

Acnamino[®] MR 100mg Capsules (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Acnamino MR is and what it is used for
2. What you need to know before you take Acnamino MR
3. How to take Acnamino MR
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1. What Acnamino MR is and what it is used for

Acnamino MR 100mg Capsules (referred to as Acnamino MR throughout this leaflet) contain the active ingredient minocycline. Minocycline is a tetracycline antibiotic used in the treatment of acne. It is thought that acne is partly due to, or made worse by, infection with a type of bacteria called *Propionibacterium Acnes*. Treating acne with Acnamino MR is intended to reduce the infection with this bacterium and so help in the overall treatment of acne

2. What you need to know before you take Acnamino MR

Do not take Acnamino MR:

- if you are allergic to minocycline or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any medicines from the group of antibiotics called Tetracycline (e.g. oxytetracycline, tetracycline, doxycycline).
- if you are pregnant, think you might be pregnant or are trying to become pregnant. Acnamino MR may cause harm to the foetus.
- if you are breastfeeding. Medicines from the Tetracycline group (as Acnamino MR) passes through the breast milk.
- If the person that the medicine has been prescribed for is under the age of 12.
- if you have kidney failure.

The use of Acnamino MR during tooth development (last half of pregnancy, breast-feeding infants and children under the age of 12 years) may cause dental staining and/or incomplete development of the hard tooth surface leading to pitted, small or mis-shaped sensitive teeth prone to tooth decay (enamel hypoplasia).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Acnamino MR if:

- You have liver problems
- You have Systemic Lupus Erythematosus (SLE) i.e. swelling and tissue damage due to the immune system attacking the body's cells and tissues.
- You have had, or think you might have, kidney disease
- You have a condition called Myasthenia Gravis i.e. serious weakness in the muscles

Children

Do not give this medicine to children under the age of 12 years.

Take special care with Acnamino MR:

Acnamino 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 Acnamino MR.

If you are having tests on your urine for substances called Catecholamines (sometimes measured to look for problems with the adrenal gland), you should tell the doctor ordering the test that you are taking minocycline because it may interfere with the test and give the wrong result.

Other medicines and Acnamino MR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed, before you start taking Acnamino MR. It is especially important that you tell your doctor or pharmacist if you are taking any of the following:

- Medicines to thin your blood (e.g. warfarin). The dose of these medicines may need to be reduced whilst you are taking Acnamino MR
 - Diuretics (to regulate body water content), for example, thiazides, furosemide or amiloride
 - Antibiotics called beta-lactams (to treat infections). For example, penicillins (e.g. ampicillin, amoxicillin) and cephalosporins (e.g. cefalexin, cefaclor, cefadroxil)
 - Vitamins or any preparations containing iron, calcium, aluminium, magnesium, bismuth or zinc salts which can prevent Acnamino 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 Acnamino MR
 - Quinapril (ACE inhibitor) - a medicine used to treat heart disease and high blood pressure
 - Ranitidine bismuth citrate, sucralfate and tripotassium dicitratobismuthate (ulcer healing drugs)
 - Antacids such as calcium carbonate, sodium bicarbonate, aluminium or magnesium compounds
 - Kaolin (to treat diarrhoea or stomach upset)
 - Oral contraceptives (the "pill"). Taking Acnamino MR may make oral contraceptives less effective. It is very important that you do not become pregnant while taking Acnamino MR and you should take advice from your doctor on extra

- precautions needed to avoid pregnancy
- Isotretinoin (sometimes used to treat severe acne) or other retinoids or retinol should not be taken shortly before, during or shortly after a course of Acnamino MR
- Strontium ranelate (to treat osteoporosis)
- Ergotamine and methysergide (ergot alkaloids) - medicines used to treat migraines
- Any medicines that can damage your liver (hepatotoxic drugs). For example: Nonsteroidal Anti-inflammatory Drugs (NSAIDs) such as aspirin, diclofenac and ibuprofen (to treat pain, fever and inflammation); isoniazide (to treat tuberculosis), phenytoin (to treat epilepsy). It is imperative that you check with your doctor or pharmacist first to see if this applies to any medicine you are taking

Acnamino MR with alcohol

It is advisable not to drink too much alcohol while taking Acnamino MR.

Drink alcohol only in moderation and within the Government's recommended limits.

Pregnancy and breast-feeding

Do not take Acnamino MR if you are pregnant or breast-feeding. If you become pregnant while taking Acnamino MR **stop taking it immediately** and tell your doctor (For further information see above 'Do not take Acnamino MR if').

Driving and using machines

It is advisable not to drive or operate machinery if you notice headaches, lightheadedness, dizziness, tinnitus (ringing in the ears), vertigo (a feeling of unsteadiness) or effects on hearing whilst you are taking Acnamino MR.

Acnamino MR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Acnamino MR

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage and frequency of administration

- **The usual dose for children over the age of 12 years and for adults** is one capsule of Acnamino MR taken at about the same time each day.
- For **elderly** patients, your doctor will advise if any dosage reduction is required.

Method of administration

- Acnamino MR capsules should be swallowed whole with a drink of water. They should not be sucked or chewed. The capsules should be taken while you are sitting upright or standing to prevent irritation of your gullet.
- It does not matter whether you take Acnamino MR on an empty stomach or after food. However, the capsules should not be taken within 3 hours of some types of antacids, vitamins and other medicines.
- Do not remove a capsule from the pack until you are due to take it.

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.

Duration of treatment

Acne responds quite slowly to antibiotics and it may be several weeks (e.g. six weeks or more) 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 Acnamino 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 skin colouration or a condition called Systemic Lupus Erythematosus (SLE) which can include pain or stiffness of joints, rash or fever. Your doctor will also take blood tests to measure your blood count and to assess how your liver and kidneys are working.

If you take more Acnamino MR than you should

If you have accidentally taken an overdose of Acnamino 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 Acnamino MR capsules left or not.

If you forget to take Acnamino 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 to make up for a forgotten dose.

4. Possible side effects

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

Serious side effects:

- If any of the following happen, **stop taking Acnamino MR and tell your doctor immediately or go to the emergency department at your nearest hospital.**
- Severe allergic reaction that cause symptoms such as swelling of your throat, tongue, face, eyelids, mouth, lips or body, difficulty breathing or breathing very fast, difficulty



swallowing, tightness in your throat or chest, wheezing, coughing or noisy breathing, feeling faint, dizzy or fainting. You may also develop a rash that's swollen, raised or itchy. These are symptoms of a life threatening allergic reaction (anaphylaxis/anaphylactoid reaction) (rare)

- Allergic skin reactions such as: skin rashes made up of circular patches that are darker in the middle and lighter around the outside that may blister and peel, often with involvement of the mouth, throat eyes and genital areas (Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis) (very rare) or a red, scaling rash with skin peeling (exfoliative dermatitis) (very rare). Sometimes these types of reactions can occur with inflammation of one or more major body organs and with flu-like symptoms like a fever, sore throat and joint pain and swelling of the glands
- Inflammation of the heart muscles or area around the heart, symptoms include – flu like symptoms, fever, chest pain or shortness of breath, irregular heartbeat, feeling lightheaded (myocarditis) (rare)
- Inflammation of lining around your heart, symptoms include – flu like symptoms, chest pain that is felt on the left hand side of the chest or behind your breast bone that gets worst when coughing, swallowing or taking a deep breath and gets better when leaning forward (pericarditis) (rare)
- When your laboratory results shows a high number of eosinophils (a type of white blood cell that supports your immune system), symptoms include but not limited to weight loss, fever, night sweat, swelling and confusion (eosinophilia) (rare)
- Inflammation of the liver, muscle and joint pain, fever, flu like symptoms, tummy pain, dark urine, pale grey coloured poo, yellowing of the eye and skin and itchy skin (hepatitis) (rare)
- Liver damage, liver failure (very rare)
- Inflammation of the kidney which can cause swollen ankles, blood in the urine, decrease in number of times you wanting to urinate or high blood pressure (nephritis)
- Inflammation of the lung tissues which causes breathlessness, cough and raised temperature (pneumonitis) (frequency not known)
- Fever and lymphadenopathy (swollen or enlarged lymph nodes) may be present
- Swelling of the blood vessels resulting in symptoms such as muscle pain, cramps, unusual tiredness or weakness, spitting blood (vasculitis) (very rare)
- Joint pain (arthralgia) (rare)
- Joint stiffness or joint swelling, extreme tiredness and rash over your nose and cheeks accompanied by swollen glands (systemic lupus erythematosus) (rare) or other joint problems together with fever, muscle pain
- Any staining or discoloration (slight blue/black/grey or muddy-brown) on your body or of secretions. Staining can appear on your skin, teeth or nails, inside of the mouth, eyes, in body secretions (e.g. tears, breast milk or sweat). Staining of some internal tissues such as the thyroid gland and bones can also occur. (rare)

Staining may appear at any time during treatment with Acnamino MR but is more common during long-term treatment. Staining usually disappears a few months after discontinuation of the drug, although some muddy-brown skin pigmentation may persist, particularly in areas exposed to the sun

Other side effects

The following effects that can occur are usually mild, rare or very rare but if you experience any symptoms which are severe, persist or worry you, contact your doctor or pharmacist:

Common: may affect up to 1 in 10 people

- Dizziness (light-headedness)

Uncommon: may affect up to 1 in 100 people

- Fever

Rare: may affect up to 1 in 1,000 people

- 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 capsules and seek advice from your doctor
- Loss of hair (alopecia)
- Severe skin rashes, as they may be life threatening
- Headaches, occasionally with eyesight problems including blurred vision, "blind" spots, permanent loss of vision or double vision
- Build up of pressure around the brain (intracranial hypertension)
- Cough
- Shortness of breath (dyspnoea)
- Hearing problems such as loss of hearing, ringing in the ears (tinnitus) or unsteadiness (vertigo)
 - 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". See also Section 2 of this leaflet
 - Vomiting
 - Nausea
 - Increased liver enzymes (liver problems)
 - Increased serum urea (kidney problems)
 - Acute kidney failure (rapid loss of your kidneys ability to remove waste), Interstitial nephritis (kidney condition characterized by swelling in between the kidney tubules)
 - Abnormally low levels of white blood cells, resulting in an increase in infections (neutropenia, leucopenia)
 - Reduction of blood platelets, which increase risk of bleeding or bruising (thrombocytopenia)
 - Swollen, stiff or painful joints or muscle pain. Tender, bruise like swelling of the shins
 - Pain in the abdomen, pale stools or difficulty passing urine
 - Sudden unexplained fever or sore throat, extreme tiredness, unexplained bruising or bleeding
 - Numbness, tingling feelings (like pins and needles) in

the hands and feet

- Eating disorder causing loss of weight (anorexia)

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

- Abnormal thyroid function (show up only in blood test results)
- Worsening of asthma
- Reduction in red blood cells which can make the skin pale and yellowish and can cause weakness or breathlessness (anaemia)
- Swelling of the pancreas which can lead to pain in the centre of your abdomen, spreading to the back, nausea, vomiting and fever (pancreatitis)
- 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
- Build up of fluid in the brain or swelling of the brain due to increased pressure (bulging fontanelle)
- Infiltration of eosinophils, a type of white blood cells, into the lungs causing breathing difficulties, chest tightness, pain, fever, cough and wheezing (pulmonary eosinophilia)
- Heartburn or difficulty in swallowing, lower abdominal pain or blood and mucous in stools, sometimes due to swelling of the gullet or ulcers in the gullet (oesophageal ulceration)
- Incomplete development of the hard tooth surface leading to pitted, small or mis-shaped sensitive teeth prone to tooth decay
- Inflammation of the digestive tract due to a bacterial infection (enterocolitis)
- Inflammation of the oesophagus (oesophagitis)
- Inflammation of the tongue (glossitis)
- A severe form of colitis which affects the lining of the colon causing abdominal discomfort and diarrhea (pseudomembranous colitis)
- Oral cavity discoloration (including tongue, lip and gum)
- Loss of appetite, feeling sick, itchy skin, vomiting blood, build up of fluid in the legs and abdomen (liver failure or cirrhosis)
- Yellowing of the skin or whites of the eyes (jaundice)
- A worsening or development of symptoms of SLE (systemic lupus erythematosus) or a worsening of the symptoms of myasthenia gravis (weakness of muscles)
- Inflammation of blood vessels, often with skin rash
- Swelling and redness of the tongue, inside of the mouth, or around the eyes (angioedema)
- Inflammation of blood vessels of all sizes affecting both veins and arteries, symptoms include fever, fatigue, joint pain, purple skin discolorations, weight loss and numbness/tingling of arms and legs (vasculitis)
- Redness or swelling of the area round the tip of the penis (balanitis)
- Discolouration of secretions such as sweat or tears

Not known: frequency cannot be estimated from the available data

- Uncontrollable shaking of the muscles (Convulsions)
- Sedation (Sleepiness)
- Inflammation of the liver that occurs when your body's immune system turns against your liver (autoimmune hepatitis)
- A form of relapsing vasculitis affecting medium size blood vessels, symptoms include weight loss, muscle and joint pain, skin rashes and ulcers and numbness/tingling of arms and legs (polyarteritis nodosa)
- Severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis)

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 Website: 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 Acnamino MR

Store the capsules in the original package.

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 outer carton and on each blister strip after EXP. 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 Acnamino MR contains

The active substance is minocycline. Each capsule contains 100 mg of the active substance minocycline as minocycline hydrochloride.

The other ingredients are: microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, iron oxide red (E-172), silica colloidal anhydrous, iron oxide yellow (E-172), hypromellose phthalate, triethyl citrate, opadry OY-S-24932 pink (which contains hypromellose 2910, macrogol 6000, titanium dioxide (E-171), talc, iron oxide red (E-172)), carnauba wax, hard Gelatin Capsule (which contains gelatin, titanium dioxide (E-171), yellow iron oxide (E-172), black iron oxide (E-172), red iron oxide (E-172)).

What Acnamino MR looks like and content of the pack

Acnamino MR is a hard gelatin capsule, with an opaque-buff body and an opaque-brown cap, containing one pink film-coated tablet, and one peach enteric-coated tablet. These MR capsules are intended to provide "modified release" of the active substance minocycline so that some is released in the stomach and some in the small intestine.

Acnamino MR is available in packs of 56 capsules, in foil blister strips.

Marketing Authorization Holder and Manufacturer

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This leaflet was last revised in January 2026.



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