

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr MYLAN-ABACAVIR/LAMIVUDINE

Abacavir (as Abacavir Sulfate)/Lamivudine Tablets

Read this carefully before you start taking **MYLAN-ABACAVIR/LAMIVUDINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYLAN-ABACAVIR/LAMIVUDINE**.

Serious Warnings and Precautions

Hepatitis B Infections

If you have a hepatitis B infection, you should not stop taking MYLAN-ABACAVIR/LAMIVUDINE without instructions from your healthcare professional as your hepatitis may worsen or reoccur. Your healthcare professional will monitor your conditions for several months after stopping treatment with MYLAN-ABACAVIR/LAMIVUDINE.

Hypersensitivity Reaction

You should be screened for the HLA-B*5701 gene variation prior to starting or re-starting treatment with MYLAN-ABACAVIR/LAMIVUDINE, unless you have been screened previously and this is documented. Patients who have the HLA-B*5701 gene variation have a high risk of developing a hypersensitivity reaction (serious allergic reaction) to abacavir, which is in the drug MYLAN-ABACAVIR/LAMIVUDINE. This hypersensitivity reaction **can be life threatening** if you continue to take MYLAN-ABACAVIR/LAMIVUDINE.

If you get two or more of the following groups of symptoms while taking MYLAN-ABACAVIR/LAMIVUDINE contact your healthcare professional immediately to find out if you should stop taking MYLAN-ABACAVIR/LAMIVUDINE:

SYMPTOM(S)	
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, or abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness or achiness
Group 5	Shortness of breath, cough or sore throat

A list of these symptoms is on the Warning Card provided by your pharmacist. You should carry this Warning Card with you at all times. **If you notice these symptoms while taking MYLAN-ABACAVIR/LAMIVUDINE, call your healthcare professional immediately. Your healthcare professional may advise you to stop taking MYLAN-ABACAVIR/LAMIVUDINE.**

If you stop MYLAN-ABACAVIR/LAMIVUDINE because of a serious allergic reaction, never take MYLAN-ABACAVIR/LAMIVUDINE or any other medicine containing abacavir (such as ZIAGEN or

TRIUMEQ) again, regardless of whether you have the HLA-B*5701 gene variation or not. Within hours you may experience a life threatening lowering of your blood pressure or death. If you stop MYLAN-ABACAVIR/LAMIVUDINE for any other reason, even for a few days, and you are not allergic to MYLAN-ABACAVIR/LAMIVUDINE, talk with your healthcare professional before taking it again. Taking MYLAN-ABACAVIR/LAMIVUDINE again may cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.

If your healthcare provider tells you that you can take MYLAN-ABACAVIR/LAMIVUDINE, again, start taking it when you are around medical help or people who can call a healthcare professional if you need one.

Occasionally, reactions have developed in people who start taking abacavir again, and had only one symptom on the Warning Card before they stopped taking it.

If you are hypersensitive to MYLAN-ABACAVIR/LAMIVUDINE, return all your unused MYLAN-ABACAVIR/LAMIVUDINE tablets for safe disposal. Ask your healthcare professional or pharmacist for advice.

What is MYLAN-ABACAVIR/LAMIVUDINE used for?

MYLAN-ABACAVIR/LAMIVUDINE is a medicine used in combination with other antiretrovirals to treat Human Immunodeficiency Virus (HIV) infection.

How does MYLAN-ABACAVIR/LAMIVUDINE work?

MYLAN-ABACAVIR/LAMIVUDINE contains the active ingredients abacavir sulfate and lamivudine. These belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs), which are used to treat HIV infection.

MYLAN-ABACAVIR/LAMIVUDINE does not cure HIV; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body fight infection. You must be sure to be seen regularly by your health care provider.

What are the ingredients in MYLAN-ABACAVIR/LAMIVUDINE?

Medicinal ingredients: 600 mg abacavir (as abacavir sulfate) and 300 mg lamivudine.

Non-medicinal ingredients: Colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, silicified microcrystalline cellulose and talc. *Coating:* D&C yellow # 10 aluminum lake, D&C red # 30, FD&C red # 40, polyethylene glycol, polysorbate, hypromellose and titanium dioxide.

MYLAN-ABACAVIR/LAMIVUDINE comes in the following dosage forms:

600 mg abacavir /300 mg lamivudine fixed dose combination tablets.

Do not use MYLAN-ABACAVIR/LAMIVUDINE if:

- you previously had an allergic reaction (hypersensitivity) to the active ingredient abacavir, which is also included in medicines called ZIAGEN and TRIUMEQ (see **What are the ingredients in MYLAN-ABACAVIR/LAMIVUDINE?**).

- you previously had an allergic reaction to the active ingredient lamivudine which is included in medicines called 3TC, COMBIVIR or any of the other ingredients found in MYLAN-ABACAVIR/LAMIVUDINE (see **What are the ingredients in MYLAN-ABACAVIR/LAMIVUDINE?**).
- you have the HLA-B* 5701 gene variation.
- you have liver disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYLAN-ABACAVIR/LAMIVUDINE. Talk about any health conditions or problems you may have, including if you:

- have kidney or liver disease (including hepatitis B or C)
- have previously taken any other NRTI class medicine
- have been tested and know whether or not you have a gene variation called HLA-B*5701

Other warnings you should know about:

MYLAN-ABACAVIR/LAMIVUDINE can cause serious side effects, including:

- **Lactic Acidosis and Severe Liver Problems:** The class of medicines to which MYLAN-ABACAVIR/LAMIVUDINE belongs (NRTIs) can cause a condition called lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver. Symptoms of lactic acidosis include feeling of weakness, loss of appetite, sudden unexplained weight loss, upset stomach and difficulty breathing or rapid breathing. This rare, but serious side effect occurs more often in women. If you have liver problems you may also be more at risk of getting this condition.
- **Heart Attack:** Some HIV medicines including MYLAN-ABACAVIR/LAMIVUDINE may increase your risk of heart attack. If you have heart problems, smoke or suffer from diseases that increase your risk of heart disease such as high blood pressure and diabetes, tell your healthcare professional.
- **Risk of Infections:** You may continue to develop other infections and other illnesses associated with HIV while you are taking MYLAN-ABACAVIR/LAMIVUDINE. You should therefore keep in regular contact with your healthcare professional.
- **Immune Reconstitution Inflammatory Syndrome:** Changes to your immune system 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.

Autoimmune disorders happen when the immune system attacks healthy body tissue. This may happen after you start taking medicines for HIV infection. Examples of this include: Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system), polymyositis (which affects the muscles), or autoimmune hepatitis (which affects the liver). Autoimmune disorders may occur many months after the start of treatment.

See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

Blood Tests:

Your blood sugar levels (glucose) or level of fats (lipids) in your blood may increase with HIV treatment.

Your healthcare professional will decide when to do blood tests, to check for these and other side effects, and will interpret the results.

Pregnancy and Newborns:

If you are pregnant, or planning to become pregnant, talk to your healthcare professional before taking MYLAN-ABACAVIR/LAMIVUDINE. It is not known if MYLAN-ABACAVIR/LAMIVUDINE is safe to use during pregnancy. Your healthcare professional will decide whether you should continue to take MYLAN-ABACAVIR/LAMIVUDINE if you are pregnant. If you are pregnant and taking MYLAN-ABACAVIR/LAMIVUDINE to prevent passing HIV to your unborn baby continue to follow your healthcare professionals' recommendations. If you have questions about the risks to your baby talk to your healthcare professional. If you take MYLAN-ABACAVIR/LAMIVUDINE while you are pregnant, talk to your healthcare professional about how you can be included in the Antiretroviral Pregnancy Registry.

Babies born to mothers who have taken Nucleoside Reverse Transcriptase Inhibitors (NRTIs) like MYLAN-ABACAVIR/LAMIVUDINE during pregnancy or labour have had increased levels of lactate in their blood. The increases are usually temporary. There have also been very rare reports of problems that affect the baby's nervous system such as delayed development and seizures. The long-term effects of MYLAN-ABACAVIR/LAMIVUDINE are not known.

Breastfeeding:

Do not breastfeed while taking MYLAN-ABACAVIR/LAMIVUDINE. There is a risk of passing HIV-1 to your baby if you breastfeed. MYLAN-ABACAVIR/LAMIVUDINE can also be passed through breast milk and could harm your baby. If you are breastfeeding or planning to breastfeed, talk with your healthcare professional about the best way to feed your baby.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MYLAN-ABACAVIR/LAMIVUDINE:

- Emtricitabine, to treat HIV
- Methadone, to treat pain and drug addiction
- Retinoids, to treat skin conditions
- Riociguat, to treat high blood pressure
- Sorbitol-containing medicines (usually liquids)
- Trimethoprim sulphamethoxazole (co-trimoxazole), an antibiotic used to treat Pneumocystis jiroveci pneumonia (often referred to as PCP) or toxoplasmosis

MYLAN-ABACAVIR/LAMIVUDINE should not be taken with:

- 3TC (lamivudine)
- COMBIVIR (zidovudine / lamivudine)
- ZIAGEN (abacavir sulfate)
- TRUVADA (emtricitabine / tenofovir disoproxil fumarate)
- COMPLERA (emtricitabine / rilpivirine hydrochloride / tenofovir disoproxil fumarate)
- ATRIPLA (efavirenz / emtricitabine / tenofovir disoproxil fumarate)
- EMTRIVA (emtricitabine)
- STRIBILD (elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil fumarate)
- TRIUMEQ (dolutegravir sodium / abacavir sulfate / lamivudine)

- DELSTRIGO (doravirine / lamivudine / tenofovir disoproxil fumarate)
- DOVATO (dolutegravir sodium / lamivudine)
- DESCOVY (emtricitabine / tenofovir alafenamide hemifumarate)
- GENVOYA (elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide hemifumarate)
- ODEFSEY (emtricitabine / rilpivirine hydrochloride / tenofovir alafenamide hemifumarate)
- BIKTARVY (bictegravir sodium / emtricitabine / tenofovir alafenamide hemifumarate)
- SYMTUZA (darunavir ethanolate / cobicistat / emtricitabine / tenofovir alafenamide hemifumarate)

Some of these medicines are already in MYLAN-ABACAVIR/LAMIVUDINE.

How to take MYLAN-ABACAVIR/LAMIVUDINE:

- Take MYLAN-ABACAVIR/LAMIVUDINE **exactly as your healthcare professional has advised you, and try not to miss any doses.**
- MYLAN-ABACAVIR/LAMIVUDINE can be taken with or without food.
- Swallow the tablet whole with water.

If you stopped taking MYLAN-ABACAVIR/LAMIVUDINE:

If you stop taking MYLAN-ABACAVIR/LAMIVUDINE because of side effects or illness, you must contact your healthcare professional before restarting to make sure that symptoms of a hypersensitivity reaction have not been missed. In some cases your healthcare professional will ask you to restart MYLAN-ABACAVIR/LAMIVUDINE under direct medical supervision or in a place where you will be able to get ready access to medical care if needed.

Usual dose:

The usual dose in adults (18 years and up) is one tablet once a day.

Overdose:

If you think you, or a person you are caring for, have taken too much MYLAN-ABACAVIR/LAMIVUDINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is important to take this medicine as prescribed to ensure you get maximum benefit. If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

What are possible side effects from using MYLAN-ABACAVIR/LAMIVUDINE?

These are not all the possible side effects you may feel when taking MYLAN-ABACAVIR/LAMIVUDINE. If you experience any side effects not listed here, tell your healthcare professional.

A hypersensitivity reaction (serious allergic reaction) has been reported in patients who have been treated with abacavir. This is described in the Serious Warnings and Precautions Box in the beginning of this leaflet. It is important that you read and understand the information about this serious reaction.

MYLAN-ABACAVIR/LAMIVUDINE contains both abacavir sulfate and lamivudine. The most common side effects for this combination are nausea, vomiting, diarrhea, upper abdominal pain, headache, high temperature (fever), lethargy (unusual lack of energy), fatigue, trouble sleeping, depression/depressed mood, loss of appetite, hair loss, joint and muscle pain, abacavir hypersensitivity (serious allergic reaction) and skin rash (without any other illness).

Other side effects (very rare) include serious skin reactions and severe anemia.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypersensitivity to abacavir: Serious allergic reaction and 2 or more of the following symptoms: fever, skin rash, nausea, vomiting, diarrhea, abdominal pain, severe tiredness, achiness, general ill feeling, sore throat, shortness of breath.		X	
UNCOMMON			
Blood problems and symptoms such as anemia (lowered red blood cell count – resulting in fatigue, breathlessness), low white blood cell count (neutropenia – increasing chance of infection), reduced platelets (blood cells important for blood clotting – could increase chance of bruising) and increases in enzymes produced by the liver.		X	
RARE			
Pancreatitis (inflammation of the pancreas) and symptoms such as nausea, vomiting and abdominal pain.		X	
Lactic acidosis (high level of acid in the blood): Weight loss, fatigue, malaise, abdominal pain, shortness of breath, severe hepatomegaly (swollen and enlarged liver) with symptoms of liver problems such as nausea, vomiting, abdominal pain, weakness and diarrhea.		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
FREQUENCY NOT KNOWN			
Immune Reconstitution Inflammatory Syndrome and Autoimmune Disorders: fever, redness, rash or swelling, fatigue, joint or muscle pain, numbness or weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, chest pain or rapid heart rate, yellowing of the eyes and skin		X	
Heart Attack: chest pain or discomfort, pain in the jaw, neck or back or pain radiating down the left arm, shortness of breath, nausea, dizziness		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at controlled room temperature between 15°C and 30°C.

As with all medicines, keep MYLAN-ABACAVIR/LAMIVUDINE out of the reach and sight of children.

Do not take your medicine after the expiry date shown on the bottle, blister and/or the carton.

If you want more information about MYLAN-ABACAVIR/LAMIVUDINE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

This leaflet was prepared by Mylan Pharmaceuticals ULC.

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INFORMATION FOR PRESCRIBERS:

A copy of the warning card included with the MYLAN-ABACAVIR/LAMIVUDINE carton is shown below.

WARNING CARD

MYLAN-ABACAVIR/LAMIVUDINE (abacavir sulfate/lamivudine) Tablets

Patients taking MYLAN-ABACAVIR/LAMIVUDINE (abacavir sulfate/lamivudine) may develop a hypersensitivity reaction (a serious allergic reaction) which can be life threatening if you continue to take MYLAN-ABACAVIR/LAMIVUDINE. **If you notice two or more of the following sets of symptoms while taking MYLAN-ABACAVIR/LAMIVUDINE, contact your healthcare professional immediately to find out if you should stop taking MYLAN-ABACAVIR/LAMIVUDINE:**

SYMPTOM(S)	
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, or abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness or achiness
Group 5	Shortness of breath, cough or sore throat

If you have already had this reaction to **MYLAN-ABACAVIR/LAMIVUDINE, never take any medicine containing abacavir, such as ZIAGEN (abacavir sulfate) or TRIUMEQ (dolutegravir/ abacavir/lamivudine) again. If you take any medicine containing abacavir, such as MYLAN-ABACAVIR/LAMIVUDINE, ZIAGEN or TRIUMEQ again, within hours you may experience a life-threatening lowering of your blood pressure or death.**

Carry this card with you at all times.

You should return all of your unused MYLAN-ABACAVIR/LAMIVUDINE to your healthcare professional or pharmacist for proper disposal.

Mylan Pharmaceuticals ULC
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