

<div><div>MEDICATION GUIDE</div><div>Maraviroc Tablets</div><div>(mah-RAV-er-rock)</div></div>
<div><div>What is the most important information I should know about maraviroc tablets?</div><div><div>Maraviroc tablets can cause serious side effects including serious liver problems (liver toxicity).</div><div>Some people who take maraviroc tablets can develop a severe rash or an allergic reaction before liver problems happen and may be life-threatening. Stop taking maraviroc tablets and call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:</div><div><div><div><div><div>• an itchy rash on your body (allergic reaction)</div><div>• your skin or the white part of your eyes turns yellow (jaundice)</div><div>• dark or “tea-colored” urine</div></div><div><div>• vomiting</div><div>• pain, aching, or tenderness on the right side of your stomach area</div></div></div></div><div>Your healthcare provider will do blood tests to check your liver before you begin treatment with maraviroc and as needed during treatment with maraviroc tablets.</div></div></div></div>
<div><div>What are maraviroc tablets?</div><div><div>Maraviroc tablet is a prescription Human Immunodeficiency Virus-1 (HIV-1) medicine given with other HIV-1 medicines to treat CCR5-tropic HIV-1 infection in adults and children 2 years of age and older weighing at least 22 lb (10 kg). HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).</div><div>Use of maraviroc tablet is not recommended in people with dual/mixed- or CXCR4-tropic HIV-1.</div><div>Maraviroc tablets should not be used in children weighing less than 22 pounds (10 kg).</div></div></div>
<div><div>Do not take maraviroc tablets if you have severe kidney problems or are on hemodialysis and are also taking certain other medications.</div></div>
<div><div>Before you take maraviroc tablets, tell your healthcare provider about all of your medical conditions, including if you:</div><div><div><div>• have or have had liver problems including hepatitis B or C virus infection.</div><div>• have heart problems.</div><div>• have kidney problems.</div><div>• have low blood pressure or take medicines to lower blood pressure.</div><div>• are pregnant or plan to become pregnant. It is not known if maraviroc tablets may harm your unborn baby.</div></div><div><div>Pregnancy Registry. There is a pregnancy registry for women who take maraviroc tablets during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.</div><div><div>• are breastfeeding or plan to breastfeed. Do not breastfeed if you take maraviroc tablets. You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. Talk to your healthcare provider about the best way to feed your baby.</div></div></div><div><div>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.</div><div><div>• Some medicines may interact with maraviroc tablets. Keep a list of your medicines to show your healthcare provider and pharmacist.</div><div>• You can ask your healthcare provider or pharmacist for a list of medicines that interact with maraviroc tablets.</div></div></div></div></div>
<div><div>Do not start taking a new medicine without telling your healthcare provider.</div><div><div>Your healthcare provider can tell you if it is safe to take maraviroc tablets with other medicines. Your healthcare provider may need to change your dose of maraviroc tablets when you take it with certain medicines. You should not take maraviroc tablets if you also take St. John's wort (<i>Hypericum perforatum</i>).</div></div></div>
<div><div>How should I take maraviroc tablets?</div><div><div><div>• Take maraviroc tablets exactly as your healthcare provider tells you.</div><div>• Do not change your dose or stop taking maraviroc tablets without first talking with your healthcare provider.</div><div>• If you miss a dose of maraviroc tablets, take it as soon as you remember. Do not take 2 doses at the same time. If you are not sure about your dosing, call your healthcare provider.</div><div>• Stay under the care of a healthcare provider during treatment with maraviroc tablets.</div><div>• Swallow maraviroc tablets whole. Do not chew the tablets.</div><div>• Maraviroc tablets may be taken with or without food.</div><div>• Your healthcare provider will prescribe a dose of maraviroc tablets based on your child's body weight and other medicines they are taking.</div><div>• Tell your healthcare provider if your child has trouble swallowing tablets. Maraviroc comes as tablets or as a liquid (oral solution).</div><div>• Do not run out of maraviroc tablets. The virus in your blood may increase and the virus in your blood may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.</div><div>• If you take too much maraviroc tablets, call your healthcare provider or go to the nearest hospital emergency room right away.</div></div></div></div>
<div><div>What are the possible side effects of maraviroc tablets?</div><div><div>Maraviroc tablets can cause serious side effects including:</div><div><div><div>• See “What is the most important information I should know about maraviroc tablets?”</div><div>• Severe skin rash and allergic reactions. Severe and potentially life-threatening skin reactions and allergic reactions have been reported in some people taking maraviroc tablets. If you develop a rash with any of the following symptoms, stop using maraviroc tablets and contact your healthcare provider right away:</div><div><div><div>• fever</div><div>• generally ill feeling</div></div><div><div>• problems breathing</div><div>• yellowing of the skin or whites of your eyes</div></div></div></div></div></div></div>

Size: 150 x 350 mm
Colour: Black

<ul style="list-style-type: none">• muscle aches• blisters or sores in your mouth• blisters or peeling of the skin• redness or swelling of the eyes• swelling of the mouth or face or lips• Heart problems including heart attack.• Low blood pressure when standing up (postural hypotension) that can cause dizziness or fainting. You should avoid driving or operating heavy machinery if you have dizziness during treatment with maraviroc tablets.• Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you develop new symptoms during treatment with maraviroc tablets.• Possible chance of infection or cancer. Maraviroc tablets affects other immune system cells and therefore may possibly increase your chance for getting other infections or cancer. <p>The most common side effects of maraviroc tablets in adults include colds and cold-like symptoms, cough, fever, rash, bloating and gas, indigestion, constipation, and dizziness.</p> <p>The most common side effects of maraviroc tablets in children include vomiting, abdominal pain, diarrhea, nausea, and dizziness.</p> <p>These are not all the possible side effects of maraviroc tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>	<ul style="list-style-type: none">• dark or tea-colored urine• pain, aching, or tenderness on the right side below the ribs• loss of appetite• nausea/vomiting
<p>How should I store maraviroc tablets?</p> <ul style="list-style-type: none">• Store maraviroc tablets at room temperature from 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] <p>Keep maraviroc tablets and all medicines out of the reach of children.</p>	
<p>General information about the safe and effective use of maraviroc tablets.</p> <p>Medicines are sometimes prescribed for purposes other than those mentioned in a Medication Guide. Do not use maraviroc tablets for a condition for which it was not prescribed. Do not give maraviroc tablets to other people, even if they have the same symptoms that you have. It may harm them.</p> <p>You can ask your pharmacist or healthcare provider for the information about maraviroc tablets that is written for health professionals.</p>	
<p>What are the ingredients in maraviroc tablets?</p> <p>Active ingredient: maraviroc</p> <p>Inactive ingredients: colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate. The tablets are coated with Opadry II White contains lecithin, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.</p>	
<p>The brands listed are trademarks of their respective owners and are not trademarks of the Hetero Labs Limited.</p> <p>This Medication Guide has been approved by the U.S. Food and Drug Administration.</p>	

Medication Guide available at <http://camberpharma.com/medication-guides>



Manufactured for:
Camber Pharmaceuticals, Inc.,
Piscataway, NJ 08854

Manufactured by:
HETERO™
Hetero Labs Limited
Jeedimetla, Hyderabad - 500 055,
India

Issued: 01/2022