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

The medicine is dispensed with a physician's prescription only

CELSENTRI 150 mg

CELSENTRI 300 mg

Film-coated tablets

Each CELSENTRI 150 mg tablet contains 150 mg maraviroc

Each CELSENTRI 300 mg tablet contains 300 mg maraviroc

For the list of inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

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?

CELSENTRI is a medicine that belongs to a group called CCR5 co-receptor antagonists. CELSENTRI 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 CELSENTRI 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 CELSENTRI.

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, to peanuts, soya or to any of the additional ingredients contained in the medicine as listed in section 6 "Additional information" 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

CELSENTRI can cause serious side effects, including serious liver problems (liver toxicity). Some people taking CELSENTRI can develop a severe rash or an allergic reaction before liver problems occur, which may be life-threatening. **Stop taking CELSENTRI and refer to the physician immediately if any of the following signs or symptoms of liver problems occur:**
- an itchy rash on the body (allergic reaction).
- yellowing of the skin or whites of the eyes (jaundice).
- dark or tea-colored urine.
- vomiting.
- pain, aching, or tenderness on the right side of the stomach area.

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

Before beginning treatment with CELSENTRI, tell the 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 CELSENTRI may harm your unborn baby.
- you are breast-feeding or plan to breast-feed. **Do not breast-feed if you are taking CELSENTRI.** Do not breast-feed if you have HIV-1, due to the risk of passing HIV-1 to your baby. Consult the physician about the best way to feed your baby.

Children and adolescents
CELSENTRI 150 and 300 mg film-coated tablets are not intended for children and adolescents under 18 years of age.

Tests and follow-up
The physician will ask you to do blood tests to check your liver before you start treatment with CELSENTRI and as needed during treatment with CELSENTRI.

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 CELSENTRI. Keep a list of the medicines you are taking to show the physician and pharmacist. You can ask the physician or pharmacist for a list of the medicines that interact with CELSENTRI.

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

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

Pregnancy and breast-feeding

Pregnancy

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

Breast-feeding

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

Driving and operating machinery

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

Important information about some of the ingredients of the medicine

CELSENTRI contains soya lecithin and sodium.
If you are allergic to peanuts or soya, do not use CELSENTRI.
CELSENTRI 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.
CELSENTRI comes in 150 mg and 300 mg tablets. The physician will prescribe the dosage that is right for you.
Swallow CELSENTRI tablets whole. Do not chew the tablets.

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

CELSENTRI can be taken with or without food.

Do not change the dosage of the medicine and do not stop taking CELSENTRI without first talking with the physician.

Do not exceed the recommended dosage.

If you accidentally have taken 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 forgot 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 the physician.

You should be under follow-up by a physician during the course of treatment with CELSENTRI.
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 CELSENTRI supply starts to run low, get more from the 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 CELSENTRI 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.

CELSENTRI 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 CELSENTRI. If you develop a rash with any of the following symptoms, stop using CELSENTRI and contact the physician right away:
  - fever
  - generally ill feeling
  - muscle aches
  - blisters or sores in the 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 the 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)** that may cause dizziness or fainting. Avoid driving and operating heavy machinery if you have dizziness while taking CELSENTRI.
- **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 the

physician immediately if you develop new symptoms during the course of treatment with CELSENTRI.

- **Possible risk of infection or cancer.** CELSENTRI affects other immune system cells and therefore may increase your chance for getting other infections or cancer.

The most common side effects of CELSENTRI 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 CELSENTRI. **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) 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.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL 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, with the text “MVC 150” debossed on one side and plain on the other.
300 mg tablets: blue, oval, film-coated, with the text “MVC 300” debossed 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: ViiV Healthcare UK Ltd., London, England.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  CELSENTRI 150 mg: 139-61-31670
  CELSENTRI 300 mg: 139-62-31671

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Cel PT v7B