

# 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 of the other ingredients of this medicine (listed in section 6)
- have a condition called **Systemic Lupus Erythematosus (SLE)**
- have had complete **kidney failure**
- are **pregnant or breast-feeding**
- 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
- have **impaired liver or kidney function**
- 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** (intercranial hypertension)
- 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 **affect how the liver works** (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 thin the blood) e.g. warfarin
- **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** (used for indigestion) 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

Talk to your doctor before taking Minocycline Tablets with alcohol.

### Pregnancy, breast-feeding and fertility

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 Tablets.

### 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 medicinal product.

### Minocycline 100mg Tablets contain sunset yellow

May cause allergic reactions.

### Tests

Tell your doctor or nurse that you are taking Minocycline Tablets 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.

### 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.

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 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. Your doctor will then give you another antibiotic to take, called rifampicin.

#### 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. It is important to finish the course of antibiotics as instructed by your doctor.

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.

### If any of the following side effects happen, stop taking the tablets and tell your doctor or go to your nearest hospital emergency department immediately:

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

- **allergic reactions** such as 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) or 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
- reduction in all types of blood cells resulting in frequent or recurrent infections causing fever, severe chills, mouth ulcers or chest infections (leucopenia), unexplained bruising or bleeding for longer than usual (thrombocytopenia)
- 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 (e.g. sunbeds). Symptoms include tingling, burning or redness of the skin. If symptoms occur avoid direct exposure to sunlight or artificial light.

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

- reduction in red blood cells which cause pale, yellow skin and weakness or breathlessness (haemolytic 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
- 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.

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

- fits
- a disease in which the body's immune system attacks liver cells, causing inflammation of the liver (autoimmune hepatitis)
- drug-induced allergic reaction that includes fever, rash, and blood abnormalities (**Drug rash with eosinophilia and systemic symptoms - DRESS**)
- a reduction in white blood cells causing high temperature and ulcers in the mouth and throat (agranulocytosis)
- 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
- 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, cough
- pins and needles in the hands or feet or a reduction in the sense of touch
- 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
- 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
- hair loss, 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, inflammation or ulcers in your food pipe, inflammation of the tongue
- problems with the surface of your teeth
- high levels of bilirubin which can be seen in a blood test
- flaky skin (exfoliative dermatitis)
- 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)
- 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 in the number of white blood cells and substances in the lungs which can be seen in an x-ray, inflammation of the lungs caused by an infection (pneumonitis)
- drowsiness.

### 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) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Minocycline Tablets

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

Store below 25°C in a dry place. Protect from light.

Do not take this medicine after the expiry date which is 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, impressed "C" on one side and "M" on the reverse.  
100mg tablets are orange, circular, biconvex, film-coated tablets, impressed "C" on one side and "M" "N" on the reverse.

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

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

This leaflet was last revised in June 2020.