

## Package leaflet: Information for the user

### Maraviroc 150 mg film-coated tablets Maraviroc 300 mg film-coated tablets maraviroc

The full name of your medicine is maraviroc 150 mg or 300 mg film-coated tablets. These are referred to as maraviroc tablets throughout this leaflet

**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 maraviroc tablets are and what they are used for
2. What you need to know before you take maraviroc tablets
3. How to take maraviroc tablets
4. Possible side effects
5. How to store maraviroc tablets
6. Contents of the pack and other information

#### 1. What maraviroc tablets are and what they are used for

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

**Maraviroc is used to treat Human Immunodeficiency Virus type-1 (HIV-1) in adults and adolescents weighing at least 30 kg.**

Maraviroc 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*.

Maraviroc, 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 maraviroc tablets

##### Do not take maraviroc tablets

- if you are **allergic** to maraviroc or to peanut or soya or to any of the other ingredients of maraviroc tablets (*listed in section 6*).
- ➔ **Check with your doctor** if you think this applies to you.

##### Warnings and precautions

Talk to your doctor or pharmacist before taking or giving maraviroc tablets.

Your doctor must take blood samples to test whether maraviroc is an appropriate treatment for you.

Some people taking maraviroc 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 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 maraviroc. 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 feel better. When getting up, do so as slowly as possible.
- **tuberculosis (TB)** or serious **fungal infections**. Maraviroc 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 maraviroc tablets' 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 maraviroc.  
➔ **Tell your doctor** before starting treatment if you think any of these apply to you.

### 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 maraviroc tablets.

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

### Older people

Maraviroc tablet 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 maraviroc tablets.

### Children

The use of maraviroc has not been tested in children under the age of 2 or weighing less than 10 kg. Therefore maraviroc is not recommended in children younger than 2, or weighing less than 10 kg.

### Other medicines and maraviroc tablets

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

Tell your doctor or pharmacist if you begin taking a new medicine while taking maraviroc tablets.

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

Some medicines may change the amount of maraviroc in the body when they are taken at the same time as maraviroc. 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 are taking any of these medicines. This will allow your doctor to prescribe the right dose of maraviroc tablets.

### **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 maraviroc tablets.

Breast-feeding is **not recommended** in women living with HIV, because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients in maraviroc tablets can also pass into breast milk. If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

### **Driving and using machines**

Maraviroc can make you dizzy.

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

### **Maraviroc tablet contains soya lecithin**

If you are allergic to peanut or soya, do not use this medicinal product.

### **Maraviroc tablet contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take maraviroc tablets**

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 maraviroc oral solution, if you are unable to swallow tablets.

### **How much to take**

#### **Adults**

**The recommended dose of maraviroc tablet is 150 mg, 300 mg or 600 mg twice per day** 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.

**Maraviroc tablets can be taken with or without food.** Maraviroc should always be taken by mouth.

Maraviroc 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 maraviroc tablets than you should**

If you accidentally take or give too much maraviroc:

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

#### **If you forget to take or give maraviroc tablets**

If you miss a dose of maraviroc tablet, 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 stop taking maraviroc tablets**

Keep taking maraviroc tablets 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 to stop treatment, it is important to keep taking maraviroc tablets correctly, as described above.

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

#### **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.

#### **Serious side effects — get medical help immediately**

##### **Serious allergic or skin reactions**

Some people taking maraviroc 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 maraviroc.

If you get any of the following symptoms while you're taking maraviroc:

- 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 maraviroc tablets.**

##### **Liver problems**

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

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 maraviroc tablets.**

##### **Other side effects**

##### **Common side effects**

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

- diarrhoea, feeling sick, 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, pharmacist or nurse. 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](http://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 maraviroc tablets**

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

Do not use this medicine after the expiry date which is stated on the outer carton, blister, bottle and the label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

**6. Contents of the pack and other information****What Maraviroc tablets contains**

The active substance is maraviroc.

Each 150 mg film-coated tablet contains 150 mg of maraviroc.

Each 300 mg film-coated tablet contains 300 mg of maraviroc.

**The other ingredients are:**

Tablet core: Cellulose microcrystalline, sodium starch glycolate (Type A), silica colloidal anhydrous, magnesium stearate & calcium hydrogen phosphate.

Tablet coating: Poly (vinyl alcohol) (E1203), talc (E553b), titanium dioxide (E171), macrogol (MW3350) (E1521), lecithin (soya) (E322) & indigo carmine aluminium lake (E132).

**What Maraviroc tablets looks like and contents of the pack**Maraviroc 150 mg tablets

Blue, oval, biconvex, film-coated tablets, debossed with “HM” on one side and “150” on the other side.

Maraviroc 300 mg tablets

Blue, oval, biconvex, film-coated tablets, debossed with “HM” on one side and “300” on the other side.

Maraviroc tablets are available in blister packs containing 60 tablets and HDPE bottle containing 60 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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