

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

## **Posaconazole 100 mg Ofek Pharma**

### **Delayed release tablets**

#### **Active ingredient**

Each tablet contains posaconazole 100 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about **Posaconazole 100 mg Ofek Pharma**. If you have any further questions, consult your doctor or pharmacist.

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

**Posaconazole 100 mg Ofek Pharma** is intended for use in adults aged 18 years and older.

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

**Posaconazole 100 mg Ofek Pharma** is used to prevent and treat different types of fungal infections

**Posaconazole 100 mg Ofek Pharma** is used to treat the following types of fungal infections in adults when other antifungal medicines have not worked or their intake has had to be stopped:

- infections caused by fungi of the *Aspergillus* family and resistant to treatment with amphotericin B or itraconazole, or when the patient cannot receive these medicines;
- infections caused by fungi of the *Fusarium* family and resistant to treatment with amphotericin B, or when the patient cannot receive this medicine;
- infections caused by fungi that cause conditions known as chromoblastomycosis and mycetoma and resistant to treatment with itraconazole, or when the patient cannot receive this medicine;
- infections caused by a fungus called *Coccidioides* and resistant to treatment with amphotericin B, itraconazole or fluconazole, or when the patient cannot receive these medicines.
- fungal infection called *Zygomycosis* in patients intolerant to or with disease that is refractory to alternative therapy.

This medicine can also be used to prevent fungal infections in adults who are at high risk of getting a fungal infection, such as:

- patients who have a weak immune system due to chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndrome (MDS).
- patients receiving high-dose immunosuppressive therapy after hematopoietic stem cell transplant (HSCT).

**Therapeutic group:** antifungal medicines

This medicine works by killing or stopping the growth of some types of fungi that can cause infections.

## 2. Before using this medicine

### Do not use this medicine if:

- You are sensitive (allergic) to posaconazole or to any of the other ingredients in this medicine (see section 6).
- You are taking terfenadine, astemizole, cisapride, pimozone, halofantrine, quinidine, any medicine that contains ergot alkaloids, such as ergotamine or dihydroergotamine, or a medicine from the statin class such as simvastatin, atorvastatin or lovastatin.
- You have started taking venetoclax or your venetoclax dose is being slowly increased for treatment of chronic lymphocytic leukaemia (CLL).
- You are breastfeeding.

See section “**Drug interactions**” below for more information, including information on other medicines which may interact with **Posaconazole 100 mg Ofek Pharma**.

### Special warnings about using this medicine

#### Before treatment with Posaconazole 100 mg Ofek Pharma, tell your doctor if:

- You have ever had an allergic reaction to another antifungal medicine, such as ketoconazole, fluconazole, itraconazole or voriconazole.
- You have or have ever had liver problems. You may need to undergo blood tests while you are taking this medicine.
- You develop severe diarrhoea or vomiting, as these conditions may limit the effectiveness of this medicine.
- You have an abnormal heart rhythm (as observed in ECG tracing) called prolonged QTc interval.
- You have weakness of the heart muscle or heart failure.
- You have a very slow heartbeat.
- You have a heart rhythm disturbance.
- You have any problem with potassium, magnesium or calcium levels in the blood.
- You are taking vincristine, vinblastine or other vinca alkaloids (medicines used to treat cancer).
- You are taking venetoclax (a medicine used to treat cancer).

If you develop severe diarrhoea or vomiting while taking **Posaconazole 100 mg Ofek Pharma**, talk to your doctor or pharmacist straight away, as this may stop the medicine from working properly. See section 4 for more information.

### Drug interactions

**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.**

**Do not take Posaconazole 100 mg Ofek Pharma if you are taking any of the following medicines:**

- terfenadine (used to treat allergies)
- astemizole (used to treat allergies)
- cisapride (used to treat stomach problems)
- pimozone (used to treat symptoms of Tourette’s syndrome and mental illness)
- halofantrine (used to treat malaria)
- quinidine (used to treat abnormal heart rhythm).

**Posaconazole 100 mg Ofek Pharma** can increase the levels of these medicines in the blood, which may lead to very serious changes in your heart rhythm.

- any medicine that contains ergot alkaloids, such as ergotamine or dihydroergotamine, used to treat migraines. **Posaconazole 100 mg Ofek Pharma** can increase the amount of these medicines in the blood, which may lead to a severe decrease in blood flow to your fingers or toes and could cause damage to them.
- a medicine of the statin class, such as simvastatin, atorvastatin or lovastatin, used to treat high levels of cholesterol.
- venetoclax, when used at the start of the treatment of a type of cancer, chronic lymphocytic leukaemia (CLL).

Do not take **Posaconazole 100 mg Ofek Pharma** if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

In addition to the medicines listed above, there are other medicines that carry a risk of heart rhythm problems, which may be greater when they are taken with **Posaconazole 100 mg Ofek Pharma**. Please make sure to tell your doctor about all the medicines you are taking (prescription or non-prescription).

Certain medicines may increase the risk of side effects caused by **Posaconazole 100 mg Ofek Pharma** due to increasing the amount of **Posaconazole 100 mg Ofek Pharma** in the blood.

The following medicines may decrease the effectiveness of **Posaconazole 100 mg Ofek Pharma** by decreasing the amount of **Posaconazole 100 mg Ofek Pharma** in the blood:

- rifabutin and rifampicin (used to treat certain infections). If you are taking rifabutin, you will need to perform a blood test and you will need to look out for some possible side effects of rifabutin.
- phenytoin, carbamazepine, phenobarbital or primidone (used to treat or prevent epileptic fits).
- efavirenz and fosamprenavir used to treat HIV infection.

**Posaconazole 100 mg Ofek Pharma** may also increase the risk of side effects of certain other medicines by increasing the amount of these medicines in the blood. These medicines include:

- vincristine, vinblastine and other vinca alkaloids (used to treat cancer)
- venetoclax (used to treat cancer)
- ciclosporin (used, among other things, to prevent transplant rejection)
- tacrolimus and sirolimus (used to prevent transplant rejection)
- rifabutin (used to treat certain infections)
- medicines used to treat HIV called protease inhibitors (including lopinavir and atazanavir, which are given with ritonavir)
- midazolam, triazolam, alprazolam or other benzodiazepines (used as sedatives or muscle relaxants)
- diltiazem, verapamil, nifedipine, nisoldipine or other calcium channel blockers (used to treat high blood pressure)
- digoxin (used to treat heart failure)
- glipizide or other sulfonylureas (used to treat high blood sugar level)
- all-trans retinoic acid (ATRA), also called tretinoin (used to treat certain blood cancers).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking **Posaconazole 100 mg Ofek Pharma**.

### Using this medicine and food

Take the tablets with food.

### **Pregnancy and breastfeeding**

Tell your doctor if you are pregnant or think you are pregnant before you start taking **Posaconazole 100 mg Ofek Pharma**.

Do not take **Posaconazole 100 mg Ofek Pharma** if you are pregnant, unless you have been told to do so by your doctor. If you are a woman who could become pregnant, you should use effective contraception while you are taking this medicine. If you become pregnant while taking **Posaconazole 100 mg Ofek Pharma**, contact your doctor straight away.

Do not breastfeed while taking **Posaconazole 100 mg Ofek Pharma**. This is because small amounts of **Posaconazole 100 mg Ofek Pharma** may pass into breast milk.

### **Driving and using machines**

You may feel dizzy, sleepy, or have blurred vision while taking **Posaconazole 100 mg Ofek Pharma**. These effects may affect your ability to drive or use tools or machines. If you suffer from these side effects, do not drive or use any tools or machines, and contact your doctor.

### **Important information about some of this medicine's ingredients**

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

## **3. How to use this medicine?**

Do not replace Posaconazole 100 mg tablets with Posaconazole 100 mg oral suspension without talking to your doctor or pharmacist, because this may result in medicine inefficacy or increased risk of side effects.

Always take **Posaconazole 100 mg Ofek Pharma** as instructed by your doctor. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. The dosage and duration of treatment will be determined by the doctor only.

The recommended dosage is usually 300 mg (three 100 mg tablets) twice a day on the first day of treatment, thereafter 300 mg (three 100 mg tablets) once a day. The duration of treatment may depend on the type of infection that you have and may be individually adapted for you by your doctor. Do not adapt your dose yourself before consulting your doctor, or change your treatment regimen without consulting your doctor.

**Do not exceed the recommended dose.**

#### **How to take this medicine:**

- Swallow the tablet whole with some water.
- Do not crush, chew or break the tablet.
- Take the tablets with food.

#### **If you have accidentally taken a higher dose than you should**

If you have taken an overdose of **Posaconazole 100 mg Ofek Pharma**, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

#### **If you forget to take the medicine**

- If you forget a dose, take it as soon as you remember.
- However, if it is almost time for your next dose, skip the missed dose and go back to your regular

intake schedule.

- Do not take a double dose to make up for the forgotten dose.

Complete the full course of treatment as instructed by your doctor.

Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

Like with all medicines, using **Posaconazole 100 mg Ofek Pharma** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

**Tell your doctor or pharmacist straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

- nausea or vomiting, diarrhoea
- signs of liver problems, which include yellowing of your skin or whites of the eyes, unusually dark urine or abnormally light faeces, nausea for no reason, stomach problems, loss of appetite or unusual tiredness or weakness, an increase in liver enzymes observed in blood tests
- allergic reaction

##### **Additional side effects**

Tell your doctor or pharmacist if you notice any of the following side effects:

Common side effects: the following effects may affect up to 1 in 10 users

- a change in the salt level in your blood shown in blood tests - signs include feeling confused or weak
- abnormal skin sensations, such as numbness, tingling, itching, pins and needles, pricking or burning
- headache
- low potassium levels – shown in blood tests
- low magnesium levels – shown in blood tests
- high blood pressure
- loss of appetite, abdominal pain or upset stomach, passing wind, dry mouth, changes in taste
- heartburn (a burning sensation in the chest rising up to the throat)
- low level of neutrophils, a type of white blood cell (neutropenia), that can be shown in blood tests. This may increase your risk of infections.
- fever
- feeling weak, dizzy, tired or sleepy
- rash
- itching
- constipation
- rectal discomfort

Uncommon side effects: the following effects may affect up to 1 in 100 people

- anaemia - signs include headaches, feeling tired or dizzy, shortness of breath or looking pale and a low level of haemoglobin in blood test results
- low level of platelets (thrombocytopenia) shown in blood tests – this may lead to bleeding
- low level of leukocytes, a type of white blood cell (leukopenia) shown in blood tests – this may increase your risk of infections
- high level of eosinophils, a type of white blood cell (eosinophilia) – this may happen if you have inflammation
- inflammation of the blood vessels
- heart rhythm problems
- epileptic fits (seizures)
- nerve damage (neuropathy)
- abnormal heart rhythm observed in a heart tracing (ECG), palpitations, slow or fast heartbeat
- high or low blood pressure
- inflammation of the pancreas (pancreatitis) – this may cause severe abdominal pain
- interruption of oxygen supply to the spleen (splenic infarction) - this may cause severe abdominal pain
- severe kidney problems – signs include passing more or less urine, that has a different colour than usual
- high blood levels of creatinine – shown in blood tests
- cough, hiccups
- nose bleeds
- severe sharp chest pain when breathing in (pleuritic pain)
- swelling of lymph glands (lymphadenopathy)
- reduced feeling of sensitivity, especially on the skin
- tremor
- high or low blood sugar levels
- blurred vision, sensitivity to light
- hair loss (alopecia)
- mouth ulcers
- chills (shivering), feeling generally unwell
- pain, back or neck pain, pain in arms or legs
- water retention (oedema)
- menstrual problems (abnormal vaginal bleeding)
- inability to sleep (insomnia)
- being completely or partially unable to talk
- swelling of the mouth
- abnormal dreams or difficulty sleeping
- problems with coordination or balance
- mucosal inflammation
- stuffy nose
- difficulty breathing
- chest discomfort
- feeling bloated
- mild to severe nausea, vomiting, cramps and diarrhoea, usually caused by a virus, abdominal pain
- belching
- feeling nervous

Rare side effects: the following effects may affect up to 1 in 1,000 people

- pneumonia – signs include sensation of shortness of breath and production of coloured phlegm
- high blood pressure in the lung blood vessels in the lungs (pulmonary hypertension). This may cause serious damage to your lungs and heart.
- blood problems, such as unusual blood clotting or prolonged bleeding
- severe allergic reactions, including widespread blistering rash and skin peeling
- mental problems, such as hearing voices or seeing things that do not exist
- fainting
- problems thinking or talking, jerking movements, especially in the hands, that you cannot control
- stroke – signs include pain, weakness, numbness or tingling in the limbs
- partial loss of the visual field (a spot in the visual field) or a dark spot in the visual field
- heart failure or heart attack, which could lead to the heart stopping beating and death, heart rhythm problems, with sudden death
- blood clots in the legs (deep vein thrombosis) – signs include intense pain or swelling of the legs
- blood clots in the lungs (pulmonary embolism) – signs include sensation of shortness of breath or pain while breathing
- bleeding into the stomach or gut – signs include vomiting blood or passing blood in stool
- blockage of the gut (intestinal obstruction), especially in the ileum. The blockage will prevent the intestinal contents from passing through to the lower bowel. Signs include feeling bloated, vomiting, severe constipation, loss of appetite and cramps
- haemolytic uraemic syndrome, when breakdown of red blood cells occurs (hemolysis), which may happen with or without kidney failure
- pancytopenia, low level of all blood cells (red and white blood cells and platelets) shown in blood tests
- large purple spots on the skin (thrombotic thrombocytopenic purpura)
- swelling of the face or tongue
- depression
- double vision
- breast pain
- adrenal glands not working properly. This may cause weakness, tiredness, loss of appetite, skin discolouration
- pituitary gland not working properly. This may cause low blood levels of certain hormones that affect the function of male or female sex organs
- hearing problems
- pseudoaldosteronism, which results in high blood pressure with a low potassium level (observed in blood test)

Side effects of unknown frequency: frequency cannot be estimated from the available data

- Some patients have also reported feeling confused after taking **Posaconazole 100 mg Ofek Pharma**

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il/>

## 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C in the original package.  
Tablets in a bottle package – shelf life after opening: 40 days.
- Do not throw away any medicine via wastewater or household waste. Ask the 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 the following inactive ingredients: hypromellose acetate succinate, hydroxypropyl cellulose, microcrystalline cellulose, croscarmellose sodium, opadry II 85F92209 yellow, polyvinyl alcohol part hydrolyzed, titanium dioxide, macrogol/PEG, talc, colloidal silicon dioxide, magnesium stearate, iron oxide yellow.

### **What the medicine looks like and contents of the pack:**

Elongated yellow coated tablets, with “100” debossed on one side.

Pack sizes: Blister package in a carton containing 24 tablets, a bottle with child-proof cap containing 60 tablets.

Not all pack sizes may be marketed.

### **Registration holder's name and address:**

Ofek Pharma Ltd., 22 Snir St., Bnei Dror, 4581500.

### **Manufacturer's name and address:**

Haimen Pharma Inc.,  
No. 163, Zhuhai Rd., Binjiang Street,  
Haimen District, Nantong, Jiangsu 226100,  
China

### **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

170-67-37135-99

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