better to avoid this combination.

Note: you may be familiar with the above mentioned medicines under another name, often the brand name. In this section only the active substance or the group of active substances of the medicine has been named and not the brand name. You should therefore look carefully at the packaging or in the package leaflet to establish the active substance of the medicine you are using.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Minocycline must not be used during pregnancy. The reasons are:

- Minocycline can harm the development of the bones and teeth of the unborn child.
- Minocycline can also cause liver damage to the mother.

Breastfeeding

Minocycline must not be used when breast-feeding because this can harm the development of the bones and teeth of the child.

Driving and using machines

Minocycline Eurogenerics can cause lightheadedness, visual disturbances, dizziness, ringing in the ears, a feeling of dizziness or spinning (vertigo). Make sure you are not affected before driving or operating machinery.

Minocycline Eurogenerics contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Minocycline Eurogenerics

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The initial dose is 50 mg every 12 hours. When the infection decreases, the maintenance dose can be reduced to 50 mg once a day or 100 mg every two days.

The acne treatment must be sustained for at least 4 to 6 weeks and preferably no longer than 6 months (see section “Warnings and precautions”).

If the acne does not improve during the first weeks of the treatment, please contact your doctor.

Method of administration

The tablets must be taken when sitting or standing with a large amount of water to avoid irritation of the oesophagus. Do not lie down immediately after taking the tablets. The tablets can be taken during meals and can also be taken with milk if they cause stomach complaints.

If you take more Minocycline Eurogenerics 50 mg than you should

If you take more Minocycline Eurogenerics 50 mg than you should, contact your doctor or pharmacist immediately. In the event of an overdose, the following symptoms can appear: vomiting, attacks of fever, jaundice, bruising, black stools containing blood, and fluid loss. Drink a large amount of water in case of an overdose.

If you forget to take Minocycline Eurogenerics 50 mg

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

Take the forgotten dose as soon as possible and then abide by the usual schedule. However, if the next dose is due in a few hours, then do not take the forgotten dose and wait until the appropriate time to take the next tablet.

If you stop taking Minocycline Eurogenerics 50 mg

If you suddenly stop, often forget doses or fail to complete the course of treatment, the bacteria causing the infection (and the symptoms of the disease) will multiply again, so that the symptoms of the disease can return or get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the tablets immediately and seek urgent medical advice if the following occur:

- **allergic reactions** (anaphylaxis, hypersensitivity): blood spots, bruising and discolouring to the skin (purpura), shock, flaky skin (exfoliative dermatitis), increase in the number of white blood cells and one or more of the following: inflammation of the liver (hepatitis), inflammation of the lungs caused by an infection (pneumonitis), inflammation of the kidneys, inflammation of the

heart muscle (myocarditis) or membrane around the heart (pericarditis), fever, swelling of the lymph nodes.

- **Lupus-like syndrome:** presence of antinuclear antibodies in the blood, joint pain (arthralgia), inflammation (arthritis), stiffness or swelling of joints and one or more of the following: fever, muscle pain (myalgia), inflammation of the liver (hepatitis), skin rash, inflammation of blood vessels.
- **Serum sickness-like syndrome:** fever, itchy skin rash, rash, joint pain (arthralgia), inflammation (arthritis), stiffness or swelling of joints, increase in the number of white blood cells.
- **raised pressure in the skull:** headache, visual problems including blurred vision, “blind” spots, double vision, permanent loss of vision. Bulging of the skull can occur in infants
- **growth of bacteria resistant to tetracyclines:** inflammation of the intestines, inflammation of the tongue and mouth, inflammation of the female genitals causing itching, discharge or pain on passing urine, irritation around your bottom, stomach upset.
- development or worsening of existing **systemic lupus erythematosus (SLE)**, symptoms include large areas of red scaly patches on the face, hair loss, weight loss, painful joints and fever.
- **symptoms of liver damage:** fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever.
- **a change in colour** of the skin, nails, teeth, mucous membrane of the mouth, bones, thyroid, eyes, breast milk, tears or sweat (hyperpigmentation).
- **Agranulocytosis** (disappearance of the granulocytes from the blood)

Tell your doctor if the following side effects occur:

Uncommon (may affect up to 1 in 100 people)

- changes in the numbers and types of your blood cells,
- skin rash which may be itchy with or without pale or red raised patches, swelling of the face, lips, tongue or throat
- fever

Rare (may affect up to 1 in 1,000 people)

- if you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test
- blood vessel inflammation
- dizziness, headache
- feeling or being sick, diarrhoea, vomiting, loss of appetite, underdevelopment of tooth enamel, inflammation or ulceration of the gut
- thrush around your bottom, genital area or mouth, inflammation of male genitals
- increased levels of urea in the blood
- hair loss, skin reactions including red patches (erythema multiforme), severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), a severe rash with reddening, peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis), sensitivity to sunlight or artificial light (e.g. sunbeds),
- joint pain (arthralgia), inflammation (arthritis), stiffness or swelling of joints, muscle pain (myalgia), systemic lupus erythematosus (SLE), if you already suffer from SLE
Minocycline Eurogenerics may make your condition worse.
- inflammation of the liver (hepatitis) and kidneys

Very rare (may affect up to 1 in 10,000 people)

- inflammation of the tongue, mouth or intestines, difficulty swallowing, indigestion, pseudomembranous colitis (watery diarrhoea, fever and cramps)
- acute kidney failure
- changes in thyroid function. You should tell your doctor, if you notice swelling of your thyroid nodes or if you feel pain in your neck or throat.

- liver failure, jaundice (yellowing of the skin or whites of the eyes), inflammation of the pancreas (pancreatitis), abnormal liver function test results

Not known (frequency cannot be estimated from the available data):

- low white blood cell count (agranulocytosis)

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown:

- decreased level of vitamin B, ascorbic acid and folic acid
- hallucination, tingling or pins and needles in the hands and feet, feeling of dizziness or spinning (vertigo), decreased sensitivity to touch, fits, drowsiness
- impaired hearing, ringing in the ears
- bone pain, thinning or weakening of bones
- painful blue-red nodules on the skin (erythema nodosum)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minocycline Eurogenerics

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the packaging after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Minocycline Eurogenerics contains

- The active substance is minocycline hydrochloride dihydrate.
Minocycline Eurogenerics 50 mg contains 57.93 mg minocycline hydrochloride dihydrate equivalent to 50 mg minocycline base.
- The other ingredients are: povidone K25, lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium, colloidal silicon dioxide (E551), magnesium stearate (E470b), hypromellose 2910, Macrogol 6000 (E1521), yellow iron oxide (E172), titanium dioxide (E171).

What Minocycline Eurogenerics looks like and contents of the pack

Minocycline Eurogenerics 50 mg film-coated tablets are light yellow, round, biconvex tablets with a smooth, mat surface.

PVC/PVDC/Aluminium blister packs with 10, 20, 30, 40, 42, 50, 80, 84, 90, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer*Marketing Authorisation Holder*

Eurogenerics NV – Heizel Esplanade b22 – 1020 Brussels

Manufacturer

Sanico NV – Veedijk 59 – 2300 Turnhout

Laboratórios Atral, S.A - Rua da Estação 42, Vala do Carregado - 2600-726 Castanheira do Ribatejo - Portugal

This medicinal product is authorised in the Member States of the EEA under the following names:

BE Minocycline EG 50 mg filmomhulde tabletten

LU Minocycline EG 50 mg comprimés pelliculés

NL Minocycline Eurogenerics 50 mg filmomhulde tabletten

Registered as: RVG110440

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