

## Acnamino<sup>®</sup> 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, 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, 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
4. Possible side effects
5. How to store Acnamino MR
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#### 1. What Acnamino MR is and what it is used for

**The name of your medicine** is Acnamino MR 100mg Capsules (referred to as Acnamino MR throughout this leaflet).

**The active ingredient** in your medicine is minocycline. Minocycline is one of a group of antibiotics called Tetracyclines.

**Acnamino MR is used** for 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 you are less than 12 years old.
- 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).

##### Acnamino MR may or may not be suitable for you 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

Tell your doctor or pharmacist if you have any of the above conditions before you start taking Acnamino MR.

**If you have any questions or are not sure about anything, ask your doctor before you start to take Acnamino MR.**

##### Take special care with 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:

- 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
- 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

- Kaolin (to treat diarrhoea or stomach upset)
- 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
- Antibiotics called beta-lactams (to treat infections). For example, penicillins (e.g. ampicillin, amoxicillin) and cephalosporins (e.g. cefalexin, cefaclor, cefadroxil)
- 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.
- 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
- 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.

##### Acnamino MR with food, drink and 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. Acnamino MR can be taken with food or drink.

##### 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, dizziness, lightheadedness, vertigo (a feeling of unsteadiness), tinnitus (ringing in the ears) 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.
- Some **elderly** people may need a lower dose. Your doctor will advise you about this.

##### 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.

##### 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.** 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.

Your doctor may decide to continue your treatment with Acnamino MR for longer than 6 months, and will ask to see you on a regular basis, usually at least once every 3 months. These regular visits will enable your doctor 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

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.

If you have accidentally taken too many capsules of Acnamino MR (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. 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.

**Do not be alarmed by the list of possible side effects. You may not experience any of them. Your doctor has judged the benefits of Acnamino MR outweigh the risk of 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 sudden onset of wheezing, shortness of breath, tightness in chest, swelling of the face, eyelids, mouth, lips, tongue or body and a drop in blood pressure resulting in loss of consciousness. These allergic responses might sometimes be linked to an increase in blood cells called eosinophils
- Swelling of the heart muscle or area around the heart resulting in symptoms such as fever, chest pain or difficulty breathing
- Swelling of the blood vessels resulting in symptoms such as muscle pain, cramps, unusual tiredness or weakness, spitting blood
- Kidney problems
- Liver problems
- Headaches, occasionally with eyesight problems including blurred vision, "blind" spots, permanent loss of vision or double vision
- Joint pains, stiffness or swelling or other joint problems together with fever, muscle pain and/or rashes
- Allergic skin reactions such as: skin rashes that may blister and peel, often with involvement of the mouth, eyes and genital areas (Stevens-Johnson Syndrome) or redness and scaling of the skin (exfoliative dermatitis). Sometimes these types of reactions can occur with inflammation of one or more major body organs and with fever and swelling of the glands
- Severe and/or bloody diarrhoea
- Swelling of the pancreas or pancreatitis, is very serious condition resulting in symptoms such as severe upper abdominal pain, spreading to the back, and often with nausea and vomiting

#### **Serious side effects:**

- Hepatitis (inflammation of the liver), liver damage, liver failure
- Acute kidney failure (rapid loss of your kidneys ability to remove waste), Interstitial nephritis (kidney condition characterized by swelling in between the kidney tubules)
- Anaemia resulting in tiredness, paleness and blood test showing red blood cells breaking up
- A worsening or development of symptoms of SLE (systemic lupus erythematosus) or a worsening of the symptoms of myasthenia gravis
- Lupus-like syndrome which includes fatigue, joint pain and arthritis, and overall feeling of sickness.
- Serum sickness-like syndrome (hypersensitivity reaction)

#### **Contact your doctor immediately if you notice any of the following side effects:**

- Any staining or discoloration (slight blue/black/grey or muddy-brown) on your body or of secretions so that your treatment can be reviewed. 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.  
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
- Diarrhoea, sickness or unexpected bleeding while taking a contraceptive pill. 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. See also Section 2 of this leaflet.

#### **Other possible side effects of Acnamino MR are:**

##### **Common: may affect up to 1 in 10 people**

- Dizziness or feeling light-headed

##### **Uncommon: may affect up to 1 in 100 people**

- Fever

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.

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

- Loss of appetite
- Sore mouth
- Hearing problems such as loss of hearing, ringing in the ears or unsteadiness
- Loss of hair
- 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
- Cough
- Numbness or tingling feelings (like pins and needles)
- Increasing frequency or infections or unexplained or unusual bruising or bleeding (as a result of drop in numbers of white blood cells) or in small cells called platelets)
- Increased sensitivity to stimulation such as pain etc.
- Pain in the abdomen or difficulty passing urine
- Sore throat, unexplained bruising or bleeding
- Dyspnoea (shortness of breath)
- Diarrhoea, nausea, vomiting
- Increased liver enzymes (liver problems)
- Increased serum urea (kidney problems)

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

- Worsening of asthma
- Incomplete development of the hard tooth surface leading to pitted, small or mis-shaped sensitive teeth prone to tooth decay
- Heartburn or difficulty in swallowing, sometimes due to swelling of the gullet or ulcers in the gullet, lower abdominal pain or blood and mucous in stools
- Itching around the anus
- Redness or swelling of the area round the tip of the penis
- Abnormal function of the thyroid gland (show up only in blood test results)
- Sleepiness
- Fits
- Severe skin rashes, as they may be life threatening
- Swollen, stiff or painful joints or muscle pain. Tender, bruise like swelling of the shins
- Yellowing of the skin or whites of the eyes, pale stools
- Extreme tiredness
- Lower abdominal pain or blood and mucous in stools
- Convulsions
- 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.

**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.**

#### **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](http://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 modified release brown and cream coloured, hard gelatin capsule. 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**

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

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