

Maraviroc Waymade

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Maraviroc Waymade?

Maraviroc Waymade contains the active ingredient maraviroc. Maraviroc Waymade is used in combination with other medicines to treat HIV.

For more information, see Section [1. Why am I using Maraviroc Waymade?](#) in the full CMI.

2. What should I know before I use Maraviroc Waymade?

Do not use if you have ever had an allergic reaction to [medicine] or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Maraviroc Waymade?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Maraviroc Waymade and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Maraviroc Waymade?

- The usual dosage is either 150 mg, 300 mg or 600 mg twice a day.
- The dose you take will depend on whether you are taking any other medicines with Maraviroc Waymade.
- Swallow the tablets whole with a glass of water. Do not chew.
- Maraviroc Waymade can be taken with or without food

More instructions can be found in Section [4. How do I use Maraviroc Waymade?](#) in the full CMI.

5. What should I know while using Maraviroc Waymade?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you
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	<p>are using Maraviroc Waymade.</p> <ul style="list-style-type: none"> ● Tell your doctor immediately if you become pregnant whilst taking Maraviroc Waymade.
Things you should not do	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly or change the dose without talking to your doctor. ● Do not take this medicine to treat any other complaints.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools until you know how Maraviroc Waymade affects you. ● Maraviroc Waymade may cause dizziness and light-headedness in some people.
Looking after your medicine	<ul style="list-style-type: none"> ● Store Maraviroc Waymade below 25°C. ● Keep this medicine in the pack until it is time to take it.

For more information, see Section [5. What should I know while using Maraviroc Waymade?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported include diarrhoea, constipation, nausea or vomiting, stomach pain or discomfort, indigestion, dizziness, abnormal sense of taste, problems sleeping or abnormal sleep, rash, loss of appetite, muscle spasms or pain, cough, joint pain, fever, colds, upper respiratory tract infections or flu-like symptoms.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Maraviroc Waymade

Active ingredient(s): *maraviroc*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Maraviroc Waymade.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Maraviroc Waymade .

Where to find information in this leaflet:

- [1. Why am I using Maraviroc Waymade ?](#)
- [2. What should I know before I use Maraviroc Waymade?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Maraviroc Waymade?](#)
- [5. What should I know while using Maraviroc Waymade?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Maraviroc Waymade?

Maraviroc Waymade contains the active ingredient maraviroc. Maraviroc Waymade is belongs to a group of medicines called CCR5 blockers.

Maraviroc Waymade is used in combination with other medicines to treat human immunodeficiency virus (HIV).

Maraviroc Waymade reduces the amount of HIV in your body and helps your immune system. It stops the HIV-1 virus entering the CD-4 cells in your blood (also called T-cells). These are the cells in your immune system that the HIV virus attacks.

Maraviroc Waymade works by blocking the most common entry point into the CD-4 cells – called the 'CCR5 receptor'. Because the virus cannot enter the cell, it cannot attack it, and this prevents further damage to your immune system.

Maraviroc Waymade only stops the HIV-1 virus entering the cell, not HIV-2 (another rarer kind of the HIV virus). Maraviroc Waymade also only stops types of HIV-1 virus that enter using the CCR5 receptor. As a result, your doctor would have done a blood test to check what strain of HIV-1 virus you have before they prescribed you this medicine.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus.

Maraviroc Waymade does not cure HIV. You should use proper precautions to prevent transmission of HIV to others from occurring. Discuss with your doctor the precautions needed to avoid infecting other people.

2. What should I know before I use Maraviroc Waymade?

Warnings

Do not use Maraviroc Waymade if:

- you are allergic to maraviroc, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- have liver problems, hepatitis B or hepatitis C infection so that your liver function can be monitored
- have a history of low blood pressure, low blood pressure upon standing up (known as postural hypotension) or are taking any medicine to lower your blood pressure
- have kidney problems
- have heart problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known if Maraviroc Waymade can harm your unborn child. Your doctor can discuss with you the benefits and risks of taking Maraviroc Waymade whilst pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not breastfeed if you are infected with HIV because the virus can be transmitted through breastmilk. It is not known whether the active ingredient in Maraviroc Waymade can pass into your breastmilk. Therefore, you should not breastfeed whilst taking Maraviroc Waymade.

Children

Maraviroc Waymade has not been studied in children less than 18 years of age

Clinical Trials

More treatment-naïve patients in clinical trials using maraviroc had treatment failures and developed resistance to lamivudine compared to patients using efavirenz.

3. What if I am taking other medicines?

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

Some medicines may interfere with Maraviroc Waymade and affect how it works.

- efavirenz, etravirine, raltegravir, lopinavir, darunavir, delavirdine, elvitegravir, atazanavir, nelfinavir, indinavir, saquinavir, boceprevir, telaprevir – medicines used to treat HIV or hepatitis C infections
- ketoconazole, itraconazole – medicines used to treat fungal infections
- clarithromycin, telithromycin, rifampicin, rifabutin –
- medicines used to treat bacterial infections
- medicines containing St John's Wort (*hypericum perforatum*). St John's Wort can prevent Maraviroc Waymade from working properly. Therefore, you should not take St John's Wort together with Maraviroc Waymade
- carbamazepine, phenobarbital, phenytoin – medicines used to treat seizures

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Maraviroc Waymade.

4. How do I take Maraviroc Waymade?

How much to take

- The usual dosage is either 150 mg, 300 mg or 600 mg twice a day.
- The dose you take will depend on whether you are taking any other medicines with Maraviroc Waymade. Your doctor will tell you the dose to take and when to take these others medicines.
- Follow the instructions provided and use Maraviroc Waymade until your doctor tells you to stop.

It is important to take all your anti-HIV medicines as prescribed and at the right time of day. This can help your medicines to work better. It also lowers the chance of your medicines becoming less effective in fighting HIV (also known as drug resistance).

How to take Maraviroc Waymade

- Swallow the tablet whole with a drink of water. Do not chew the tablet.
- You can take Maraviroc Waymade with or without food.

If you forget to use Maraviroc Waymade

Maraviroc Waymade should be used regularly at the same time each day.

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 Maraviroc Waymade as you would normally.

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

If you use too much Maraviroc Waymade

If you think that you have used too much Maraviroc Waymade, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include dizziness or lightheadedness when you stand up. If this happens, lie down until you feel better and when you get up, get up slowly.

5. What should I know while using Maraviroc Waymade?

Things you should do

Call your doctor straight away if you:

- become pregnant whilst taking Maraviroc Waymade
- Remind any doctor, dentist or pharmacist you visit that you are using Maraviroc Waymade.

Stay in regular contact with your doctor

Things you should not do

- Do not stop using this medicine or change the dose
- Do not start taking any other medicines without first speaking to your doctor
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Maraviroc Waymade affects you.

Maraviroc Waymade may cause dizziness and light-headedness in some people.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place (below 25°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g. pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV.

If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, discuss with your doctor immediately.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • diarrhoea • constipation • nausea or vomiting • stomach pain or discomfort • indigestion • loss of appetite <p>Neurological related:</p> <ul style="list-style-type: none"> • dizziness • abnormal sense of taste • problems sleeping or abnormal sleep <p>Skin related:</p> <ul style="list-style-type: none"> • rash <p>General body related:</p> <ul style="list-style-type: none"> • muscle spasms or pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● cough ● joint pain ● fever ● colds, upper respiratory tract ● infections or flu-like symptoms 	

Serious side effects

Serious side effects	What to do
<p>Neurological related:</p> <ul style="list-style-type: none"> ● weakness, tiredness, headaches, being short of breath, dizziness and looking pale, fainting ● convulsions, fits or seizures, shaking or tremors ● any mental problems, such as ● epilepsy or fits ● loss of reflexes ● hallucinations ● inability to move the muscles in the face ● lower back pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● feeling dizzy, faint or light headed when standing up ● unexpected muscle aches or pain, ● paralysis or weakness <p>General body related:</p> <ul style="list-style-type: none"> ● swollen glands in the neck, armpit or groin ● tingling or burning sensation in the hands or feet ● signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers ● signs of infection such as ● meningitis – fever, nausea, vomiting, headache, stiff neck and sensitivity to bright light ● pneumonia – fever, chills, shortness of breath, cough, phlegm and occasionally blood <p>Gastrointestinal related:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> ● loss of appetite, vomiting and/or ● upper right stomach pain, feeling ● generally unwell, fever, itching <p>Kidney or liver related:</p> <ul style="list-style-type: none"> ● yellowing of the skin and eyes ● passing less or more urine than ● normal or a change in the colour ● of your urine, dark coloured urine <p>Blood related:</p> <ul style="list-style-type: none"> ● bleeding problems such as ● bleeding or bruising more easily than normal, nosebleeds ● bleeding from the back passage (rectum) 	

Possible chance of infection or cancer

Although there is no evidence from clinical trials of an increase in serious infections or cancer, maraviroc Waymade affects other immune system cells and

therefore may potentially increase your chance of getting other infections or cancer.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Maraviroc Waymade contains

Active ingredient (main ingredient)	maraviroc
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<p>Other ingredients (inactive ingredients)</p>	<p>calcium hydrogen phosphate</p> <p>magnesium stearate</p> <p>microcrystalline cellulose</p> <p>sodium starch glycollate</p> <p>hypromellose</p> <p>The film-coating (Opadry II complete film coating system 85F18422 White) contains:</p> <p>macrogol 3350</p> <p>polyvinyl alcohol</p> <p>purified talc</p> <p>titanium dioxide</p>
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Do not take this medicine if you are allergic to any of these ingredients.

What Maraviroc Waymade looks like

150 mg film-coated tablets are white to off white in colour, oval shaped and marked "NAV 125" on one side.

Available in blister packs of 30, 60, 90 or 180 tablets.
AUST R 422790.

300 mg film-coated tablets are white to off white in colour, oval shaped and marked "NAV 124" on one side.

Available in blister packs of 30 or 60 tablets. AUST R 422791.

Who distributes Maraviroc Waymade

Distributed by:
Clinect Pty Ltd
120-134 Atlantic Drive, Keysborough
VIC 3173, Australia

Free Call Australia: 1800 899 005

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