

PATIENT INFORMATION LEAFLET

Minocin MR®

MINOCIN MR®100mg Modified Release Capsules (Minocycline)

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 further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you personally and you should 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

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

1. WHAT MINOCIN MR IS AND WHAT IT IS USED FOR

Minocycline, the active ingredient in MINOCIN MR, is a tetracycline antibiotic used in the treatment of acne. Acne results from clogging of skin pores. In its mildest form this causes whiteheads and blackheads. If these become infected, spots appear. MINOCIN MR reduces the infection and allows the spots to heal.

2. BEFORE YOU TAKE MINOCIN MR

Do not take these capsules if any of the following apply to you unless you have told your doctor or pharmacist:

- you have had an allergic reaction to any tetracycline antibiotic in the past (e.g. oxytetracycline, tetracycline, doxycycline or minocycline), or any of the components of MINOCIN MR;
- you are pregnant, breastfeeding or trying for a baby;
- the person that the medicine has been prescribed for is under the age of 12;
- you have kidney disease;

Tell your doctor or pharmacist if:

- you are taking any of the following: anticoagulants e.g. warfarin; penicillin antibiotics e.g. amoxicillin; isotretinoin (or other retinoids or retinol); quinapril, ergotamine, methysergide, indigestion remedies, vitamins or any preparations containing iron, calcium, aluminium, magnesium, bismuth or zinc salts; diuretics (to regulate body water content);
- you are taking any other medicines including those that you have bought without a prescription;
- you are taking preparations containing iron, calcium, aluminium, magnesium, bismuth or zinc salts which can prevent MINOCIN MR 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 MINOCIN MR;
- you have a condition called systemic lupus erythematosus (SLE) or myasthenia gravis;
- you have liver disease.

MINOCIN MR may affect some medical tests. If you visit a hospital or clinic for any medicinal tests you should tell your doctor concerned you are taking MINOCIN MR.

Taking other medicines

If you take a contraceptive pill and get diarrhoea or sickness or bleed when you don't expect to, your pill may not work (please see "4. Possible Side Effects").

Taking MINOCIN MR with food and drink

It is recommended that whilst taking MINOCIN MR alcohol consumption should remain within the Government's recommended limits.

3. HOW TO TAKE MINOCIN MR

Always take your capsules exactly as your doctor tells you to. This information will also be on the pharmacist's label. If you are not sure how to take your capsules your pharmacist will be able to help you.

The usual dose is one capsule every day.

For elderly patients, your doctor will advise if any dosage reduction is required.

MINOCIN MR should be taken at the same time(s) each day.

MINOCIN MR should be swallowed whole with a drink of water. The capsules should be taken while you are sitting or standing. They should not be sucked or chewed. It does not matter whether you take MINOCIN MR on an empty stomach or after food.

Do not remove a capsule from the pack until you are due to take it. The container protects the capsules from moisture, which may spoil them.

Never take more capsules than the doctor has told you to, it will not help you get better any faster and it could be harmful to you.

Acne responds quite slowly to antibiotics and it may be several weeks before you see any improvement in your acne and even longer before the full benefits are seen. For this reason it is important to finish taking all of the capsules prescribed for you by your doctor and return to see him/her when you have been asked to do so. If, however, your acne has not improved after a treatment period of six months, you should return to your doctor to have your treatment reviewed.

If your doctor decides to continue your treatment with MINOCIN MR for longer than 6 months, your doctor should ask to see you on a regular basis, usually once every 3 months, to examine you for any possible side effects related to the liver or unusual pigmentation or a condition called Systemic Lupus Erythematosus (SLE) which can include pain or stiffness of joints, rash or fever.

Your doctor will also monitor your blood and renal function during therapy.

If You Take More MINOCIN MR Than You Should


If you have accidentally taken an overdose of MINOCIN MR, that is more capsules than the doctor has told you to take, you should get medical help immediately, either by calling your doctor or by going to the nearest hospital accident and emergency department. Always take the labelled medicine container with you, whether there are any MINOCIN MR capsules left or not.

If You Forget To Take MINOCIN MR

If you do miss a dose you should take it as soon as possible. This will help to keep a constant amount of medicine in the blood.

However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose.

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4. POSSIBLE SIDE EFFECTS

Like all medicines MINOCIN MR may cause side effects although not everybody gets them. Most people do not get side effects with this medicine. The following effects that can occur are usually mild but if you experience any symptoms which are severe, persist or worry you, contact your doctor or pharmacist:

- Stomach upsets, diarrhoea, sickness, loss of appetite or sore mouth. If you take a contraceptive pill and get diarrhoea or sickness or bleed when you don't expect to, your "pill" may not work. You should use a different or additional means of birth control (e.g. a condom or diaphragm/cap) to ensure you are protected. Read the leaflet that came with your "pill";
- Headache, dizziness, hearing problems such as ringing in the ears, light-headedness, or unsteadiness. Make sure you know how you react to this medicine before you drive, use machines or do anything else that could be dangerous if you are dizzy or not alert;
- Skin problems such as rashes most commonly due to increased sensitivity of the skin to sunlight, itching, redness, scaling or blistering. You should avoid direct exposure to sunlight or artificial light. If you experience skin discomfort then stop taking your tablets and seek advice from your doctor;
- Cough;
- Loss of hair.

The following effects are rare or very rare, but you should contact your doctor immediately if any of them happen to you:

- Anaphylaxis/anaphylactoid reactions (including a sudden, generalised allergic reactions that may lead to life-threatening shock [symptoms include difficulty in breathing, wheezing, rash, swelling, drop of blood pressure, fast pulse]);
- Severe skin rashes, as they may be life threatening;
- Headache, with blurred or double vision or loss of vision;
- Swollen, stiff or painful joints or muscle pain. Tender, bruise like swellings of the shins;
- Pain in the abdomen, pale stools or difficulty passing urine;
- Yellowing of the skin or whites of the eyes;
- Sudden unexplained fever or sore throat, extreme tiredness, convulsions, unexplained bruising or bleeding;
- Pain in the upper abdomen or back;
- Swelling and redness of the tongue, inside of the mouth, or around the eyes;
- Heartburn or difficulty in swallowing, lower abdominal pain or blood and mucous in stools;
- Difficulty breathing or chest pain;
- Inflammation of the blood vessels;
- Redness or swelling of the penis;
- Red patches on the skin, white patches in the mouth or itching around the anus or vagina which may be accompanied by vaginal discharge. Vaginal inflammation which may be accompanied by pain on urinating;
- A worsening or development of symptoms of SLE (systemic lupus erythematosus) or a worsening of the symptoms of myasthenia gravis;
- Numbness, tingling feelings (like pins and needles) in the hands and feet.

Contact your doctor if you notice any staining of your skin, teeth (including adult teeth), tongue, lips, gums or nails so that your treatment can be reviewed. Slight blue/black/grey colour staining of the skin, teeth, nails, inside of the mouth, eyes, tears, breast milk or sweat has been reported. Staining may appear at any time during MINOCIN MR therapy but is more common during long-term treatment. Any blue/black/grey staining of the skin or mouth usually disappears a few months after MINOCIN MR is stopped.

Staining in the other parts of the body, although less common, may persist. A persistent muddy-brown skin stain, particularly in sunexposed areas of the skin, has also been reported. Inform your doctor without delay if you notice any staining so that your treatment can be reviewed.

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

5. HOW TO STORE MINOCIN MR

Keep out of the reach and sight of children

Do not use MINOCIN MR after the expiry date. This date is printed on the pack.

Do not store above 25°C

Blisters: Store in the original container
Keep the container in the outer carton

Bottles: Keep the container tightly closed. Store in the original container.

If your doctor decides to stop your treatment you should return any capsules that are left to your pharmacist for disposal. Medicines should not be put down the sink or toilet or in the bin.

6. FURTHER INFORMATION

What MINOCIN MR Contains

Each capsule contains 100mg of the active ingredient minocycline hydrochloride. Minocycline is one of a group of antibiotics called the tetracyclines.

The capsule body contains titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and gelatin. The capsule cap ingredients are iron oxide black (E172) and those listed for the capsule body. Other ingredients which are added so that MINOCIN MR can be swallowed easily include microcrystalline cellulose, croscarmellose sodium, hypromellose phthalate 50, hypromellose (E464) and light liquid paraffin.

What MINOCIN MR Looks Like and Contents of the Pack

MINOCIN MR is a modified release capsule and is available in one strength and a variety of pack sizes and presentations. MINOCIN MR is licensed for the following pack sizes:

- Blister packs of 2, 49 and 56.
- Bottles of 100.

MINOCIN MR is currently supplied in pack sizes of 56.

MINOCIN MR is a two piece, hard shell, size 2 capsules with an orange opaque body and a brown opaque cap containing a mixture of off-white and coloured (yellow, green, brown/black) spherical pellets.

Marketing Authorisation Holder and Manufacturer


The Product Licence is held by: Mylan Products Ltd,
Station Close, Potters Bar,
Hertfordshire,
EN6 1TL, UK

The Manufacturers are:
MEDA Pharma GmbH & Co. KG
Benzstrasse 1
61352 Bad Homburg
Germany

For any further information about this medicine, please contact the Marketing Authorisation Holder.
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