

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

This medicine is dispensed with a doctor's prescription only

## **Conjupri 2.5 mg**

## **Conjupri 5 mg**

### **Tablets**

Conjupri 2.5 mg: Each tablet contains levamlodipine\* 2.5 mg (as maleate)

Conjupri 5 mg: Each tablet contains levamlodipine\* 5 mg (as maleate)

\* Levamlodipine is the active form of amlodipine.

Inactive ingredients in this medicine, see section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. 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.

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

Conjupri is a calcium channel blocker, and can be used alone or in combination with other antihypertensive agents for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

**Therapeutic group:** Calcium channel blockers

### **2. Before using this medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to amlodipine or to any of the other ingredients in this medicine (see section 6).

#### **Special warnings about using this medicine**

**Before using Conjupri, inform your doctor of all your medical conditions, including if:**

- You have heart problems
- You have liver problems

#### **Children and adolescents**

There is no information about the efficacy and safety of using this medicine in children under the age of 6 years.

Children and adolescents aged 6-17 years: see section 3.

#### **Interactions with other medicines**

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- CYP3A enzyme inhibitors (moderate and strong) such as diltiazem, itraconazole, clarithromycin – Co-administration with amlodipine increases the concentration of amlodipine in the blood. Your doctor may adjust the dosage of amlodipine – hypotension and edema should be monitored when these medicines are co-administered with amlodipine.
- CYP3A enzyme inducers. Blood pressure should be closely monitored when co-administered with amlodipine.
- Sildenafil (for treatment of impotence and erectile dysfunction) - Hypotension should be monitored when sildenafil is co-administered with amlodipine.
- Simvastatin (for cholesterol lowering) - Co-administration with amlodipine increases the concentration of simvastatin in the blood. Adjustment of simvastatin dosage will be required.
- Cyclosporine or tacrolimus (immunosuppressants) - Co-administration with amlodipine may increase the concentration of cyclosporine/tacrolimus in the blood.

#### **Using this medicine and food**

The medicine can be taken with or without food.

#### **Pregnancy and breastfeeding**

##### Pregnancy

Inform your doctor if you are pregnant or plan to become pregnant. There is limited information about deleterious effect of the medicine on the fetus.

##### Breastfeeding

If you are breastfeeding or plan to breastfeed, consult your doctor about the best way to feed your baby during treatment with Conjupri. Conjupri can pass into breast milk.

#### **Driving and using machines**

Conjupri may affect the ability to drive and operate machines. If the medicine makes you nauseous, dizzy or tired, do not drive or use machines and consult your doctor immediately.

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

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

#### **The recommended dosage is usually:**

Adults: The initial dosage is 2.5 mg once daily. The maximum dosage is 5 mg once daily.

Thin, fragile or elderly patients, or patients with hepatic insufficiency – The doctor may prescribe the dosage of 1.25 mg once daily, combined with other antihypertensive therapy.

Children aged 6–17 years: 1.25 mg to 2.5 mg once daily.

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

If you have to take a dose of 1.25 mg, you can split Conjupri 2.5 mg tablets into two halves along the score line.

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

Overdose is expected to cause excessive peripheral vasodilation with marked hypotension and possible reflex tachycardia.

If you have taken an overdose, 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 this medicine**

If you forget to take this medicine at the scheduled time, **do not take a double dose**. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take 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**

As with any medicine, using Conjupri may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

##### **Conjupri may cause serious side effects, including:**

- **Low blood pressure (hypotension).** Conjupri may cause low blood pressure, especially in people with a condition called severe aortic stenosis. Tell your doctor if you experience weakness or dizziness.
- **Worsening of chest pain (angina pectoris) or heart attack.** Conjupri may cause worsening of chest pain or heart attack after starting treatment or increasing the dosage, especially in people with a condition called severe obstructive coronary artery disease. **If that happens, call your doctor right away or go directly to a hospital emergency room.**

##### **The most common side effects of Conjupri include:**

- swelling (edema) of the legs or ankles
- tiredness
- nausea
- abdominal pain
- sleepiness
- dizziness
- flushing (hot or warm feeling in the face)
- heart palpitations (fast heartbeat)

##### **Uncommon side effects (affect 1–10 in 1,000 users):**

Cardiovascular system: irregular heart rate (arrhythmia), slow heart rate (bradycardia), chest pain, reduced peripheral blood flow (ischemia), syncope, fast heart rate (tachycardia), inflammation of blood vessels (vasculitis)

Central and peripheral nervous system: numbness, peripheral neuropathy, paresthesia, tremor, vertigo

Gastrointestinal system: decreased appetite (anorexia), constipation, difficulty swallowing, diarrhea, flatulence (gas), pancreatitis, vomiting, gingival overgrowth (gingival hyperplasia)

General: allergic reaction, asthenia, back pain, hot flushes, malaise, pain, stiffness, weight gain, weight loss

Musculoskeletal system: arthralgia, osteoarthritis (arthrosis), muscle cramps, myalgia

Psychiatric: sexual dysfunction, insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization

Respiratory system: difficulty breathing, nosebleed

Skin: edema (angioedema), erythema multiforme, itching, rash

Senses: abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus (ringing in the ears)

Urinary system: increased urination frequency, urination disorder, nocturia

Autonomic nervous system: dry mouth, increased sweating

Metabolism and nutrition: increased blood glucose, thirst

Blood system: decreased white blood cell count, purpura, low platelet count

**Side effects of unknown frequency** (the frequency of these effects has not been established yet)

- Breast enlargement in men (gynecomastia)
- Jaundice and liver enzyme elevation
- Extrapyramidal disorder

**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.**

#### Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or 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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the bottle. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C. Store in the original package to protect from light.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of 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:**

Pregelatinized starch, microcrystalline cellulose, betadex, colloidal silicon dioxide, magnesium stearate.

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

Conjupri 2.5 mg: white to off-white, capsule shaped tablets, with a score line on each side, engraved with "OE" on one side and "B47" on the other side.

Conjupri 5 mg: white to off-white, capsule shaped tablets, engraved with "OE" on one side and "B48" on the other side.

The tablets are available in plastic bottles containing 30 or 90 tablets. The bottle is closed with a child-resistant cap.  
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:**  
CSPC Ouyi Pharmaceutical Co., Ltd. Shijiazhuang, Hebei, China, 052160

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Registration numbers of the medicine in the Ministry of Health National Drug Registry:  
Conjupri 2.5 mg: 176-44-37508-99  
Conjupri 5 mg: 176-45-37509-99