

**PATIENT LEAFLET IN ACCORDANCE WITH  
THE PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

The medicine is dispensed  
with a physician's prescription only

# **CESENTRI 150 mg**

# **CESENTRI 300 mg**

## **Film-coated tablets**

**Each CESENTRI 150 mg tablet contains 150 mg maraviroc**

**Each CESENTRI 300 mg tablet contains 300 mg maraviroc**

A list of the additional ingredients is detailed in section 6. Pay attention to the important information about some of the ingredients of the medicine in section 2.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or the 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.

## **1. WHAT IS THE MEDICINE INTENDED FOR?**

CESENTRI is a medicine that belongs to a group called CCR5 co-receptor antagonists. CESENTRI is given with other antiretroviral medicines to treat adults with a CCR5-tropic HIV-1 infection only.

- In patients who have not received previous treatments: More patients treated with CESENTRI experienced virological failure and developed resistance to lamivudine as compared to efavirenz.
- Tropism test with use of a highly sensitive tropism assay is required for appropriate use of CESENTRI.

## **Therapeutic group**

Antiviral, CCR5 co-receptor antagonist

## **2. BEFORE USING THE MEDICINE**

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

- You are sensitive (allergic) to the active ingredient or to peanuts or soya or to any of the additional ingredients contained in the medicine as listed in section 6 and section 2 "Important information about some of the ingredients of the medicine".
- You have severe kidney problems or are on hemodialysis and are taking certain other medications.

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

**CESENTRI can cause serious side effects, including serious liver problems (liver toxicity).** Some people taking CESENTRI can develop a severe rash or an allergic reaction before liver problems occur, which may be life-threatening. **Stop taking CESENTRI and refer to your physician immediately if any of the following signs or symptoms of liver problems occur:**

- an itchy rash on your body (allergic reaction)
- yellowing of your skin or whites of your eyes (jaundice)
- dark or tea-colored urine
- vomiting
- pain, aching, or tenderness on the right side of your stomach area

Your physician will ask you to do blood tests to check your liver before starting treatment with CESENTRI and as needed during treatment with CESENTRI.

**Before beginning treatment with CESENTRI, tell your physician about all your medical conditions, including if:**

- you have or have had liver problems, including hepatitis B or C virus infection.
- you have heart problems.
- you have kidney problems.
- you have low blood pressure or are taking medicines to lower blood pressure.
- you are pregnant or plan to become pregnant. It is not known if CESENTRI may harm your unborn baby.
- you are breastfeeding or plan to breastfeed. **Do not breastfeed if you are taking CESENTRI.** Do not breastfeed if you have HIV-1, due to the risk of passing HIV-1 to your baby. Consult your physician about the best way to feed your baby.

## **Children and adolescents**

CESENTRI 150, 300 mg film-coated tablets is not intended for children and adolescents under 18 years of age.

## **Tests and follow-up**

Your physician will ask you to do blood tests to check your liver before you start treatment with CESENTRI and as needed during treatment with CESENTRI.

## **Drug interactions**

**If you are taking, or have recently taken, other medicines including non-prescription medicines, nutritional supplements, vitamins and herbal supplements, tell the physician or the pharmacist.** Certain medicines may interact with CESENTRI. Keep a list of your medicines to show your physician and pharmacist. You can ask your physician or pharmacist for a list of the medicines that interact with CESENTRI.

**Do not start taking a new medicine without consulting with your physician.** Your physician can tell you if it is safe to take CESENTRI with other medicines. Your physician may need to change your dose of CESENTRI when you take it with certain medicines.

**Do not take preparations containing St. John's wort (*Hypericum perforatum*) with CESENTRI.**

## **Pregnancy and breastfeeding**

### **Pregnancy**

Before the treatment with CESENTRI, tell the physician if you are pregnant or plan to become pregnant. It is not known if CESENTRI may harm your unborn baby.

### **Breastfeeding**

**Do not breastfeed if you are taking CESENTRI.** Do not breastfeed if you have HIV-1, due to the risk of passing HIV-1 to your baby. Consult your physician about the best way to feed your baby.

## **Driving and operating machinery**

If you have dizziness due to use of CESENTRI, avoid driving and operating dangerous machinery.

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

CESENTRI contains soya lecithin and sodium. If you are allergic to peanuts or soya, do not use CESENTRI. CESENTRI contains less than 1 mmol sodium (23 mg) in each tablet, that is to say it is essentially sodium-free.

## **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the medicine according to the physician's instructions.

Check with the physician or the pharmacist if you are uncertain about the medicine dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

CESENTRI comes in 150 mg and 300 mg tablets. The physician will prescribe the dosage that is right for you.

Swallow CESENTRI tablets whole. Do not chew the tablets.

**There is no information about crushing or chewing. Do not halve as there is no score line.**

CESENTRI can be taken with or without food.

**Do not change your dosage and do not stop taking CESENTRI without first talking with your physician.**

**Do not exceed the recommended dosage.**

**If you accidentally take a higher dosage**

**If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician**

or proceed to a hospital emergency room and bring the package of the medicine with you.

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

If you forgot to take the dose, take it as soon as you remember. Do not take two doses together. If you are uncertain about your dosage, talk to your physician.

You should be under follow-up by your physician during the course of treatment with CESENTRI.

Persist with the treatment regimen as recommended by the physician.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the physician.

When your CESENTRI supply starts to run low, get more from your physician. This is very important because the amount of virus in your blood may increase and it will be harder to treat it.

**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 other questions regarding use of the medicine, consult the physician or the pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, use of CESENTRI may cause side effects in some of the users. Do not be alarmed by the list of side effects. You may not experience any of them.

**CESENTRI may cause serious side effects, including:**

- See section 2: "Special warnings regarding the use of the medicine".
- **Serious skin rash and allergic reactions.** Severe and potentially life-threatening skin reactions and allergic reactions have been reported in some people who took CESENTRI. If you develop a rash with any of the following symptoms, stop using CESENTRI and contact your physician right away:
  - fever
  - generally ill feeling
  - muscle aches
  - blisters or sores in your mouth
  - blisters or peeling of the skin
  - redness or swelling of the eyes
  - swelling of the mouth, face or lips
  - problems breathing
  - yellowing of the skin or whites of your eyes
  - dark or tea-colored urine
  - pain, aching, or tenderness on the right side, below the ribs
  - loss of appetite
  - nausea/vomiting
- **Heart problems** including heart attack.
- **Low blood pressure when standing up (postural hypotension),** which may cause dizziness or fainting. Avoid driving and operating heavy machinery if you have dizziness while taking CESENTRI.
- **Changes in the immune system (a condition called Immune Reconstitution Syndrome)** can occur when you start taking anti-HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your physician immediately if you develop new symptoms during the course of treatment with CESENTRI.
- **Possible chance of infection or cancer.** CESENTRI affects other immune system cells and therefore may increase your chance for getting other infections or cancer.

**The most common side effects of CESENTRI in adults include** colds, cold-like symptoms, cough, fever, rash, bloating and gas, indigestion, constipation and dizziness.

These are not all the possible side effects of CESENTRI. **If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

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

## **5. HOW TO STORE THE MEDICINE?**

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not induce vomiting unless explicitly instructed to do so by the physician. Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- There are no special storage conditions. It is recommended to store it at room temperature.

## **6. FURTHER INFORMATION**

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

Tablet core:

Cellulose, microcrystalline  
Calcium hydrogen phosphate, anhydrous  
Sodium starch glycolate

Magnesium stearate

Film-coat:

Poly (vinyl alcohol)  
Talc  
Titanium dioxide  
Macrogol 3350  
Soya lecithin  
Indigo carmine aluminium lake (E132)

• What the medicine looks like and the contents of the package:

150 mg tablets: blue, oval, film-coated, debossed with "MVC 150" on one side and plain on the other.

300 mg tablets: blue, oval, film-coated, debossed with "MVC 300" on one side and plain on the other.

Blister packs, packaged in a carton. Each package contains: 10, 30, 60, 90 or 180 tablets.

Not all pack sizes may be marketed.

• License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

• Manufacturer: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany.

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

CESENTRI 150 mg: 139-61-31670

CESENTRI 300 mg: 139-62-31671

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