

## Consumer Medicine Information

### What is in this leaflet

Please read this leaflet carefully before you start taking Celsentri. This leaflet answers some common questions about Celsentri.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Celsentri against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Celsentri is used for

Celsentri is used in combination with other anti-HIV medicines in the treatment of HIV-1 infection. Its active ingredient, maraviroc, belongs to a group of medicines called CCR5 blockers.

Celsentri prevents the entry of HIV-1 into the cells in your blood that are attacked by the HIV virus (called CD4 or T-cells). Celsentri works by blocking the CCR5 receptor which is the most common gateway the HIV virus uses to gain entry into these cells.

Celsentri reduces the amount of HIV in your body and enhances your immune system.

You should be aware that Celsentri is not a cure for HIV or AIDS and that appropriate precautions should be taken to prevent transmission.

Celsentri should be taken in combination with other medicines used to treat HIV.

**Ask your doctor if you have any questions about why Celsentri has been prescribed for you.**

Your doctor may have prescribed Celsentri for another reason.

This medicine is only available with a doctor's prescription.

### Before you take Celsentri

#### **When you must not use it**

Do not take CESENTRI if you have an allergy to:

- any medicine containing maraviroc
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### **Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- liver problems including Hepatitis B or Hepatitis C, as your liver function may need to be closely monitored. If you notice symptoms of hepatitis (loss of appetite, fever, feeling sick/being sick and/or yellowing of skin or eyes), rash and/or itching, you should stop taking Celsentri and inform your doctor immediately.
- a history of low blood pressure and/or if you are taking any medication to lower blood pressure
- kidney problems, particularly if you are taking certain antibiotics (clarithromycin, telithromycin), antifungal medicines (ketoconazole, itraconazole) and/or protease inhibitors (except for tipranavir/ritonavir)
- problems with your heart or circulatory system as there is only limited experience in patients with serious problems of this type

**Tell your doctor if you are pregnant or plan to become pregnant.** It is not known if Celsentri can harm your unborn child. Your doctor can discuss with you the risks and benefits involved if you do need to take Celsentri during your pregnancy.

**Tell your doctor if you are breast-feeding.** You must not breast-feed if you are infected with HIV because the virus may be transmitted through the breast milk. It is not known whether the active ingredient in Celsentri can pass into your breast milk. Therefore, mothers must not breast-feed during treatment with Celsentri.

If you have not told your doctor about any of the above, tell him/her before you start taking Celsentri.

Your doctor may take blood samples to test whether Celsentri is an appropriate treatment for you.

### ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Celsentri may interfere with each other. These include:

Insert any specific interactions as dot points, as per PI. Avoid long lists of dot points by grouping similar medicines whenever possible. Include what they are used for.

- lopinavir, saquinavir, atazanavir, ritonavir and other protease inhibitors, medicines used to treat viral infections
- delavirdine, efavirenz and nevirapine, medicines used to treat viral infections
- ketoconazole and itraconazole, medicines used to treat fungal infections
- clarithromycin, telithromycin, rifampicin and rifabutin, medicines used to treat bacterial infections
- nefazodone, a medicine used to treat depression

These medicines may be affected by Celsentri or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Medicines containing St. John's wort (*Hypericum perforatum*) are likely to prevent Celsentri from working properly and should not be taken together with Celsentri.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take Celsentri**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

### ***How much to take***

The usual dose of Celsentri is 150 mg, 300 mg or 600 mg twice per day depending on other medicines that you are taking at the same time as Celsentri. Always take the dose recommended by your doctor.

### ***How to take it***

Celsentri tablets should be taken by mouth in combination with other anti-HIV medicines. Your doctor will tell you the dosage for the other anti-HIV medicines and whether or not you should take them at a different time to Celsentri

Celsentri tablets may be taken with or without food.

### ***When to take it***

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

**It is very important to take all your anti-HIV medicines as prescribed**

**and at the right times of day. This can help your medicines work better. It also lowers the chance that your medicines will stop working to fight HIV (drug resistance).**

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### ***If you forget to take it***

**If it is almost time for your next dose skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or Poisons Information Centre – the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766 or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much Celsentri. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include dizziness or light-headedness

when you stand or sit up quickly. If this happens, lie down until you feel better. When you get up, do so as slowly as possible.

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## While you are taking Celsentri

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Celsentri.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Continue to use safe sexual practices while taking Celsentri. Celsentri has not been shown to decrease the chance of giving HIV to your partner.**

### ***Things you must not do***

**Do not take Celsentri to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

**Do not take any other medication unless your doctor is aware of it.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Celsentri affects you.**

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Celsentri.**

This medicine helps most people with HIV infection but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Frequently it is difficult to tell whether side effects are the result of taking Celsentri, effects of the HIV disease or side effects of other medicines you may be taking. For this reason it is very important to inform your doctor of any change in your condition. Your doctor may want to change your dose or advise you to stop taking Celsentri.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- diarrhoea
- nausea or vomiting
- headache
- stomach pain or discomfort
- indigestion
- constipation
- dizziness
- abnormal sense of taste
- problems sleeping
- rash
- loss of appetite
- muscle spasms or pain
- cough

These are the more common side effects of your medicine.

**Tell your doctor as soon as possible if you notice any of the following:**

- tiredness, being short of breath and looking pale

- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds
- swollen glands in the neck, armpit and/or groin
- bleeding from the back passage (rectum)
- weakness, tiredness, loss of appetite, weight loss, stomach pain and swelling, nausea, vomiting, ankle swelling, and yellowing of the skin and/or eyes
- chest pain, fever, cough and shortness of breath (pneumonia)
- muscle aches or pain
- fainting
- epilepsy or fits
- inability to move the muscles in the face
- tingling or burning sensation in the hands or feet
- loss of reflexes
- hallucination
- low back pain, blood in your urine, a change in the colour of your urine, passing less or more urine than normal and/or a general feeling of itchiness (kidney disease)
- passing more urine than normal
- breathing difficulties such as shortness of breath

These are uncommon serious side effects which may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- symptoms of hepatitis such as loss of appetite, fever, feeling sick/being sick and/or yellowing of skin or eyes, rash and/or itching
- chest pain or angina
- severe upper stomach pain, often with nausea and vomiting

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## After taking Celsentri

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### Storage

**Keep your Celsentri tablets in the pack or bottle until it is time to take them.**

If you take the tablets out of the pack or bottle they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store Celsentri or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep Celsentri where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### What Celsentri looks like

Celsentri film-coated tablets are blue in colour and oval-shaped. The tablets are marked with “MVC 150” or “MVC 300” on one side.

Celsentri 150 mg and 300 mg film-coated tablets are supplied in plastic bottles of 180 tablets or in blister packs of 60 tablets.

### Ingredients

#### Active Ingredients:

The active ingredient in Celsentri is maraviroc. Each tablet contains either 150 mg or 300 mg of maraviroc.

#### Inactive Ingredients:

Celsentri also contains microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), sodium starch glycollate and magnesium stearate. The film-coat [Opadry II Blue (85G20583)] contains indigo carmine CI73015, soya lecithin, macrogol 3350, polyvinyl alcohol, talc and titanium dioxide.

### Supplier

Celsentri is supplied in Australia by:

ViiV Healthcare Pty Ltd  
Level 4  
436 Johnston Street  
Abbotsford Victoria 3067  
Australia

Celsentri is supplied in New Zealand by:

GlaxoSmithKline NZ Limited  
Private Bag 106600  
Downtown  
Auckland  
NEW ZEALAND

Telephone: (09) 367 2900

Facsimile: (09) 367 2506

### Australian Registration Numbers

- CELENTRI 150 mg film-coated tablets in blister packs AUST R 137329
- CELENTRI 300 mg film-coated tablets in blister packs AUST R 137331

This leaflet was prepared on 29 November 2011.

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