

Package leaflet: information for the user

CELSENTRI 20 mg /mL oral solution maraviroc

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

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 contains a medicine called maraviroc. Maraviroc belongs to a group of medicines called CCR5 antagonists. CELSENTRI works by blocking a receptor called CCR5 which HIV uses to enter and infect your blood cells.

CELSENTRI is used to treat Human Immunodeficiency Virus type-1 (HIV-1) in adults, adolescents and children of 2 years and older, and weighing at least 10 kg.

CELSENTRI must be taken in combination with other medicines which are also used to treat the HIV infection. These medicines are all called *anti-HIV medicines or antiretrovirals*.

CELSENTRI, as part of combination therapy, reduces the amount of virus in your body, and keeps it at a low level. This helps your body to increase the CD4 cell count in your blood. CD4 cells are a type of white blood cell that are important in helping your body to fight infection.

2. What you need to know before you take CELSENTRI

Do not take CELSENTRI

- if you (or your child, if they are the patient) are **allergic** to maraviroc or to any of the other ingredients of CELSENTRI (*listed in section 6*).

→ **Check with your doctor** if you think this applies to you or your child.

Warnings and precautions

Talk to your doctor or pharmacist before taking or giving CELSENTRI.

Your doctor must take blood samples to test whether CELSENTRI is an appropriate treatment for you (or your child, if they are the patient).

Some people taking CELSENTRI have developed serious allergic reactions or skin reactions (*see also 'Serious side effects' in section 4*).

Before taking this medicine, make sure that your doctor knows if you (or your child) have or in the past had any of the following:

- **liver** problems, including chronic **hepatitis B** or **C**. Only a limited number of people with liver problems have taken CELSENTRI. Your liver function may need to be closely monitored. (*See also 'Liver problems' in section 4*).
 - **low blood pressure**, including dizziness when you stand up or sit up quickly, or if you are taking any medicines to lower blood pressure. This is due to a sudden fall in blood pressure. If this happens, lie down until you (or your child) feel better. When getting up, do so as slowly as possible.
 - **tuberculosis (TB)** or serious **fungal infections**. CELSENTRI could potentially increase your risk of developing infections.
 - **kidney** problems. This is particularly important if you are also taking some other medicines (*see 'Other medicines and CELSENTRI' later in section 2*).
 - **problems with your heart or circulatory system**. Only a limited number of people with serious heart or circulatory problems have taken CELSENTRI.
- ➔ **Tell your doctor** before starting treatment if you think any of these apply to you (or your child).

Conditions you need to look out for

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems.

You need to know about important signs and symptoms to look out for while you're taking CELSENTRI.

➔ **Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.**

Protect other people

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). You (or your child) can still pass on HIV when taking this medicine, although the risk is lowered by effective treatment.

➔ Talk to your doctor about how to avoid infecting other people.

Older people

CELSENTRI has only been taken by limited numbers of people 65 years or older. If you belong to this age group, discuss with your doctor if you can use CELSENTRI.

Children

CELSENTRI has not been tested in children under the age of 2 or weighing less than 10 kg. Therefore CELSENTRI is not recommended for children younger than 2 years, or weighing less than 10 kg.

Other medicines and CELSENTRI

Tell your doctor or pharmacist if you (or your child) are taking any other medicines, have recently taken, or might take any other medicines.

Tell your doctor or pharmacist if you (or your child) begin taking a new medicine while taking CELSENTRI.

Medicines containing **St. John's Wort** (*Hypericum perforatum*) are likely to prevent CELSENTRI from working properly. **You should not take them while you're taking CELSENTRI.**

Some medicines may change the amount of CELSENTRI in the body when they are taken at the same time as CELSENTRI. These include:

- other medicines to treat **HIV** or **hepatitis C** infection (such as atazanavir, cobicistat, darunavir, efavirenz, etravirine, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, boceprevir, telaprevir)
- **antibiotics** (clarithromycin, telithromycin, rifampicin, rifabutin)
- **antifungal** medicines (ketoconazole, itraconazole, fluconazole)
- **anticonvulsant** medicines (carbamazepine, phenytoin, phenobarbital).

➔ **Tell your doctor** if you (or your child) are taking any of these medicines. This will allow your doctor to prescribe the right dose of CELSENTRI.

Pregnancy and breast-feeding

If you are pregnant, if you become pregnant, or if you are planning to have a baby:

➔ **Talk to your doctor** about the risks and benefits of taking CELSENTRI.

Women who are HIV-positive must not breast-feed, because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients in CELSENTRI can also pass into breast milk. If you are breast-feeding, or thinking about breast-feeding:

➔ **Talk to your doctor** immediately.

Driving and using machines

CELSENTRI can make you dizzy.

➔ **Don't drive, cycle, or operate tools or machines** unless you are sure you're not affected.

CELSENTRI contains sodium benzoate and sodium.

CELSENTRI contains 1 mg sodium benzoate (E 211) in each mL.

CELSENTRI contains less than 1 mmol sodium (23 mg) in each mL, that is to say essentially 'sodium free'.

3. How to take CELSENTRI

Always take or give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will advise you whether it is better to take CELSENTRI oral solution, if you (or your child) are unable to swallow tablets.

How much to take

Adults

The recommended dose of CELSENTRI is either **150 mg (7.5 ml)**, **300 mg (15 ml)** or **600 mg (30 ml) twice daily**, depending on other medicines that you are taking at the same time. Always take the dose recommended by your doctor.

People with kidney problems

If you have a kidney problem, your doctor may alter your dose.

➔ **Talk to your doctor** if this applies to you.

Adolescents and children from 2 years of age and weighing at least 10 kg

Your doctor will decide the correct dose of CELSENTRI, based on weight and on other medicines being taken at the same time.

See the diagram and instructions at the end of this section for how to measure and take (or give) a dose of medicine.

CELSENTRI can be taken with or without food. CELSENTRI should always be taken by mouth.

CELSENTRI must be taken in combination with other medicines to treat HIV. Refer to the Package Leaflets of these other medicines for guidance on how to take them.

If you take or give more CELSENTRI than you should

If you accidentally take or give too much CELSENTRI:

➔ **Contact your doctor or the nearest hospital immediately.**

If you forget to take or give CELSENTRI

If you (or your child) miss a dose of CELSENTRI, take or give the missed dose as soon as possible and then continue with the next dose at its regular time.

If it is almost time for the next dose, do not take or give the missed dose. Wait for the next dose at its regular time.

Do not take or give a double dose to make up for a forgotten dose.

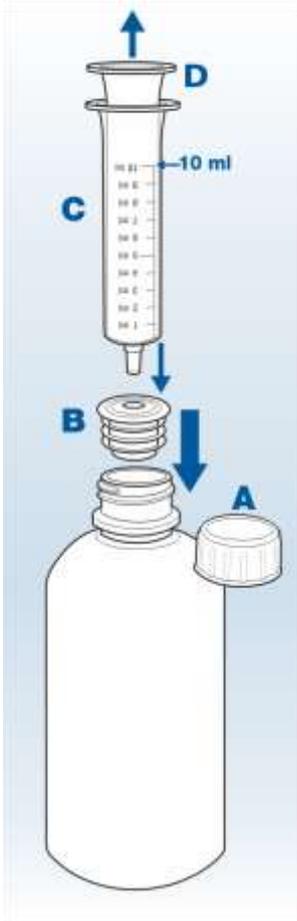
If you or your child stop taking CELSENTRI

Keep taking CELSENTRI until your doctor tells you to stop.

Taking your medicines at the right time every day is important as it makes sure the HIV infection does not increase in your body. Therefore, unless your doctor tells you (or your child) to stop treatment, it is important to keep taking CELSENTRI correctly, as described above.

If you have any further questions on the use of this medicine, ask your doctor or your pharmacist.

How to measure the dose and take the medicine



Use the oral applicator supplied with the pack to measure your dose accurately.

1. **Remove the bottle cap (A)**. Keep it safely
2. Hold the bottle firmly. **Push the plastic adapter (B) into the neck of the bottle** so it is fully inserted.
3. **Insert the applicator (C)** firmly into the adapter.
4. Turn the bottle upside down.
5. **Pull out applicator plunger (D)** until the **applicator** contains the first part of the full dose.
6. Turn the bottle the correct way up. **Remove the applicator** from the adapter.
7. **Put the applicator into your (or your child's) mouth**, placing the tip of the applicator against the inside of the cheek. **Slowly push the plunger in**, allowing time to swallow. **Do not** push too hard and squirt the liquid into the back of the throat, as that could cause choking.
8. **Repeat steps 3 to 7** in the same way until the whole dose has been taken. For example, if the dose is 15 ml, you need one and a half applicator -full of medicine.
9. **Remove and wash** the applicator thoroughly in clean water once you have finished using it. Let it dry completely before you use it again.
10. **Close the bottle tightly** with the cap, leaving the adaptor in place.

Dispose of any unused oral solution 60 days after first opening the bottle.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor if you notice anything unusual about your own health or your child's health.

Serious side effects — get medical help immediately

Serious allergic or skin reactions

Some people taking CELSENTRI have developed severe and life-threatening skin reactions and allergic reactions. These are rare, and may affect up to 1 in 1,000 people 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 (high temperature)
- blisters and peeling skin, particularly around the mouth, nose, eyes and genitals.

➔ **Get medical help immediately** if you get these symptoms. **Stop taking CELSENTRI.**

Liver problems

These are rare, and may affect up to 1 in 1,000 people taking CELSENTRI.

Signs include:

- loss of appetite
- feeling sick or being sick
- yellowing of skin or eyes
- skin rash or itching
- feeling very tired
- stomach pain or tenderness
- dark urine
- drowsiness and confusion
- fever (high temperature).

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

Other side effects

Common side effects

These may affect **1 to 10 in 100 people**:

- diarrhoea, feelingsick, stomach ache, wind (*flatulence*),
- loss of appetite
- headache, problems sleeping, depression
- rash (*see also 'Serious allergic or skin reactions' earlier in section 4*)
- feeling weak or lack of energy, anaemia (seen in blood test result)
- increase in liver enzymes (seen in blood test results), which can be a sign of liver problems (*see also 'Liver problems' earlier in section 4*).

Uncommon side effects

These may affect **up to 1 in 100 people**:

- lung infection
- fungal infection of the gullet (*oesophagus*)
- fits (*seizures*)
- feeling dizzy, faint or light headed when standing up

- kidney failure, protein in the urine
- an increase in a substance known as CPK (seen in blood test results) which is a sign that muscles are inflamed or damaged.

Rare side effects

These may affect **up to 1 in 1,000 people**:

- chest pain (caused by reduced blood flow to the heart)
- decrease in muscle size
- some types of cancer, such as of the gullet (*oesophagus*) and bile duct
- decrease in number of blood cells (seen in blood test results).

Other possible side effects of combination therapy for HIV

People taking combination therapy for HIV may get other side effects.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (*opportunistic infections*). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

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. Symptoms may include:

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

If you get any symptoms of infection or if you notice any of the symptoms above:

➔ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. It is not known how common this condition is. You may be more likely to develop it:

- if you have been taking combination therapy for a long time
- if you are also taking anti-inflammatory medicines called corticosteroids
- if you drink alcohol
- if you have a very weak immune system
- if you are overweight.

Signs to look out for include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

➔ Tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CELSENTRI

Keep this medicine out of the sight and reach of children.

Do not use CELSENTRI after the expiry date which is stated on the bottle and carton label. The expiry date refers to the last day of that month.

Store the oral solution below 30°C.

Discard 60 days after first opening. Write the date the oral solution should be discarded on the carton in the space provided. The date should be written as soon as the bottle has been opened for first use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What CELSENTRI contains

- The active substance is 20 mg of maraviroc in each ml of the solution.
- The other ingredients are: citric acid (anhydrous), sodium citrate dihydrate, sucralose, sodium benzoate (E211), strawberry flavouring (501440T), purified water

What CELSENTRI looks like and contents of the pack

CELSENTRI oral solution is supplied in a carton containing a high density polyethylene bottle, with a child resistant cap. The solution is colourless with strawberry flavouring. The bottle contains 230 ml of maraviroc solution (20 mg/ml). The pack includes an oral applicator and a bottle-adapter, which should be fitted in the bottle before use.

Marketing Authorisation Holder

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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: CELSENTRI 20 mg /mL oral solution

Reference number: 35728/0037

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in March 2021

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