



## **Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

### **Doxylin® 100 mg, tablets**

Each tablet contains Doxycycline 100 mg (as hyclate).

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read this entire leaflet carefully before you start using the 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 to treat your illness. Do not pass it on to others. It may harm them, even if you think that their illness is similar to yours.

If you are taking birth control pills during the treatment, use an additional contraceptive, since concomitant use with **Doxylin 100** may reduce the effect of birth control pills.

#### **1. What is the medicine intended for?**

This medicine contains doxycycline, an antibiotic belonging to a group of medicines called tetracyclines and used for treatment of many different types of infections including:

- Chest, lung or nasal infections, e.g. bronchitis, pneumonia, sinusitis.
- Urinary tract infections, e.g. cystitis, urethritis.
- Eye infections.
- Sexually transmitted diseases, e.g. gonorrhoea, syphilis, chlamydia.
- Fever associated with lice or tick bites.
- Malaria, when chloroquine is not effective.

In addition, **Doxylin 100** is used to prevent certain infections developing, these are scrub typhus (a disease carried by small insects), Rocky Mountain spotted fever, travelers' diarrhea, malaria, cholera and leptospirosis (a bacterial infection from contaminated water).

Anthrax

#### **Therapeutic group:**

Tetracycline antibiotics.

#### **2. Before using the medicine:**

##### **Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (doxycycline), to other tetracycline antibiotics or to any of the other ingredients this medicine contains (see section 6).
- You are pregnant or trying to become pregnant.
- You are breastfeeding.
- You suffer from a medical condition accompanied by swallowing difficulties.
- Do not use **Doxylin 100** during periods of tooth development (pregnancy, infancy or in children under 12 years of age) as such use may lead to permanent discoloration (yellow-grey-brown) or to inadequate development of the teeth.

#### **Special warnings regarding the use of the medicine:**

**Before treatment with Doxylin 100, tell the doctor if:**

- you are expected to be exposed to strong sunlight or to ultraviolet light (for example in a sunbed). Avoid exposure to strong sunlight and take appropriate precautions (long clothes, hat, protective creams etc.) while using the medicine since your skin might be more sensitive to sunburns than usual (see section 4 "Side effects"). Stop using the medicine immediately if skin redness appears.
- you suffer from kidney or liver problems.
- you suffer from myasthenia gravis (a disease which causes unusual tiredness and weakness of certain muscles, particularly in the eyelid).
- you have an immune system disease that causes joint pains, skin rashes and fever (systemic lupus erythematosus). The condition may be worsened by using **Doxylin 100**.
- you are suspected of having syphilis. The doctor will also continue to monitor your condition after ceasing treatment.
- you suffer from diarrhea or usually get diarrhea after taking antibiotics or if you have suffered from stomach or intestinal problems. If you develop severe, prolonged or bloody diarrhea during or after using **Doxylin 100**, **refer to the doctor immediately** since it may be necessary to stop the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis), which occurs following antibiotic treatment.
- you suffer from acid reflux (such as heartburn), **Doxylin 100** may make your condition worse and may not be suitable for you.
- you suffer from problems with the pancreas.
- you experience increased intracranial pressure (severe headache) with changes in vision.
- Refer to the doctor immediately if serious skin reactions appear when using this medicine, such as skin rash with blistering or peeling, mouth or genital ulcers often with flu-like symptoms (these may be signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Rash with Eosinophilia and Systemic Symptoms [DRESS]).
- If swallowing difficulties or discomfort in your throat or stomach appear after starting to use **Doxylin 100**, refer to the doctor immediately. The doctor may advise you to stop taking **Doxylin 100**.
- In long term use, **Doxylin 100** may cause infections that cannot be treated with this antibiotic. The doctor can explain the signs and symptoms of such types of infection.
- There is no medicine today that guarantees full protection against malaria. Avoid mosquito bites by using protective measures, especially in the dark hours (staying in an area protected from mosquitos, using mosquito nets, wearing long clothes and using a mosquito repellent).
- Inform the doctor if an infection worsens or if you develop a new infection.

### **Drug interactions**

**If you are taking, have recently taken or if you might take any other medicines, including non-prescription drugs and nutritional supplements, tell the doctor or pharmacist.**

Certain medicines might reduce the effectiveness of **Doxylin 100**, these include:

- Antacids (for treatment of indigestion), iron preparations, oral zinc or bismuth. Do not take these preparations at the same time of day as **Doxylin 100**.
- Carbamazepine, phenytoin (medicines for treatment of epilepsy) and barbiturates (for treatment of epilepsy or as a sedative).

**Doxylin 100** can affect the activity of other medicines, including:

- Increase the activity of warfarin or coumarin (for prevention of blood clots)
- Reduce the effectiveness of oral contraceptives. Use an additional contraceptive.

- Reduce the effectiveness of penicillin antibiotics (for treatment of infections)
- Methoxyflurane (a type of anesthetic)

### **Operation or dental surgery**

If you are about to have a general anaesthetic for an operation or dental surgery, you must tell the anaesthetist or dentist that you are taking **Doxylin 100**, as you may suffer from more side effects.

### **Tests and follow-up**

**Doxylin 100** may interfere with certain tests, tell the doctor if you need to undergo lab tests. In long term use, periodic lab tests should be performed, including blood tests, kidney and liver function.

### **Use of this medicine and alcohol consumption**

Alcohol may reduce the effect of **Doxylin 100**, therefore avoid alcohol consumption during treatment with the medicine.

### **Pregnancy, breastfeeding and fertility**

Do not take **Doxylin 100** if you are pregnant, trying to become pregnant or breastfeeding (see in section 2 "Do not use the medicine if").

### **Driving and using machines**

This medicine is not expected to affect your ability to drive or use machines.

### **Important information about some of the ingredients of the medicine**

The medicine contains lactose. If you have previously been told by a doctor that you have an intolerance to certain sugars, consult a doctor before starting treatment with the medicine. The medicine contains Sunset Yellow FCF Aluminum Lake (E110), which might cause an allergic reaction.

## **3. How to use the medicine**

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. Dosage and administration will be determined by the doctor only.

### **Do not exceed the recommended dose.**

- Take **Doxylin 100** capsules with a full glass of water when sitting or standing.
- It is recommended to take **Doxylin 100** in the morning if possible, or at least one hour before going to sleep.
- It is important not to lie down for at least 30 minutes after taking **Doxylin 100**, so that the tablet can move as quickly as possible to the stomach, to prevent irritation of the throat or esophagus (a tube transferring the food from the mouth to the stomach).
- If you have an upset stomach, **Doxylin 100** can be taken with food or milk.
- **Doxylin 100** can be taken with or without food.
- Do not halve/chew/crush the tablet, in order to prevent irritation of the throat and esophagus.
- During the treatment, it is important to be sure to drink a lot of fluids in order to reduce the risk of esophageal irritation and ulcer.

### **If you have accidentally taken a higher dosage**

If you have taken an overdose 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.

**If you forget to take the medicine**

If you forget to take the medicine at the designated time, take a dose as soon as you remember. Take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor.

**If you stop taking the medicine**

If you stop taking the medicine too soon, the infection might return. Complete the entire duration of treatment even if you feel better.

**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 further questions regarding the use of the medicine, consult a doctor or pharmacist.**

**4. Side effects**

Like any medicine, the use of **Doxilin 100** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Stop taking this medicine and refer to the doctor immediately if** you suffer from skin that is more sensitive to sunlight than normal. You may suffer from skin rash, itching, redness or severe sunburn.

**Refer to a doctor immediately if** you experience one or more of the following symptoms after taking the medicine. Although they are very rare, the symptoms can be severe.

- Symptoms of an allergic reaction: sudden wheeziness, difficulty in breathing, tightness in chest, fever, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- Upset stomach, loss of appetite, severe, persistent or bloody diarrhea (may occur up to two or three months after the last dose and may be associated with stomach pain or fever). This may occur after treatment with antibiotics and can be a sign of serious bowel inflammation.
- Headache which, if very severe, may be associated with visual disturbance such as blurred vision or loss of vision. The possible symptoms in benign intracranial hypertension include headache, vomiting, visual disturbances including blurred vision, a localized defect in the visual field bordered by an area of normal vision (scotoma), double vision (diplopia), and possible vision loss, in some cases, even permanent.

**Refer to a doctor as soon as possible with the appearance of:**

- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash, that is usually self-limiting. This occurs shortly after starting doxycycline treatment for infections with spirochete such as Lyme disease.
- Skin rash or peeling of the skin.
- Severe skin reactions which may cause you to feel unwell.
- Fever, swollen lymph nodes or skin rash. These may be symptoms of a condition known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) which can be severe and life-threatening.
- Inflammation and/or ulcers of the esophagus.
- Blood disorders, due to changes in numbers of different cell types in the blood. Symptoms may include tiredness, easy bruising or infections.
- Low blood pressure.
- Increased heart rate.
- Aches in the joints or muscles.

- Stomach pain or diarrhea.

The following side effects may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you:

**Common side effects** (effects that appear in 1-10 out of 100 users):

- Nausea or vomiting.
- Worsening of the disease called systemic lupus erythematosus (SLE). This is an allergic condition, which causes joint pain, skin rash and fever.
- Pericarditis (inflammation affecting the heart).

**Uncommon side effects** (effects that appear in 1-10 out of 1,000 users):

- Heartburn

**Rare side effects** (effects that appear in 1-10 out of 10,000 users):

- Inflammation of the pancreas which causes severe pain in the abdomen and back
- Difficulty in swallowing, painful tongue or mouth
- Skin reddening (flushing)
- Ringing or buzzing in the ears
- Soreness and itching of the rectal or genital area
- Inflammation of the bowel
- Bulging fontanelles (soft spot on infant's skull) of infants
- Increased intracranial pressure (severe headache with change in vision)
- Inflammation and damage to the liver, yellowing of the skin and eyes (jaundice)
- Abnormal liver function test results
- Discoloration of the thyroid tissue when the medicine is given for a long period. The medicine does not impair thyroid function.
- Round or oval patches of redness and swelling of the skin, blistering (hives), and itching, which usually recurs at the same site(s) on re-exposure to the medication (fixed drug eruption)
- Darker patches on your skin
- Loosening of the nail from the nail bed after exposure to the sun
- Increase in levels of urea in the blood

**Side effects with unknown frequency** (effects whose frequency has not yet been determined):

- Discoloration and/or defective development of teeth

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health via the link

“דיווח על תופעות לוואי עקב טיפול תרופתי” found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form of reporting side effects or via the following link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight 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 (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store in a dry and dark place, below 25°C.

- 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. Additional information**

##### **In addition to the active ingredient, this medicine also contains:**

Lactose monohydrate, Microcrystalline cellulose, Maize starch, Hypromellose, Copovidone, Silica colloidal anhydrous, Magnesium stearate, Titanium dioxide (E171), Macrogol 400, Sunset yellow FCF Aluminum Lake (E110), Quinoline Yellow Aluminum Lake (E104), Carnauba wax

##### **What the medicine looks like and what the package contains:**

Orange coated tablets, quadrisect on one side.

Approved package sizes: 2, 7, 10, 14, 50, 70, 100, 250 tablets. Not all package sizes may be marketed.

Revised in October 2024 according to MOH guidelines.

**Drug registration number at the national drug registry of the Ministry of Health:** 015-94-24790-00

**Manufacturer and Registration holder:** Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel