Package leaflet: Information for the user

Minocin® SA 100 mg Modified release capsules

Minocycline

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 or nurse. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Minocin SA 100 mg modified release capsules, which will be called Minocin SA capsules throughout this leaflet.

What is in this leaflet:

1. WHAT MINOCIN SA CAPSULES ARE AND WHAT THEY ARE USED FOR

Minocin SA capsules contain the active ingredient minocycline, which is an antibiotic. Minocin SA capsules are used to treat acne.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MINOCIN SA CAPSULES

Do not take Minocin SA capsules:
- If you are allergic to minocycline, other similar drugs, or any of the other ingredients of Minocin SA capsules (see list of ingredients in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you are pregnant or breast feeding
- If you have renal (kidney) failure
- If you have severe liver disease
- Minocin SA capsules should not be used in children under 12 years of age.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Minocin SA capsules if you have any of the following conditions:
- If you have liver disease
- If you have sever kidney disease
- If you are taking another drug that affects your liver
- If you have symptoms of liver disease such as yellow eyes or skin
- If you have systemic lupus erythematosus (SLE)
- If you have symptoms of SLE such as painful or swollen joints, unexplained fever or red rashes
- If you have myasthenia gravis
- If you develop an infection
- If you have areas of your skin become an unusual colour
- If you become sensitive to light
- If you develop headache and visual disturbances or blurring or double vision.

If you are taking oral contraceptives and you develop diarrhoea or breakthrough bleeding, you should use a barrier contraceptive.

Children
Children under the age of 12 should not take Minocin SA capsules.

Other medicines and Minocin SA capsules
You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Minocin SA capsules:
- Anticoagulants (blood thinners such as warfarin or heparin)
- Diuretics (water tablets)
- Quinapril (used to lower blood pressure)
- Ergot alkaloids (e.g. some migraine treatments)
- Oral contraceptives
- Retinoids (also used to treat acne and other skin conditions, e.g. isotretinoin, retinal)
- Other antibiotics

Preparations containing antacids, iron, calcium, aluminium, magnesium, bismuth or zinc salts which can prevent Minocin 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 SA.
Minocin may interfere with laboratory and other diagnostic tests.
It may still be all right for you to be given Minocin SA capsules and your doctor will be able to decide what is suitable for you.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Minocin SA capsules with food, drink and alcohol
It is advisable not to drink too much alcohol while taking Minocin SA capsules. Drink alcohol only in moderation. Minocin SA capsules can be taken with food or drink.

Pregnancy and breast-feeding
You should not take Minocin SA capsules while pregnant or breast-feeding as it might harm the baby.

Driving and using machines
Minocin SA capsules may cause headache, light headedness, dizziness and disturbed hearing. If you develop any of these symptoms you should not drive or operate machinery.

3. HOW YOU TAKE MINOCIN SA CAPSULES

The recommended dose is as follows:
Adults and the elderly: one 100 mg capsule every 24 hours.
Children over 12 years: one 100 mg capsule every 24 hours.
Children under 12 years: Minocin is not recommended.
A lower dose may be given to elderly patients on advice from their doctor.
The capsules should be swallowed whole with plenty of fluid, while sitting or standing.
Treatment of acne should be continued for a minimum of 6 weeks and where possible limited to a maximum of six months. If Minocin SA is taken for longer than six months, you should be monitored at least every three months.

If you take more Minocin SA capsules than you should:
Contact your doctor as soon as possible. Signs of overdose are dizziness, feeling sick and vomiting.
If you have any further questions on the use of this medicine, 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 the tablets immediately and seek urgent medical advice if the following occur:
- Allergic reactions, which may include collapse, cough, breathlessness and difficulties in swallowing.
- 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 a 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 the following side effects occur:
Common (may affect up to 1 in 10 people)
- Dizziness (light headedness, spinning sensation).

Uncommon (may affect up to 1 in 100 people)
- Fever

Rare (may affect 1 in 1,000 people)
- Hair loss
- Light sensitivity
- Itching
- Rash including nettle rash
- Cough
- Breathlessness, difficulty breathing
- Alteration in the numbers of red or white blood cells or platelets (your doctor can detect these with a blood test)
- Anorexia (loss of appetite)
- Deafness
- Ringing in the ears
- Diarrhoea
- Discolouration of teeth, skin
- Vomiting
- Increased liver enzymes or blood nitrogen (your doctor can detect these with a blood test)
- Liver disease including inflammation of the liver
- Disturbed immune system
- Joint pain
- Muscle pain
- Anaphylaxis/anaphylactoid reaction (experiencing shock, collapse or difficulty breathing, including fatalities)
- Nausea
- Stomatitis (inflammation in mouth)
- Erythema multiforme or erythema nodosum (a type of skin inflammation with red spots on the skin)
- Headache
- Decreased sensitivity, e.g. to touch

Very rare (may affect up to 1 in 10000) or unknown frequency
- Thrush
- Inflammation of the vagina
- Abnormal thyroid function (your doctor can detect this with a blood test)
- Inflammation of the heart or tissue surrounding the heart
- Worsening of asthma
- Indigestion
- Difficulty swallowing
- White spots on the teeth
- Inflammation of the digestive tract
- Discolouration of the mouth (including tongue, lip and gum), bone, secretions, nails
- Inflammation of the veins
- Worsening of systemic lupus erythematosus (SLE)
- Joint stiffness, joint swelling inflammation of joints (arthritis),
- Kidney damage or failure
- Inflammation of the penis glans
- Fits, convulsions
- Sedation
- Lung disorders including inflammation of the lung or a viral infection of the lungs (pneumonitis)
- Severe skin disorders, like severe skin rash with flushing, blisters or ulcers (Stevens-Johnson syndrome) or severe skin rash with flaky skin (toxic epidermal necrolysis)
- Bulging fontanelle (soft spot on head)
- Angioedema (a serious allergic reaction that causes swelling of the hands, feet or ankles, face, lips, tongue and throat and may lead to difficulty swallowing or difficulty breathing)
- Very low white blood cell count (agranulocytosis- your doctor can detect this with a blood test)
- Hypersensitivity

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MINOCIN SA CAPSULES
Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package. Do not use this medicine after the expiry date which is stated on the carton 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 FURTHER INFORMATION
What Minocin SA capsules contain:
Each capsule contains 100 mg of minocycline equivalent to 116 mg of minocycline hydrochloride dihydrate.
The other ingredients are: microcrystalline cellulose, croscarmellose sodium, hypromellose phthalate 50, hypromellose (E464), light liquid paraffin, opaspray White K-1-7000 (containing titanium dioxide E171 and hydroxypropylcellulose)
Capsule body: Titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and gelatin.
Capsule cap: titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172), yellow iron oxide (E172) and gelatin.

What Minocin SA capsules look like and contents of the pack
Modified release hard capsules. 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.

Blister packs containing 56 capsules.

Manufacturer
Meda Pharma GmbH & Co. KG, Benzstrabe 1, 61352 Bad Homburg v.d.h, Germany.

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