

Minox 50mg Film-coated tablets

Minocycline (as 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Minox
3. How to take Minox
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1 What Minox is and what it is used for

Minox belongs to a group of medicines called tetracycline antibiotics. It is also known as a broad-spectrum antibiotic and may be used to treat a wide range of infections caused by bacteria. Minox may be used for:

- respiratory tract infections such as pneumonia, bronchiectasis, lung abscess or bronchitis
- urinary tract infections
- gonorrhoea (a sexually transmitted disease)
- skin infections such as acne
- infections of the eye
- prostate infections
- ear, nose and throat infections
- nocardiosis (an infection often affecting the lungs)
- actinomycoses (an infection often affecting the throat and lungs)
- pelvic inflammatory disease (e.g. salpingitis, oophoritis)
- preventative treatment for meningitis carriers
- preventative treatment before and after surgery
- anthrax patients (an infection affecting the skin, lungs and gut) who have a penicillin allergy.

2 What you need to know before you take Minox

Do not take Minox if you:

- are **allergic** to minocycline hydrochloride, other similar antibiotics (such as tetracycline or doxycycline) or any other ingredient of this medicine (listed in section 6)
- have had complete **kidney failure**
- have severe **liver problems**
- are **pregnant** or **breast-feeding**
- are **under 8** years old.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Minox if you:

- suffer from **myasthenia gravis**, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- have **impaired liver** or **kidney function**
- develop **severe diarrhoea** or **high fever** (signs of another infection)
- have **systemic lupus erythematosus (SLE)**, a condition characterised by a rash (especially on the face), hair loss, fever, a feeling of general discomfort and illness and joint pain
- suffer from **increased pressure** in the **skull** (intracranial hypertension)
- develop headache, hallucinations, dizziness or visual problems, including blurred vision or seeing spots (scotoma)
- are sensitive to **sunlight** or **artificial light** (e.g. sunbeds).

Diarrhoea may develop while you are taking antibiotics, including this medicine. If you develop severe or prolonged diarrhoea during or after taking this medicine consult your doctor immediately.

Other medicines and Minox

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

Especially:

- **antibiotics** such as **cephalosporins** or **penicillins** e.g. phenoxymethylpenicillin (to treat infections)

- medicines which can **damage the liver** (check with your doctor or pharmacist to see if this applies to any medicines you are taking)
- **retinoids** such as isotretinoin (to treat acne)
- **anticoagulants** (to stop the blood clotting)
- **ergotamine** (to treat migraines)
- **diuretics** ('water tablets') e.g. furosemide
- **kaolin** or activated **charcoal** (to treat diarrhoea)
- **sucralfate** and **bismuth salts** (to treat ulcers)
- medicines such as **antacids** or other medicines containing **aluminium, calcium, iron, magnesium** or **zinc** salts. Do not take at the same time as minocycline, as absorption of minocycline may be reduced.

Minox with food, drink and alcohol

This medicine may be taken with or without food

Alcohol and liver dysfunction

Speak to your doctor before taking Minox with alcohol or other potentially liver damaging drugs.

Pregnancy and breast-feeding and fertility

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.

Minocycline could cause permanent discolouration and underdevelopment of tooth enamel.

Driving and using machines

Minox can cause light-headedness, 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.

3 How to take Minox

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

Swallow the tablets **whole** with a glass of **water**. The medicine may be taken with or without food.

The recommended dose is:

- **Adults (including the elderly):**
 - General infections:** 200mg a day to be taken in divided doses.
 - Acne:** 50mg twice a day for a minimum of six weeks.
 - Gonorrhoea:** initially 200mg, then 100mg every twelve hours for a minimum of four days. Females may require longer-term therapy.
 - Preventative treatment in meningitis carriers:** 100mg twice a day for five days (usually followed by a course of rifampicin).

Use in children and adolescents:

- **Children over 8 years old:** 50mg every twelve hours.
- **Children under 8 years old:** Minocycline is not recommended for use in children under 8 years of age, as it can cause permanent discolouration and under development of tooth enamel.

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

Duration of treatment:

- The duration of treatment is generally 7-14 days. Treatment should continue for at least 1-3 days after the symptoms have disappeared.
- In the case of streptococcal infections the minimum duration of therapy should be 10 days.

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If you take more Minox than you should

If you have taken more Minox than you were told, talk to your doctor or go to your nearest hospital casualty department straight-away. Symptoms of an overdose include dizziness and feeling and being sick.

If you forget to take Minox

- Do not take a double dose to make up for a forgotten dose.
- If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Minox

It is important that you take your medicine in accordance with the doctor's instructions. Do not suddenly stop using this medicine without discussing it first with your doctor, otherwise symptoms may return.

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). Dark skin individuals often exhibit more intense hyperpigmentation than individuals with fair skin.

Tell your doctor if the following side effects occur:

- **effects on the stomach and gastrointestinal tract:** feeling or being sick, diarrhoea, loss of appetite, underdevelopment of tooth enamel, inflammation of the tongue, mouth or intestines, difficulty swallowing, inflammation or ulceration of the gullet, indigestion, pseudomembranous colitis (watery diarrhoea, fever and cramps)
- **effects on the liver and kidneys:** inflammation of the liver (hepatitis), kidneys or pancreas (pancreatitis), liver failure, jaundice (yellowing of the skin or whites of the eyes), abnormal liver function test results, acute kidney failure
- **effects on the blood:** increased levels of urea in the blood, blood vessel inflammation, changes in the numbers and types of your blood cells. 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

- **effects on the nervous system:** dizziness, headache, tingling or pins and needles in the hands and feet, feeling of dizziness or spinning (vertigo), decreased sensitivity to touch, fits, drowsiness
- **effects on the skin:** hair loss, skin reactions including red patches (erythema multiforme), skin rash which may be itchy with or without pale or red raised patches, swelling of the face, lips, tongue or throat, 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), red lumps on the legs (erythema nodosum). Also a condition known as DRESS syndrome which includes skin rash, fever, swelling of the lymph nodes and an increase of eosinophils (a type of white blood cell).
- **effects on breathing:** cough, difficulty breathing, worsening of asthma, increase in the number of white blood cells in the lungs
- **effects on muscles and bones:** joint pain (arthralgia), inflammation (arthritis) stiffness or swelling of joints, muscle pain (myalgia)
- **other:** sensitivity to sunlight or artificial light (e.g. sunbeds), impaired hearing, ringing in the ears, thrush around your bottom, genital area or mouth, inflammation of male genitals, changes in thyroid function, systemic lupus erythematosus (SLE); if you already suffer from SLE minocycline may make your condition worse.

If you notice any side effects, they get worse, or if you notice any not listed, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971, Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Minox

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

Do not store above 25°C.

Store in the original carton.

Do not use this medicine after the expiry date which is stated on the blister and carton after "Exp". The expiry date refers to the last day of that month.

Do not throw away 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 Minox contains

- The active substance is minocycline (as hydrochloride). Each tablet contains 50mg minocycline (as hydrochloride).
- The other ingredients are: povidone, sodium starch glycollate (type A), microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate.
- Film-coating: hypromellose, titanium dioxide (E171), yellow iron oxide (E172).

What Minox looks like and contents of the pack

Minox 50mg Film-coated tablets are yellow-brown, round, film-coated tablets with a smooth surface, packed in blisters of PVC/Aluminium.

Pack size is 10, 50 and 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer(s)

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork.

This leaflet was last revised in 07/2016.

I.M. L/46 07-16

article no.

Salutas no.