

Package leaflet: Information for the user
Minosil 100 mg modified-release capsules
minocycline (as 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, 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Minosil is and what it is used for
2. What you need to know before you take Minosil
3. How to take Minosil
4. Possible side effects
5. How to store Minosil
6. Contents of the pack and other 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. What you need to know before you take Minosil

Do not take Minosil:

- if you are allergic to minocycline, any other tetracycline antibiotic (e.g. oxytetracycline, doxycycline) or any of the other ingredients of this medicine (listed in section 6)
- if you have complete kidney failure
- if you have severe liver problems
- if you are pregnant or breast-feeding
- if you are a child under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Minosil if you have any of the following conditions:

- if you have a liver disorder
- if you have severe kidney problems - monitoring may be required
- if you have myasthenia gravis (muscular disability)
- if you 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
- if you are having any laboratory tests on your urine, as your results may be affected
- if you are elderly
- if you have Systemic Lupus Erythematosus (SLE) - swelling and tissue damage due to the immune system attacking the body's cells and tissues
- if you develop an infection
- if areas of your skin become an unusual colour
- if you become sensitive to light
- if you develop headache and visual disturbance or blurring or double vision.

Other medicines and Minosil

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

- an oral contraceptive
 - penicillin antibiotics, e.g. amoxicillin
 - anticoagulants (blood thinners) such as warfarin
 - diuretics (water tablets) including furosemide, indapamide
 - quinapril (used to lower blood pressure)
 - 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.
- Minosil may interfere with laboratory and other diagnostic tests.

Minosil with food, drink and alcohol

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. Check with your doctor 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.

The recommended dose is as follows:

Adults, and Children over 12 years - take one 100 mg 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.

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, this medicine can cause side effects, although not everybody gets them.

Stop taking these capsules immediately and seek **urgent medical assistance** if you have any of the following:

- allergic reactions, which may include collapse, cough, breathlessness and difficulties in swallowing, swelling of the face, lips, tongue or throat and severe itching of the skin, with a red rash or raised bumps
- increased pressure in the brain resulting in lasting headache, feeling sick, being sick and changes in your eyesight including blurred vision
- persistent diarrhoea or worsening of diarrhoea, which can be a sign of serious inflammation of the bowel
- difficulty in swallowing or pain when swallowing which can be signs of inflammation and ulceration of the throat
- inflammatory reactions including fever
- serious illness with blistering of the skin, mouth, eyes and genitals.

Tell your doctor if any of the following side effects occur:

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)

- 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
- erythema multiforme or erythema nodosum (a type of skin inflammation with red spots on the skin)
- inflammation of the liver, increased liver enzymes, autoimmune reactions (the body attacks its own cells)
- anorexia (loss of appetite)
- deafness
- joint and muscle pain, skin disease
- anaphylaxis/anaphylactoid reaction (experiencing shock, collapse or difficulty breathing, including fatalities)
- 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
- rash including nettle rash.

Very rare (may affect up to 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
- hives, inflammation of the skin, hyperpigmentation of nails, Stevens-Johnson Syndrome (a type of rash), tissue swelling, patchy inflammation of small blood vessels and severe skin rash with flaky skin (toxic epidermal necrolysis)
- white spots on the teeth
- inflammation of the veins.

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

- 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
- lung disorders including inflammation of the lung or a viral infection of the lungs (pneumonitis)
- hypersensitivity
- blood vessel inflammation causing injury to organ systems (polyarteritis nodosa)
- 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 HPRAs Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Minosil

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

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. There are no special storage instructions for this product.

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 Minosil contains

The active ingredient is **minocycline**; each modified-release capsule contains 100 mg 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., Ballymacarbry, Clonmel, Co. Tipperary.

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Manufacturer

Dexcel Pharma GmbH, Carl-Zeiss-Strasse 2, 63755 Alzenau, Germany.

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