

SCHEDULING STATUS:

S4

CELSENTRI 150 mg Film-coated Tablets

CELSENTRI 300 mg Film-coated Tablets

Maraviroc 150 mg or 300 mg

Sugar-free

Read all of this leaflet carefully before you start using CELSENTRI.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- CELSENTRI has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What CELSENTRI is and what it is used for
2. What you need to know before you take CELSENTRI
3. How to take CELSENTRI
4. Possible side effects
5. How to store CELSENTRI
6. Contents of the pack and other information.

1. What CELSENTRI is and what it is used for:

CELSENTRI is an (antiviral) anti-HIV medicine called a CCR5 antagonist. HIV (Human Immunodeficiency Virus) is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

CELSENTRI works by blocking a receptor called CCR5 which HIV uses to enter and infect your blood cells. These blood cells (called CD4 or T-cells) are important in helping your body to fight infection.

CELSENTRI does not cure HIV infection; in combination with other antiretroviral medicines, it reduces the amount of virus in your bloodstream.

CELSENTRI is only taken by patients who have been identified as being infected with a particular strain of the HIV-1 virus called CCR5-tropic HIV-1 infection.

2. What you need to know before you take CELSENTRI:

Do not take CELSENTRI tablets, if you:

- Are allergic (hypersensitive) to maraviroc or any of the other ingredients contained in CELSENTRI.

Warnings and precautions:

Take special care with CELSENTRI:

- If you have liver problems including a history of hepatitis B or C.
- If you have ever had heart problems, a heart attack or angina (ischaemic heart disease), dizziness (low blood pressure) on standing (postural hypotension).
- If you have or previously had any kidney problems. Your doctor may adjust your dose of CELSENTRI.
- People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections such as tuberculosis flare up, causing signs and symptoms of inflammation. Symptoms of infection and inflammation may develop, caused by either:
  - old, hidden infections flaring up again as the body fights them
  - the immune system attacking healthy body tissue (autoimmune disorders).

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. (See “Conditions you need to look out for” in section 4.).

- People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:
  - Fat may be lost from the legs, arms, or face.
  - Extra fat may build up around the stomach, or on the breasts or internal organs.
  - Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

  If you notice changes in your body shape, **tell your doctor immediately**.
- If you experience joint aches and pain, joint stiffness or difficulty in movement **tell your doctor immediately**.
- HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). CELSENTRI will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:
  - **Use a condom** when you have oral or penetrative sex.
  - **Do not risk blood transfer** – for example, don’t share needles.
- CELSENTRI must be taken in combination with other anti-retroviral medicines (combination therapy). To control your HIV infection and to stop your illness getting worse, you must keep taking all your medicines.

Other medicines and CELSENTRI:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines can affect how well CELSENTRI works or make it more likely that you will have side effects. These include:

- Other anti-retroviral medicines (also used to treat HIV or hepatitis C infections) such as efavirenz, etravirine, lopinavir, saquinavir, darunavir, delviradine, elvitegravir, atazanavir, nelfinavir, indinavir, boceprevir or telaprevir.
- Antibiotics (used to treat infections) such as clarithromycin, telithromycin, rifabutin or rifampicin.
- Antifungal medicines (used to treat fungal infections) such as ketoconazole or itraconazole.
- St. John's Wort (a herbal remedy used for depression).
- Anticonvulsant medicines (used to treat seizures [fits]) such as carbamazepine, phenobarbitone and phenytoin.

CELSENTRI with food and drink and alcohol:

CELSENTRI tablets can be taken with or without food.

Pregnancy, breastfeeding and fertility:

If you are HIV-positive you should not breastfeed your baby, because of the chance of passing HIV to your baby. Talk to your doctor about the best way to feed your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

Driving and using machines:

CELSENTRI may cause dizziness, therefore do not drive, or operate any tools or machinery or cycle unless you are sure you are not affected.

CELSENTRI contains soya lecithin.

If you are allergic to peanut or soya do not use this medicine.

3. How to take CELSENTRI:

Do not share medicines prescribed for you with any other person.

- Always take CELSENTRI exactly as your doctor or pharmacist has told you.
- Check with your doctor or pharmacist if you are not sure.
- If you have the impression that the effect of CELSENTRI is too strong or too weak, talk to your doctor or pharmacist.

CELSENTRI comes in 150 mg and 300 mg tablets.

The usual dose of CELSENTRI is 150 mg, 300 mg, or 600 mg twice per day.

- Your doctor will prescribe the dose that is right for you.
- Take CELSENTRI twice a day.
- Swallow CELSENTRI tablets whole. Do not chew the tablets.

Always take CELSENTRI with the other anti-HIV medicines prescribed by your doctor.

It is very important to take all your anti-HIV medicines as prescribed and at the same time each day. This can help your medicines work better. It also lowers the chance that your medicines will stop working to fight HIV (resistance).

Do not change your dose or stop taking CELSENTRI or your other anti-HIV medicines without first talking with your doctor.

If you take more CELSENTRI than you should:

Call your doctor or pharmacist immediately.

If neither is available, seek immediate help at the nearest hospital or poison control centre.

If you forget to take CELSENTRI:

Take the next dose of CELSENTRI as soon as possible and then take your next scheduled dose at its regular time.

If it is less than 6 hours before your next dose, do not take the missed dose. Wait and take the next dose at the regular time.

Do not take a double dose to make up for a missed dose.

If you stop taking CELSENTRI:

When your CELSENTRI supply starts to run low, ask your doctor or pharmacist for a refill or repeat. Do not wait until you run out.

This is very important because the amount of virus in your blood may increase and CELSENTRI could stop working if it is stopped for even a short period of time.

4. Possible side effects:

CELSENTRI can have side effects.

Not all side effects reported for CELSENTRI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CELSENTRI, please consult your healthcare provider for advice.

It is very important to talk to your doctor about any changes in your health.

Conditions you need to look out for:

Liver problems:

These have been reported while taking CELSENTRI. The following may be signs and symptoms of liver problems:

- a general feeling of being sick or unwell
- feeling very tired
- loss of appetite
- stomach pain or tenderness
- itching
- yellow eyes and skin (jaundice)
- dark urine
- drowsiness and confusion
- fever.

- **Contact a doctor immediately if you get symptoms like these. Stop taking CELSENTRI**.

Serious allergic or skin reactions:

Severe and life-threatening skin reactions and allergic reactions have been reported in some patients taking CELSENTRI. If you get any of the following symptoms while you're taking CELSENTRI:

- swelling of the face, lips or tongue
- difficulty breathing
- widespread skin rash
- fever
- blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.

- **Contact a doctor immediately. Stop taking CELSENTRI**.

Symptoms of infection and inflammation:

Symptoms of infection and inflammation may develop and include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands and feet and moving upwards towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection while you're taking CELSENTRI:

- **Tell your doctor immediately**. Do not take other medicines for the infection without your doctor's advice.

See "Warnings and precautions" in section 2.

Frequent side effects:

- diarrhoea, vomiting, feeling sick, stomach-ache or pain, flatulence, constipation, indigestion
- numbness, tingling or weakness of the arms, hands, legs, or feet
- headache, dizziness, taste disturbance, feeling drowsy, problems sleeping, abnormal dreams, depression
- feeling weak, loss of appetite, lack of energy, swelling of lower legs and feet
- muscle spasm, muscle aches or pains, back pain, neck pain
- cough
- rash, unusual hair loss or thinning.

Frequent side effects that may show up in blood tests:

- increase in some substances (*enzymes*) produced by the liver
- increase in a substance (creatine phosphokinase) which may be found in blood tests when muscles are inflamed or damaged
- reduction in the number of red blood cells (*anaemia*).

Less frequent side effects:

- a severe or life-threatening skin reaction (see “Conditions you need to look out for” in section 4, Serious allergic or skin reactions)
- feeling dizzy, faint or light-headed when standing up
- allergic reactions involving liver damage or liver disease (see “Conditions you need to look out for” in section 4, Liver problems).

Not all side effects reported for CELSENTRI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CELSENTRI, please consult your doctor, pharmacist, or other healthcare professional for advice.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CELSENTRI.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store CELSENTRI:

Store CELSENTRI tablets at or below 30 °C.

Store CELSENTRI in the original package and keep the container in the outer carton.

Store all medicines out of reach of children.

Do not use the medicine after the expiry date stated on the blister foil and carton.

Take medicine that is out of date or that you no longer need to your nearest pharmacy for disposal. Do not dispose of your medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information:

What CELSENTRI contains:

Each film-coated tablet contains the active substance maraviroc.

The other ingredients are dibasic calcium phosphate (anhydrous), FD&C blue #2 aluminium lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol (macrogol 3350), polyvinyl alcohol, sodium starch glycollate, soya lecithin, talc and titanium dioxide.

What CELSENTRI looks like and contents of the pack:

Blue, biconvex, oval film-coated tablets with 'MVC 150' or 'MVC 300' on one side.

CELSENTRI 150 mg and 300 mg tablets are supplied in clear polyvinyl chloride (PVC) blisters with aluminium lidding foil backing or child-resistant aluminium/polyethylene terephthalate (PET) lidding foil backing, in a carton containing 60 film-coated tablets for the 150 mg and 300 mg strengths.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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