

PACKAGE LEAFLET: INFORMATION FOR THE USER
Minosil 100mg modified-release capsules
minocycline (as minocycline hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Minosil is and what it is used for
2. Before you take Minosil
3. How to take Minosil
4. Possible side effects
5. How to store Minosil
6. Further information

1. WHAT MINOSIL IS AND WHAT IT IS USED FOR

Minocycline belongs to a group of antibiotics called tetracyclines and is used for the treatment of acne.

2. BEFORE YOU TAKE MINOSIL

Do NOT take Minosil if you:

- are allergic (hypersensitive) to minocycline, any other tetracycline antibiotic (e.g. oxytetracycline, doxycycline) or any of the ingredients in the product (see *Section 6*)
- have complete kidney failure
- have severe liver problems
- are pregnant or breast-feeding
- are a child under 12 years of age.

Take special care with Minosil if you:

- have a liver disorder
- have severe kidney problems - monitoring may be required
- have myasthenia gravis (muscular disability)
- are taking an oral contraceptive i.e. the pill; if diarrhoea or breakthrough bleeding occur there is a possibility that you may not be protected against pregnancy
- are having any laboratory tests on your urine, as your results may be affected
- are elderly
- have Systemic Lupus Erythematosus (SLE) - swelling and tissue damage due to the immune system attacking the body's cells and tissues.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:

- an oral contraceptive
- penicillin antibiotics, e.g. amoxicillin
- anticoagulants (blood thinners) such as warfarin
- diuretics (water tablets) including furosemide, indapamide
- preparations containing antacids, iron, calcium, aluminium, magnesium, bismuth or zinc salts which can prevent Minosil from working effectively when taken at the same time. It is recommended that any indigestion remedies, vitamins or other supplements containing these are taken at least 3 hours before or after your dose of Minosil.
- ergot alkaloids or their derivatives, e.g. ergotamine or dihydroergotamine (for migraine)
- isotretinoin which is also used to treat acne; both this drug and minocycline have been associated with increased pressure around the brain.

Taking Minosil with food and drink

These capsules may be taken with or without food.

It is recommended that alcohol consumption should remain within the governments recommended limits.

Pregnancy and breast-feeding

Do NOT take Minosil if you are trying for a baby, are pregnant or breast-feeding.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Avoid driving or operating machinery while taking Minosil as this medicine may cause light-headedness, dizziness, hearing problems and headaches.

3. HOW TO TAKE MINOSIL

Always take this medicine exactly as your doctor has told you; you should check with him/her if you are not sure.

You may take these capsules with or without food. The capsules should be swallowed whole with plenty of fluids while sitting or standing.

Dose

Adults, and Children over 12 years - take one 100mg capsule every 24 hours.

Elderly - your doctor may reduce your dose

Kidney and liver problems - your doctor may reduce your dose

Children under 12 years - not recommended.

Duration of treatment

It is important to remember that acne responds quite slowly to antibiotics and it may take several weeks (e.g. six weeks or more) before the full benefits are seen. If however there is no improvement after 6 months, you should review your treatment with your doctor.

Tests

If your doctor advises you to take Minosil for longer than 6 months, you will be examined at least every 3 months for side effects such as unusual pigmentation (skin discolouration), symptoms of hepatitis (inflammation of the liver) or a condition called Systemic Lupus Erythematosus (SLE) which can cause pain or stiffness in the joints. Your doctor will also monitor your blood and kidney function during this extended Minosil treatment.

If you take more Minosil than you should

If you take too much medicine, contact your doctor, pharmacist or nearest hospital casualty department straight away. Keep this leaflet and the pack of Minosil with you. Symptoms of overdose include dizziness, nausea and vomiting.

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If you forget to take Minosil

If you miss a dose, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten capsule.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Minosil may cause side effects, although not everybody gets them.

STOP taking these capsules and **seek immediate medical assistance** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Common (affecting between 1 in 10 and 1 in 100 users)

- dizziness.

Uncommon (affecting between 1 in 100 and 1 in 1,000 users)

- fever.

Rare (affecting between 1 in 1,000 and 1 in 10,000 users)

- blood abnormalities - Symptoms are :-
- Increase in frequency of infections as a result of a drop in numbers of white blood cells (leucopenia)
- breathlessness, wheezing, diarrhoea and fever (eosinophilia)
- mouth ulcers, sore throat, burning sensation when passing water (neutropenia)
- unexplained bruising or bleeding (thrombocytopenia)
- hearing problems such as ringing in the ears
- nausea, vomiting, diarrhoea, discolouration of teeth, inflammation in the mouth
- inflammation of the liver, increased liver enzymes, autoimmune reactions (the body attacks its own cells)
- anorexia (loss of appetite)
- joint and muscle pain, skin disease
- headache, changes in sense of touch, "pins and needles", raised pressure around the brain, spinning sensation
- cough, breathlessness
- hair loss, rashes, hyperpigmentation of skin, photosensitivity, itching
- increase in the results for kidney function test.

Very rare (affecting less than 1 in 10,000 people)

- blood disorders, i.e. haemolytic anaemia, symptoms are fatigue or tiredness
- pancytopenia, symptoms are pale skin, weakness
- inflammation of the heart muscle
- abnormal thyroid function, discolouration of the thyroid
- underdevelopment of teeth, inflammation of the tongue, difficult/painful swallowing, inflammation or ulceration of the food pipe, indigestion, inflammation of the colon with bloody diarrhoea or mucus, inflammation of the pancreas
- discolouration of bodily fluids
- liver failure, jaundice (yellowing of the skin and whites of the eyes)
- thrush in mouth and genitals, inflammation of the vulva and vagina
- arthritis, bone discolouration, SLE (see symptoms outlined in 'Take special care' section)
- bulging fontanelle (soft spots in the skull of infants)
- inflammation of the kidney, kidney failure
- inflammation at the tip of the penis
- worsening of asthma or other breathing difficulties
- nettle rash/hives, inflammation of the skin, hyperpigmentation of nails, Stevens-Johnson Syndrome (a type of rash), tissue swelling, patchy inflammation of small blood vessels.

Other (frequency unknown)

- agranulocytosis (deficiency of certain blood cells)
- discolouration of the mouth including the lips, tongue and gums
- convulsions, sedation
- inflammation of the air sacs in the lungs
- skin reaction due to light - avoid direct exposure to artificial or natural light.

Inform your doctor if you notice any **pigmentation** (black/blue/grey or muddy-brown discolouration) of your skin, nails, teeth, bones, eyes, inside your mouth, breast milk or sweat. Such staining is often reversible when you stop taking Minosil but may persist or take several months to disappear in areas that are exposed to the sun.

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 MINOSIL

Keep out of the reach and sight of children.

Do not use Minosil after the expiry date stated on the blister and carton, after EXP. The expiry date refers to the last day of that month. There are no special storage instructions for this product.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Minosil contains

The active ingredient is **minocycline**; each modified-release capsule contains 100mg of minocycline (as minocycline hydrochloride). The **other** ingredients are: microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, red iron oxide (E172), silica colloidal anhydrous, ferric oxide yellow, hypromellose phthalate, triethyl citrate, Opadry OY-S-24932 Pink [this colouring contains hypromellose, macrogol, titanium dioxide (E171), talc, red iron oxide (E172)], carnauba wax, gelatin, titanium dioxide (E171), yellow iron oxide (E172), black iron oxide (E172).

What Minosil looks like and contents of the pack

Each modified-release capsule is brown and cream coloured, containing one pink film-coated tablet and one peach enteric-coated tablet. They are supplied in aluminium/PVC blister strips of pack size 2, 7, 28, 56 and 96. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary.

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Manufacturer

Dexcel Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

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