

## **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

#### **What is in this leaflet:**

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

#### **1. What MINOCIN MR is and what is it 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. What you need to know 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;

#### **Warning and precautions:**

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, lithium containing products.
- 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.

## **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.

### **Serious side effects**

Get medical attention IMMEDIATELY if you experience any of the following;

- sudden onset of swelling of your throat and tongue, difficulty breathing or breathing very fast, difficulty swallowing, tightness in your throat, 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);
- a skin rash made up of circular patches that are darker in the middle and lighter around the outside, with painful blisters on your mouth, throat, genitals or eyes (Stevens-Johnson syndrome) or a red, scaly rash with skin peeling (exfoliative dermatitis). You may also feel generally unwell with flu-like symptoms like a fever, sore throat and joint pain with these skin reactions;
- Inflammation of the heart muscles, symptoms include- flu like symptoms, chest pain or tightness of the chest, shortness of breath, irregular heartbeat, feeling lightheaded (myocarditis);
- 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);
- 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);
- 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);
- 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);
- Fever and lymphadenopathy (swollen or enlarged lymph nodes) may be present;
- joint pain (arthralgia);
- joint stiffness or joint swelling, extreme tiredness and rash over your nose and cheeks accompanied by swollen glands (systemic lupus erythematosus);
- Hyperpigmentation of various body sites (e.g. skins, nails, teeth, oral mucosa, bones, thyroid, eyes (including sclera and conjunctiva), breast milk, lacrimal secretions and perspiration);

### **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 tablets and seek advice from your doctor;
- loss of hair (alopecia);
- severe skin rashes, as they may be life threatening;

- Headache, with blurred or double vision or loss of vision;
- feeling of dizziness or “spinning” (vertigo);
- build up of pressure around the brain (intracranial hypertension);
- Cough.
- shortness of breath (dyspnoea);
- hearing problems such as ringing in the ears (tinnitus). 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;
- 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”
- Vomiting;
- increased liver enzymes (liver problems);
- increased serum urea (kidney problems);
- Swelling in legs, ankles, and around the eyes, feeling confused or fatigued, and too little urine leaving the body (acute kidney failure);
- Abnormally low levels of white blood cells, resulting in an increase in infections (neutropenia);
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia);
- 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;
- 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);
- difficulty breathing or chest pain (myocarditis);

**Very rare** (*may affect 1 in 10,000 people*)

- abnormal thyroid function, including brown-black discoloration of the thyroid;
- reduction in red blood cells which can make the skin pale or yellow and cause weakness or breathlessness (anaemia);
- Swelling of the pancreas which can lead to pain in the centre of your abdomen, nausea 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);
- difficulty in breathing or wheezing (bronchospasm);
- 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 (oesophageal ulceration);
- teeth defect where the outer lining of the teeth is missing or thinned (enamel hypoplasia);
- 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 diarrhoea (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);

- serious liver problems (e.g. hepatic cholestasis and hyperbilirubinemia);
- 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 the blood vessels of all sizes affecting both veins and arteries, symptom includes fever, fatigue, joint pain, purple skin discolorations, weight loss and numbness/tingling of arms and legs (vasculitis);
- redness or swelling 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.
- 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);

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 MINOCINMR is stopped.

Staining in the other parts of the body, although less common, may persist. A persistent muddy-brown skin stain, particularly in sun exposed 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](http://www.mhra.gov.uk/yellowcard) [or search for MHRA Yellow Card in the Google Play or App Store](#). 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. Contents of the pack and other 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:

(i) Blister packs of 2, 49 and 56.

(ii) 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:**

Mylan Products Ltd

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### **Manufacturer:**

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