

PATIENT INFORMATION LEAFLET

Minocycline 50mg and 100mg 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, please 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 sideeffects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What this medicine 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 this medicine is and what it is used for

Minocycline belongs to a group of medicines called tetracyclines. It is an antibiotic used to treat a wide range of bacterial infections. It works by killing or stopping the growth of the bacteria such as chlamydia, rickettsia, mycoplasma, brucella and borrelia burgdorferi.

Minocycline is used to treat the following:

- Eye infections (trachoma)
- Urinary tract infections
- Uterus and ovary infections (including pelvic inflammatory disease, salpingitis, oophoritis)
- Prostate gland infections (prostatitis)
- Sexually transmitted diseases (lymphogranuloma (LGV) and syphilis)
- Respiratory infections (including pneumonia, bronchiectasis, lung abscess, bronchitis)
- Genital infections (including epididymitis)
- Swelling of knees and other large joints (Lyme disease)
- Skin infections such as moderate to severe acne
- Infections in patients with allergy to penicillin-containing medicines
- Sores or abscesses (actinomycosis)
- Infectious disease affecting the lungs, brain and/or skin (nocardiosis)
- Prevention of meningitis
- Psittacosis, infection passed from birds to humans (symptoms include fever, dry cough, severe muscle pain and headache)
- Infections passed from animals to humans known as:
 - Brucella (symptoms include fever and general feeling of being unwell).
Minocycline is normally given with other antibiotics such as streptomycin
 - Leptospirosis (symptoms include high fever, headache and yellowing of the skin)
- Typhus, infection transmitted from lice (symptoms include severe headache, widespread rash and prolonged high fever)
- Q fever, infection transmitted by contaminated unpasteurised milk or ticks (symptoms include flu-like illness)
- Rocky Mountain spotted fever, infection transmitted by ticks (symptoms include fever, muscle pain and reddish rash, like measles)
- Ear, nose and throat infections
- Preventative treatment before and after surgery.

2. What you need to know before you take Minocycline

Do not take if:

- You are allergic to Minocycline, tetracycline medicines or any of the other ingredients of this medicine (listed in section 6)
- You are pregnant or breast-feeding (see 'Pregnancy and breast-feeding' section)
- Your kidneys do not work at all
- You are under 12 years of age

Warnings and precautions

Talk to your doctor before taking Minocycline if:

- You have liver or kidney problems.
- You are taking oral contraceptives (see 'Other medicines and Minocycline' section)
- You are taking medicines which can harm your liver e.g. paracetamol (see 'Other medicines and Minocycline' section)
- You drink alcohol (see "Taking Minocycline with food and alcohol" section)
- You have a muscle disease called Myasthenia Gravis
- You suffer from acne, as you may need a lower dose
- You suffer from increased pressure in the skull (intracranial hypertension)
- You suffer from abnormal sensitivity of the skin to sunlight (photosensitivity)
- You have an allergic condition which causes joint pain, skin rashes and fever (Systemic Lupus Erythematosus [SLE])

Other medicines and Minocycline

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

Minocycline **should not be taken** with the following:

- Penicillin's (antibiotics), such as amoxicillin
- Cephalosporins such as cefaclor

Other medicines which **may interact or be affected by** with Minocycline:

- Oral contraceptives. It is possible that your oral contraception may not work if you have diarrhoea or bleed between periods. You should use a barrier method of contraception to prevent pregnancy
- Medicines for thinning the blood, such as warfarin (anticoagulants). A reduced dose of the anticoagulant may be required
- Medicines used to increase frequency of urination such as furosemide (diuretics)
- Medicines which can damage your liver such as paracetamol
- Retinoids such as isotretinoin (to treat acne)
- ACE inhibitors such as quinapril (to treat heart conditions)
- Ergotamine (to treat migraines)
- Ergometrine (to induce abortion or labour)
- Minocycline is known to interfere with laboratory tests

The absorption of Minocycline may be reduced by the following:

- Medicines for indigestion, such as alginates (antacids)
- Medicines and supplements containing calcium, aluminium, iron, magnesium, bismuth and zinc salts
- Kaolin (to treat diarrhoea)
- Sucralfate (to treat ulcers)

Taking Minocycline with food and alcohol

Drinking alcohol should be avoided if you are being treated with Minocycline.

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 for advice before taking this medicine.

Pregnancy

You should **not** take Minocycline if you are pregnant as it may affect the bones of the developing baby. Permanent yellow-grey brown discolouration of the teeth and incomplete or defective formation of the enamel of the teeth (enamel hypoplasia) can occur when Minocycline is administered during pregnancy.

Breast-feeding

You should **not** take Minocycline whilst breast-feeding. It passes into the milk and may cause permanent tooth discolouration and incomplete or defective formation of the enamel of the teeth (enamel hypoplasia).

Driving and using machines

Minocycline may cause you to have a feeling of dizziness, 'spinning' (vertigo) or light-headedness. It may also cause visual disturbances or ringing in the ears (tinnitus). If affected, you are advised not to drive or operate machinery.

3. How to take Minocycline

Always take Minocycline exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally
- The tablets should be swallowed whole. Do not chew the tablets

After 6 months of treatment

- If, after a 6 month course, there is no improvement in your condition, your doctor should stop treatment with Minocycline and change to another medicine.
- If your course of Minocycline continues for longer than 6 months, you should be monitored at least every 3 months by your doctor.

Adults and elderly people

General infections:

200mg to be taken daily, in divided doses.

For acne:

50mg to be taken twice daily or 100mg to be taken once daily, for at least 6 weeks.

Gonorrhoea:

200mg to be taken initially, followed by 100mg every 12 hours for a minimum of 4 days. Females may require longer treatment.

For prevention of meningitis:

100mg to be taken twice daily for 5 days, usually followed by a course of the antibiotic rifampicin.

Older people with serious kidney problems:

Caution is advised if you are older and suffer from severe kidney problems.

Use in children

- In children over 12 years of age, the recommended dose is 50mg every 12 hours.
- Children **under 12 years of age** should **not** be given Minocycline.

If you take more Minocycline than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose include: dizziness, nausea (feeling) and vomiting (being sick).

If you forget to take Minocycline

Take it as soon as you remember, unless it is nearly time for your next dose, If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Minocycline

It is important to keep taking Minocycline for as long as your doctor has told you to.

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

4. Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis)
- Potentially serious adverse drug reaction (hypersensitivity syndrome)
- A type of delayed allergic reaction (serum sickness syndrome)
- A type of allergic reaction to a medicine causing skin lesions (fixed drug eruption)
- Long-term inflammation of skin and/or intestines (Systemic Lupus Erythematosus [SLE]) may develop or become worse, if you already have it
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioneurotic oedema)
- A rare form of blood vessel inflammation that affects the skin and the kidneys. It results in skin rash with joint inflammation and stomach cramps (anaphylactoid purpura)
- Increased pressure in the skull resulting in headache and blurred vision (intracranial pressure/hypertension). Treatment should be stopped if this develops
- Inflammation of the lungs likely due to an allergic reaction (pulmonary eosinophilia)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- Severe blistering of skin, mouth, eyes and genitals (Stevens–Johnson Syndrome)
- Fever, general ill feeling, swollen/enlarged lymph nodes and skin eruption (Drug Rash with Eosinophilia and Systemic Symptoms [DRESS])
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)
- Difficulty in breathing/shortness of breath/wheezing (dyspnoea, bronchospasm), worsening of existing asthma, inflammation of the lungs (pneumonitis)
- Inflammation of the mouth (stomatitis) or tongue (glossitis), thrush around mouth, bottom or genital area (oral and anogenital candidiasis), inflammation of vulva and vagina (vulvovaginitis)
- Medicine-induced liver inflammation in which the body's immune system attacks liver cells (auto-immune hepatotoxicity, autoimmune hepatitis)
- Unusual darkening of patches of skin or nails (hyperpigmentation), changes in the colour of the eye and of tears, discolouration of inside of the cheeks and tongue (generally reversible on discontinuation of treatment)

Common side effects (may affect up to 1 in 10 people)

- Dizziness (lightheadedness)

Uncommon side effects (may affect up to 1 in 100 people)

- Fever

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

- Reduction in white blood cells (leucopenia, neutropenia)
- Reduction in blood platelets which increases the risk of bleeding or bruising (thrombocytopenia)
- Loss of appetite (anorexia)
- Headache
- A sensation of whirling and loss of balance, feeling dizzy or giddy (vertigo)
- Impaired hearing, ringing in the ears (tinnitus)
- Inflammatory disease of the heart muscle (myocarditis)
- Swelling of the fluid-filled sac surrounding the heart (pericarditis) Cough

- Diarrhoea
- Feeling sick (nausea), being sick (vomiting)
- Discolouration of teeth
- Increases in liver function tests
- Inflammation of the liver (hepatitis)
- Hair loss (alopecia) Inflammatory condition that causes red, tender lumps to form just below the skin surface that usually affects the lower legs (erythema nodosum)
- Severe itching (pruritus)
- Skin rashes, skin rashes with the formation of wheals (urticaria)
- Inflammation of blood vessels (vasculitis)
- Pain or swelling in the joints (arthralgia), muscle pain (myalgia)
- Increased levels of urea in the blood
- Severe kidney failure
- Inflammation of the kidney (interstitial nephritis)

Very rare side effects (may affect less than 1 in 10,000 people)

- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- Abnormal thyroid function and brown-black discolouration of the thyroid
- Bulging of the skull in infants (bulging fontanelle)
- Indigestion (dyspepsia)
- Difficulty swallowing (dysphagia)
- Underdevelopment of tooth enamel (enamel hypoplasia)
- Inflammation of both the small intestine and the colon (enterocolitis)
- Inflammation of the oesophagus, the tube that carries food from the throat to the stomach (oesophagitis), ulcers in the oesophagus
- Inflammation of the pancreas (pancreatitis)
- Inflammation of the colon that occurs in some people who have taken antibiotics (pseudomembranous colitis)
- Inflammation which causes abdominal pain or diarrhoea (antibiotic-associated colitis)
- Build up of bile acids in the bloodstream causing persistent itch (hepatic cholestasis)
- Severe liver failure
- A condition in which there is too much bilirubin in the blood (hyperbilirubinaemia)
- Yellowing of the skin or whites of the eyes (jaundice)
- Peeling of the skin over large areas of the body (exfoliative dermatitis)
- Pain and inflammation in the joints (arthritis), joint stiffness, joint swelling
- Bone discolouration
- Inflammation of the head of the penis (balanitis)

Other side effects (frequency not known)

- More prone to infections due to a severe reduction in number of white blood cells (agranulocytosis)
- Inflammation of the walls of the arteries (polyarteritis nodosa)
- A dense substance which lingers within the lungs characterised by shortness of breath (pulmonary infiltration)
- Fits (convulsions)
- Sedation
- Lack of voluntary co-ordination of muscle movements (unsteadiness or clumsiness) [ataxia]
- Increased sensitivity of the skin to sunlight (photosensitivity)

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 out of the sight and reach of children.
- Store below 25°C, in a dry place. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Minocycline Tablets contain:

- Each 50mg film-coated tablet contains 50mg of minocycline hydrochloride
- Each 100mg film-coated tablet contains 100mg of minocycline hydrochloride

The other ingredients are: povidone (K-25), sodium starch glycollate, microcrystalline cellulose (PH101), colloidal anhydrous silica, magnesium stearate and purified water.

The film coating contains: hydroxypropylmethylcellulose, macrogol 6000 and the colouring agents titanium dioxide (E171) and yellow ferric oxide (E172).

What Minocycline Tablets look like and the contents of the pack:

- Minocycline 50mg are brown-yellow, round, film-coated tablets with an approximate diameter of 7mm, embossed GL50
- Minocycline 100mg are brown-yellow, round, film-coated tablets with an approximate diameter of 8mm, embossed GL100

Minocycline Tablets are available in:

- Minocycline 50mg tablets are available in packs of 2, 28, 56, 84 or 98 tablets.
- Minocycline 100mg tablets are available in packs of 2, 20, 28, 42, 49, 50 or 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation

Holder

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Product Licence Numbers:

- Minocycline 50mg: PL 42092/0021
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