

# Minocycline 50mg and 100mg tablets

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

- 1 What Minocycline tablets are and what they are used for
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### 1 What Minocycline tablets are and what they are used for

Minocycline 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. Minocycline 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 moderate to severe acne
- infections of the eye
- prostate infections
- ear, nose and throat infections
- nocardiosis (an infection often affecting the lungs)
- pelvic inflammatory disease (e.g. salpingitis, oophoritis)
- preventative treatment for meningitis carriers
- preventative treatment before and after surgery.

### 2 What you need to know before you take Minocycline tablets

**Do not take** Minocycline tablets:

- if you are **allergic** to minocycline hydrochloride, other similar antibiotics (such as tetracycline or doxycycline) or any other ingredients of this medicine (listed section 6)
- if you have had complete **kidney failure**
- if you are **pregnant** or **breast-feeding**
- if you are giving it to a **child under 12** years old.

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Minocycline tablets:

- if you suffer from **myasthenia gravis**, a condition characterised by muscle weakness, difficulty chewing and swallowing and slurred speech
- if you have **impaired liver** or **kidney function**
- if you 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.

- if you suffer from **increased pressure** in the skull (intercranial hypertension)
- if you are sensitive to **sunlight** or **artificial light** (e.g. sunbeds).

#### Children and adolescents

Minocycline tablets are not recommended for use in children under 12 years of age, as they can cause permanent discolouration and underdevelopment of tooth enamel.

#### Other medicines and Minocycline tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- **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)
- **ACE inhibitors** such as quinopril (to treat heart conditions)
- **anticoagulants** (to stop the blood clotting)
- **ergotamine** (to treat migraines)
- **ergometrine** (to induce abortion or labour)
- **diuretics** ('water tablets') e.g. furosemide
- **kaolin** (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 tablets, as absorption of Minocycline may be reduced.

#### Minocycline tablets with alcohol

Speak to your doctor before taking Minocycline tablets with alcohol.

#### Pregnancy, breast-feeding and fertility

If you are pregnant, planning to become pregnant or are breast-feeding tell your doctor or pharmacist before taking any medicine as minocycline could cause permanent discolouration and underdevelopment of tooth enamel.

#### Driving and using machines

Minocycline tablets 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 tablets contain sunset yellow.

Minocycline tablets (100mg only) contain sunset yellow (E110) which may cause allergic reactions.

#### Minocycline tablets contain lactose

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

#### Tests

During long term treatment blood, kidney and liver tests will be carried out.

### 3 How to take Minocycline tablets

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**, while **standing** or **sitting** down.

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.

### Use in children and adolescents

- **Children over 12 years old:** 50mg every twelve hours.
- **Children under 12 years old:** Minocycline tablets are not recommended for use in children under 12 years of age, as they can cause permanent discolouration and underdevelopment of tooth enamel.

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

### If you take more Minocycline tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include dizziness and feeling and being sick.

### If you forget to take Minocycline tablets

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 Minocycline tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

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

## 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): rash, blood spots, bruising and discolouring to the skin (purpura), shock, death, 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, swelling of the face, lips, tongue or throat
- **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.
- **sensitivity** to sunlight or artificial light (e.g. sunbeds). Symptoms included tingling, burning or redness of the skin. If symptoms occur avoid direct exposure to sunlight or artificial light.
- 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, secretions including breast milk, tears or sweat (hyperpigmentation).
- **difficulty breathing** including wheezing or worsening of asthma.
- Drug-induced hypersensitivity reaction that includes fever, rash, and blood abnormalities (**Drug rash with eosinophilia and systemic symptoms - DRESS**).

**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 immune system:** inflammation and weakening of blood vessels (polyarteritis nodosa).
- **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, 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), flaky skin (exfoliative dermatitis).
- **Effects on breathing:** inflammation of the lungs caused by an infection (pneumonitis), cough, 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:** fever, inflammation of the heart muscle (myocarditis) or membrane around the heart (pericarditis), 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 tablets may make your condition worse. A disease in which the body's immune system attacks liver cells, causing inflammation of the liver (autoimmune hepatitis).

### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 tablets

Keep out of the sight and reach of children.

Store below 25°C in a dry place.

Protect from light.

Do not use this medicine after the expiry date stated on the label/carton/bottle.

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 tablets contain

- Each tablet contains the active substance (the ingredient that makes the tablets work) minocycline hydrochloride PhEur equivalent to 50mg or 100mg anhydrous minocycline.
- 50mg tablets contain: hydroxypropylcellulose (E463), maize starch, magnesium stearate and lactose. The tablet coating contains hypromellose (E464), propylene glycol, purified talc, titanium dioxide (E171), iron oxides (E172).
- 100mg tablets contain: hydroxypropylcellulose (E463), maize starch, magnesium stearate and lactose. The tablet coating contains hypromellose (E464), propylene glycol, purified talc, titanium dioxide (E171), sunset yellow (E110) and quinoline yellow (E104).

### What Minocycline tablets look like and contents of the pack

50mg tablets are beige, circular, biconvex, film-coated tablets.

100mg tablets are orange, circular, biconvex, film-coated tablets.

Pack sizes: 28s, 30s, 50s, 56s, 60s, 84s, 90s, 100s, 112s, 120s, 168s, 180s, 500s, 1000s

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and manufacturer

Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in July 2016.

 **actavis**

Actavis, Barnstaple, EX32 8NS, UK