

Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Minocycline 50 mg Minocycline 100 mg Capsules

Active ingredient:

Each capsule of Minocycline 50 mg contains: minocycline 50 mg (as HCl)

Each capsule of Minocycline 100 mg contains: minocycline 100 mg (as HCl)

For a list of the other ingredients, please see section 6.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for treating your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

The medicine is active against bacteria susceptible to minocycline, e.g.: acne.

Therapeutic Group: antibiotic medicine, belonging to the tetracycline group.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, to other antibiotics from the tetracycline group, or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).
- You are pregnant or breast-feeding.
- You suffer from kidney failure.
- Do not use in children under 12 years of age.

Special warnings regarding the use of this medicine:

- If you are sensitive to any type of food or medicine, inform the doctor before taking this medicine.
- **Light sensitivity (photosensitivity):** the medicine may cause hypersensitivity upon exposure to light or tanning beds; therefore avoid unnecessary exposure to light and ensure appropriate protection when going outdoors to the sun.
- This medicine may affect laboratory test results. Therefore, inform the attending doctor that you are taking Minocycline.

Before starting treatment with Minocycline tell your doctor if:

- You suffer or have suffered in the past from impaired function of the: liver, kidneys.
- You suffer or have suffered in the past from increased pressure in the skull (increased intracranial pressure), systemic lupus erythematosus or myasthenia gravis (severe muscle weakness, difficulty in chewing and swallowing and impaired speech).
- You are sensitive to sunlight or artificial light (as in tanning beds).

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist.

Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Anticoagulants (e.g. warfarin or coumarin): lower dosages of anticoagulants may be required.

- Diuretics (e.g. furosemide): may exacerbate kidneys' toxicity.
- Antibiotics from the penicillin group: Do not use concomitantly with penicillins.
- Retinoids such as isotretinoin (for acne treatment): each of these medicines is linked with increased risk for pseudotumor cerebri (benign intracranial hypertension).
- Ergometrine (for inducing contractions or birth), ergot derivatives (for migraine treatment).
- Medicines liable to cause liver damage (check with the doctor or pharmacist the medicines that you are taking).
- Kaolin, antacids or other medicines containing magnesium, iron, calcium, zinc and aluminum: Do not take at the same time as Minocycline, in order not to impair its absorption. See "Use of this medicine and food".
- Sucralfate (for treatment of ulcers), bismuth (for relieving abdominal pain), cholestyramine or colestipol (to reduce lipids in the blood): reduce Minocycline absorption.
- Quinapril (ACE inhibitor): reduces Minocycline absorption.
- Birth control pills: both medicines can cause hyperpigmentation.

Use of this medicine and food:

- Food and moderate milk consumption do not impair the absorption of the medicine; therefore, the medicine may be taken regardless of meal times.
- Taking of Minocycline concurrently with kaolin, antacids or products containing iron, aluminum, calcium, zinc or magnesium is not recommended. If there is a need to take them concurrently, it is recommended to take them as far apart as possible (at least 3 hours).

Use of this medicine and alcohol consumption: It is recommended to avoid drinking wine and alcoholic beverages during treatment with this medicine.

Pregnancy and breast-feeding: Do not use the medicine if you are pregnant or breast-feeding. Inform the doctor if you are planning a pregnancy.

Driving and use of machinery: Use of this medicine may cause dizziness, impairment of vision or hearing (including ringing in the ears) and vertigo, which may affect your ability to drive or operate machinery, and therefore caution must be exercised when driving a vehicle, operating dangerous machinery and any activity that requires alertness.

Use in children: this medicine is not intended for infants and children under 12 years of age, since it may cause permanent discoloration and impaired development of tooth enamel.

3. How to use this medicine

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and the manner of treatment will be determined by the doctor only.

Use this medicine at set intervals as determined by the attending doctor.

The standard dosage is usually: The dosage will be determined by the doctor according to the treatment goal and the type of infection and according to your age and your general health.

If you suffer from impaired kidney function, the doctor will give you a lower dosage.

If the treatment is for acne, it will generally last for at least 6 weeks.

Do not exceed the recommended dose.

Do not chew! It is prohibited to open the capsules and to disperse its content (since the medicine may cause irritation and/or ulcers in the esophagus). Swallow the capsules whole with a glass of water.

Take the medicine while standing (or while sitting up). **Do not take the medicine when lying down** and do not lie down for at least 30 minutes after taking it.

Tests and follow-up: during prolonged treatment with this medicine, blood, liver and kidney function tests should be carried out. The doctor may decide to carry out additional monitoring.

If you have accidentally taken a higher dosage: if an overdose has been taken or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Overdose symptoms include dizziness, nausea and vomiting.

If you forgot to take the medicine: if you forgot to take this medicine at the set time, take a dose as soon as you remember, and then take the next dose at the set time. Do not take a double dose to make up for the forgotten dose.

Continue with the treatment as recommended by the doctor.

Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor or the pharmacist.

If you stop taking the medicine: if you stop taking the medicine too early, the infection is liable to return.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side Effects

Like any medicine, the use of Minocycline may cause side effects in some users. If the side effects persist or they are bothersome or get worse, consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop treatment and refer immediately to the doctor in the following cases:

- **On appearance of an allergic reaction (hypersensitivity, anaphylactic reaction) which may be manifested by the following symptoms:** rash, flaky skin, blood spots, bruising and skin discoloration, shock, increase in the number of white blood cells (eosinophilia) and one or more of the following: liver inflammation (hepatitis), lungs inflammation (caused by infection), kidney inflammation, heart muscle inflammation (myocarditis), heart membrane inflammation (pericarditis). Fever, swelling of lymph nodes, face, lips, tongue or throat. In serious cases the syndrom may be life-threatening.
- **In case of development or exacerbation of lupus erythematosus, or symptoms relating to lupus-like syndrome** that include: presence of antinuclear antibodies in the blood, joints pain, joints inflammation (arthritis), stiffness or swelling of joints, red patches and peeling of face skin, hair loss, weight loss, and one or more of the following: fever, muscle pain (myalgia), liver inflammation (hepatitis), skin rash, inflammation of blood vessels. In serious cases the syndrom may be life-threatening.
- **On appearance of serum sickness-like syndrome**, whose symptoms include: fever, rash (including itchy rash, urticaria), joint problems (including inflammation - arthritis, stiffness, swelling, pain), increase in number of white blood cells (eosinophilia). In serious cases the syndrom may be life-threatening.

- **On appearance of symptoms liable to indicate growth of bacteria resistant to the medicines of the tetracycline group:** inflammation of different body areas e.g.: mouth and tongue, intestine, female genitalia (causing itching, secretions, painful urination), irritation in your bottom area and upset stomach.
- **On appearance of sensitivity to sunlight or artificial sunlight (e.g. tanning beds):** the symptoms include: tingling, burning or redness of skin. If you feel these effects, avoid direct exposure to sunlight or artificial sunlight.
- **On appearance of changes in color (hyperpigmentation)** of different body areas, e.g.: skin, nails, teeth, mucous membrane of the mouth, bones, thyroid gland, eyes, secretions (including breast milk, tears, sweat). The phenomenon can appear without relation to dosage or treatment duration, but generally, it develops more frequently in long-term use. Report any change in skin color and stop treatment with the medicine. The phenomenon is generally reversible after stopping the treatment.
- **On appearance of breathing problems,** including wheezing or exacerbation of asthma.
- On appearance of drug-induced hypersensitivity, which may include fever, rash and changes in the blood picture (**drug rash combined with eosinophilia and general signs of DRESS**), which can be serious and life-threatening.
- **On appearance of increased pressure in the skull (intracranial hypertension)** whose symptoms include: headache, impairment of vision (e.g., blurred vision, double vision, loss of vision).
- **On appearances of symptoms that can indicate liver damage:** tiredness, weakness, loss of appetite, weight loss, abdominal pain, fever.

Refer to the doctor if the following side effects occur:

- **Effects on the stomach and gastrointestinal tract:** nausea, vomiting, diarrhea, loss of appetite, lack of development of tooth enamel, inflammation of the tongue, the mouth or the intestines; difficulty swallowing, esophageal inflammation or ulcerations, indigestion; appearance of watery diarrhea, fever and cramps (that can be symptoms of pseudomembranous colitis).
- **Effects on the liver and kidneys:** inflammation of the liver (hepatitis), kidneys or pancreas (pancreatitis); liver failure, jaundice (yellowing of the skin or the white of the eyes), abnormal liver function and acute kidney failure.
- **Effects on the blood system:** increased levels of urea in the blood, blood vessels inflammation, changes in number and type of blood cells. If you notice an increased tendency to bruising, nosebleeds, sore throats, infections, increased tiredness, breathlessness on exertion, or paleness of your skin, inform the doctor who will probably send you to perform blood tests.
- **Effects on the immune system:** inflammation and weakening of blood vessels (polyarteritis nodosa).
- **Effects on the nervous system:** dizziness, headaches, tingling or sensation of pins and needles in the hands and feet, feeling of spinning (vertigo), decreased sensitivity to touch, convulsions, drowsiness.
- **Effects on the skin:** hair loss, skin reactions including red patches (erythema multiforme), skin rash which may be itchy with/without pale or red raised patches, severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson Syndrome), severe rash with reddening, peeling and swelling of

the skin that resembles burns (toxic epidermal necrolysis), red lumps on the leg (erythema nodosum), flaky skin (exfoliative dermatitis).

- **Effects on breathing:** inflammation of the lungs caused by infection (pneumonitis), cough, increased number of white blood cells in the lungs.
- **Effects on muscles and bones:** joint pain (arthralgia), joints inflammation (arthritis), stiffness or swelling of the joints, muscle pain (myalgia).
- **Other effects:** fever, inflammation of the heart muscle (myocarditis) or heart membrane (pericarditis), impaired hearing, ringing in the ears, fungus around the bottom, genital area or the mouth, inflammation of male genitals, changes in thyroid function, lupus or exacerbation of lupus.

In any case you experience side effects that are not mentioned in this leaflet or if there is a change in your general feeling, consult the doctor immediately!

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store in the original package below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Pregelatinized maize starch, silicon dioxide colloidal, magnesium stearate, indigo carmine (FD&C blue 2), erythrosine (FD&C red 3), red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172), gelatin.

What does the medicine look like and what does the package contain?

Minocycline 50 mg: orange capsules, containing a yellow powder; packed in blisters, in packages of 30, 60 or 100 capsules.

Minocycline 100 mg: orange-blue capsules, containing a yellow powder; packed in blisters, in a package of 10 capsules.

Not all the package sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Minocycline 50 mg: 064982712900

Minocycline 100 mg: 116732712800

This leaflet was checked and approved by the Ministry of Health in April 2018.

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