

PACKAGE LEAFLET

Package leaflet: Information for the patient

Minocycline 50 mg Film-coated Tablets Minocycline 100 mg Film-coated Tablets

(minocycline hydrochloride)

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

1. What Minocycline is and what it is used for

Minocycline belongs to the tetracycline group of antibiotics. Minocycline can be used to treat a variety of infections, including bacterial infections that affect the eyes, ears, nose, throat and respiratory system (chest infections), skin infections (acne), gonorrhoea or pelvic, prostate and urinary tract infections. It can also be used to treat meningitis carriers. Minocycline can also be given to prevent infection before and after an operation.

2. What you need to know before you take Minocycline

Do not take Minocycline if you:

- are allergic to minocycline, other tetracyclines or any of the other ingredients of this medicine (listed in section 6)
- have a condition called systemic lupus erythematosus (SLE)
- need dialysis treatment
- are pregnant or breast-feeding
- are a child under 12 years old; as Minocycline can affect growing bones and teeth causing staining and reduce the amount of enamel in the teeth.

Warnings and precautions

Talk to your doctor before taking Minocycline:

- if you have problems with your liver or are taking medicines which can affect the liver (see 'Other medicines and Minocycline' below)
- if you have serious kidney problems
- if you suffer from myasthenia gravis (a disease causing muscle weakness)

During treatment

If you notice any of the following during treatment, stop taking this medicine and immediately contact your doctor or, if serious, go to your nearest hospital emergency department:

- difficulty breathing
- signs of SLE which you may see as a rash (especially on the face), hair loss, fever, a general feeling of being unwell and joint pain
- signs of liver damage which you may see as yellowing of the skin or whites of the eyes, loss of appetite and stomach pain
- growth of tetracycline-resistant bacteria, which you may see as inflammation of the tongue, mouth or vagina, inflammation of the intestines causing severe nausea and vomiting, stomach cramps or persistent diarrhoea or itching of the anus
- increased pressure in the head which you may see as headache or problems with your vision
- patches of darker skin colour.

Avoid strong sunlight or ultra violet light as Minocycline can make the skin more sensitive. If your skin becomes red and patchy, tell your doctor as he may need to stop treatment

Urine tests

Tell your doctor or nurse that you are taking Minocycline before you take a urine test as minocycline may affect the results.

If your treatment lasts for longer than 6 months your doctor will give you a blood test every 3 months to check for the presence of SLE and that your liver is working properly.

Other medicines and Minocycline

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, herbal medicines or any of the following:

- any medicine that can affect how the liver works (hepatotoxic medicine)
- anticoagulants to thin the blood e.g. warfarin
- antacids, used for indigestion
- ulcer healing medicine, such as sucralfate, bismuth salts
- medicines containing zinc salts, iron, calcium, aluminium or magnesium
- kaolin, a medicine used to treat diarrhoea
- quinapril an ACE inhibitor, used to treat high blood pressure
- a penicillin antibiotic
- diuretics ('water' tablets)
- retinoids such as isotretinoid (often used to treat acne) or retinol
- ergotamine, a medicine used to treat migraines
- ergometrine, a medicine used to induce abortion or labour

Minocycline with food, drink and alcohol

Do not drink alcohol during treatment. The absorption of minocycline can be reduced by food, milk or milk products.

Pregnancy and breast-feeding

Do not take minocycline if you are pregnant or plan to become pregnant, as it can affect the development of your unborn baby.

Do not breast-feed if you are taking minocycline as it can pass into breast milk.

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.

Driving and using machines

Do not drive or use machines if you suffer from dizziness, headaches, a spinning sensation when standing still (vertigo), light-headedness, problems with your sight, hearing problems or ringing in the ears (tinnitus) while taking minocycline.

Minocycline contains lactose and sunset yellow (E110)

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

This medicine also contains sunset yellow (E110) which may cause allergic reactions.

Information on sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Minocycline

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

It is important that you complete the course of treatment as directed by your doctor, even if you feel better.

- Swallow the tablets whole with plenty of fluid
- Avoid taking at the same time as food, milk or milk products as these can reduce the absorption of Minocycline.
- Take whilst sitting or standing upright: this medicine **should not** be taken immediately before bedtime or if lying down.

Patients being treated for certain diseases may need monthly blood tests to check the infection is clearing up.

Use in adults and the elderly: The recommended dose is 200 mg daily in divided doses.

The following doses may be given to treat the specific infection:

Acne: 50 mg twice daily for at least 6 weeks.

Gonorrhoea: For men, take a single starting dose of 200 mg followed by 100 mg every 12 hours for at least 4 days. Females may need to be treated for longer.

To prevent meningitis infection: 100 mg twice daily for 5 days. Your doctor will then give you another antibiotic to take, called rifampicin.

Use in children and adolescents

Minocycline must not be given to children under 12 years of age.

Only the 50 mg strength tablets are recommended in children over 12 years. The recommended dose is 50 mg every 12 hours.

If you have kidney disease your doctor may give you a lower dose.

Directions for use

Swallow the tablets whole with plenty of liquid while standing or sitting down

If you take more Minocycline than you should

Contact your doctor or hospital emergency department immediately. You may be sick (vomiting), have dizziness or nausea (feel sick).

If you forget to take Minocycline

Take your dose as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Minocycline

Do not stop taking Minocycline without talking to your doctor first. It is important to finish the course of antibiotic as instructed by your doctor.

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.

If any of the following happen, stop taking Minocycline and tell your doctor immediately or, if serious, go to your nearest hospital emergency department:

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

- allergic reactions such as severe skin rashes, red itchy swollen skin, joint pain, swelling of the face, lips, mouth, tongue or throat resulting in difficulty breathing. This may also occur with high levels of white blood cells, and one or more of the following: inflammation of the liver (hepatitis), lungs (pneumonitis), kidneys, heart muscle (myocarditis) and membrane around the heart (pericarditis). You may also have a fever and swollen glands
- severe headaches with changes in eyesight such as loss of vision, blurred or double vision
- frequent or recurrent infections causing fever, severe chills, mouth ulcers or chest infections. These may be signs of low levels of white blood cells (leucopenia)
- shortness of breath during exercise, fatigue, chest pain or pressure. These may be signs of an inflamed heart muscle (myocarditis)
- sudden sharp chest pain made worse by coughing or deep breathing. This may be a sign of inflammation of the membrane around the heart (pericarditis)
- yellowing of skin or whites of eyes, dark urine, pale stools, loss of appetite and stomach pain. These may be signs of serious problems with your liver
- pain, inflammation, stiffness or swelling of the joints with fever, muscle pain, inflammation of the liver (hepatitis), rash or inflammation of blood vessels
- producing little or no urine, pain or discomfort passing urine, producing cloudy or dark urine with lower back pain. These may be signs of serious problems with your kidneys
- inflammation of the tongue, mouth or vagina, inflammation of the intestines causing severe nausea and vomiting, stomach cramps or diarrhoea, itching of the anus. These may be signs of the growth of tetracycline-resistant bacteria
- painful purple lumps on the skin (erythema nodosum)
- patches of darker skin colour
- sensitivity to sunlight or artificial light (sunbeds). You may have tingling, burning or redness of the skin. If this occurs avoid direct exposure to sunlight or artificial light

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

- a reduction in all types of blood cells resulting in frequent or recurrent infections (see leucopenia above), unexplained bruising or bleeding for longer than usual (thrombocytopenia) and tiredness, weakness or pale skin (anaemia)
- other breathing problems such as shortness of breath at rest, wheezing, coughing with chest tightness or worsening of asthma
- watery diarrhoea possibly with blood, loss of appetite, stomach cramps and feeling sick (nausea or being sick (vomiting)). These may be signs of inflammation in your intestines
- severe stomach pain which radiates to your back. This may be a sign of an inflamed pancreas
- severe skin reactions, blistering of the skin, mouth, eyes and genitals, flaking or peeling of the skin
- rash (especially on the face), hair loss, weight loss, fever, a general feeling of being unwell and joint pain. These may be signs of systemic lupus erythematosus (SLE)

Not known (cannot be estimated from the available data)

- fits
- a drug induced allergic reaction the includes a skin rash, high fever, changes in the levels of blood cells (drug reaction with eosinophilia and systemic symptoms – DRESS)

- fever, itchy rash, pain, inflammation, stiffness or swelling of the joints, increase in the number of white blood cells. These may be signs of a serum sickness like syndrome

Other possible side effects include:

Common (may affect up to 1 in 10 people)

- dizziness

Uncommon (may affect up to 1 in 100 people)

- fever

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

- an increase in the number of a specific type of white blood cell which can be seen in a blood test
- unexplained bruising or bleeding for longer than normal. This may be a sign of low levels of blood platelets
- a feeling of spinning when standing or sitting still (vertigo), ringing in ears, other hearing problems
- loss of appetite, diarrhoea, feeling or being sick
- headache
- pins and needles in the hands or feet or a reduction in the sense of touch
- cough
- a change in the colour of your teeth
- an increase in levels of liver enzymes or urea which can be seen in a blood test
- hair loss
- red round lumps under the skin usually below the knee
- a skin reaction that keeps appearing in the same area every time you take the medicine
- skin itching, skin rash, nettle rash, redness or pain, swelling or tenderness around a vein (vasculitis)
- joint pain, muscle pain

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

- bulging fontanelle (soft spot on head) of babies
- fungal infection in the mouth or genital area (thrush)
- abnormal thyroid function
- indigestion, difficulty swallowing
- problems with the surface of your teeth
- inflammation of your food pipe or ulcers in your food pipe
- high levels of bilirubin which can be seen in a blood test
- flaky skin
- a change in the colour of finger or toe nails, inside the mouth, bone, eyes, thyroid, secretions such as breast milk, tears or sweat to blue, black, grey or muddy brown
- swelling or stiffness of joints
- inflammation of joints (arthritis)
- inflammation of the head of the penis

Not known (cannot be estimated from the available data)

- a rash of small red or purple spots
- an increase of substances in the lungs which can be seen in an x-ray
- drowsiness

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minocycline

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

Do not use this medicine after the expiry date which is stated on the blister, label or carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light.

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 contains

The active substance is minocycline hydrochloride.

The other ingredients are lactose (see 'Minocycline contains lactose and sunset yellow (E110)'), sodium starch glycolate (see 'Information on sodium'), povidone, microcrystalline cellulose, sodium laurilsulfate (see 'Information on sodium') and magnesium stearate. The tablet coating contains carnauba wax. The printing ink contains hypromellose, titanium dioxide, macrogol 400, quinoline yellow (E104), sunset yellow (E110) (see 'Minocycline contains lactose and sunset yellow (E110)') and indigo carmine (E132).

What Minocycline looks like and contents of the pack

Minocycline 50 mg film-coated tablets are round, orange/brown with two sides that curve out, marked with 'MN50' on one side and 'G' on the other.

Minocycline 100 mg film-coated tablets are round, orange/brown with two sides that curve out, marked with 'MN100' on one side and 'G' on the other.

Minocycline is available in plastic bottles with a plastic cap of 10 (100 mg only), 50, 100, 250 and 500 tablets or blister packs of 10 (100 mg only), 20 (50 mg only) 28, 50 and 84 (50 mg only) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, U.K.

Manufacturer

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Mylan Hungary Kft, Mylan utca 1, Komárom, 2900, Hungary

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