Approved Patient Information Leaflet

SCHEDULING STATUS S4

MYLTEGA

Film coated tablets

Dolutegravir 50 mg

Read all of this leaflet carefully before you start taking MYLTEGA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MYLTEGA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MYLTEGA is and what it is used for

MYLTEGA is a type of medicine known as an anti-retroviral (ARV).

It belongs to a group of medicines called integrase inhibitors (INIs).

MYLTEGA is used to treat HIV (human immunodeficiency virus) infection in adults aged 18 years and older.
MYLTEGA is also used in combination therapy (i.e., MYLTEGA with other anti-retroviral medicines).

2. What you need to know before you take MYLTEGA

Do not take MYLTEGA

- if you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of MYLTEGA (listed in section 6).
- if you have liver disease or if your liver is not functioning normally.
- if you are taking a medicine called metformin (this medicine is used for diabetes - lowering of sugar levels in the body).
- if you are taking medicines called dofetilide and pilsicainide (these medicines are used to treat abnormal rate of muscle contractions in the heart).
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with MYLTEGA:

- If you get any rash as it may be an indication that you are having an allergic reaction. You should stop taking MYLTEGA and contact your doctor immediately if you get other symptoms of an allergic reaction such as fever, fatigue, muscle or joint aches, blisters, sores in your mouth, swelling of your feet or face.
- If you get any other symptoms of other serious infections, usually due to your already weakened immune system. When you start treatment you may find that old, hidden infections (such as tuberculosis) flares up,

causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight against these infections

- If you notice that there is a change in the distribution of fat throughout your body e.g. a hump forming on your back, loss of fat from your face, collection of fat around your abdomen.
- If you experience joint aches and pains, stiffness in your joints or any difficulty with movement, it may be an indication that your bones are being damaged.
- If you are taking any other medicines even if they are non-prescription. However do not stop taking MYLTEGA without your doctor's advice.
- MYLTEGA is not a cure HIV infection, it only reduces the amount of virus in your blood therefore HIV can still be transmitted while you are taking MYLTEGA. You should therefore use condoms during intercourse.
- MYLTEGA does not reduce the risk of passing HIV to others through sexual contact or blood contaminations. Therefore, you must continue to use appropriate precautions, such as condoms.

Other medicines and MYLTEGA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you take any other anti-HIV medicines. MYLTEGA can be combined with some other anti-HIV medicines, while other combinations are not recommended.

Do not take MYLTEGA with the following medicines:

- Dofetilide or pilsicainide used to treat heart conditions,
- Metformin, which is used to treat diabetes.

MYLTEGA may have an effect on other medicines or other medicines may have an effect on MYLTEGA thus causing you to have side effects.

Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat indigestion and heartburn called antacids should only be taken at least 6 hours before you take MYLTEGA or 2 hours after taking MYLTEGA.
- Calcium and iron supplements should also only be taken at least 6 hours before you take MYLTEGA or 2 hours after taking MYLTEGA.
- Etravirine, efavirenz, nevirapine, tipranavir/ritonavir, fosamprenavir/ ritonavir which are all used in the treatment of HIV infection.
- Rifampicin which is used to treat tuberculosis.
- Phenytoin and phenobarbitone which is used to treat epilepsy.
- Oxcarbamazepine and carbamazepine used to treat epilepsy and bipolar disorder.
- St. John’s wort, a herbal remedy for depression.

MYLTEGA with food and drink:

MYLTEGA tablets can be taken with or without food.

Pregnancy, breastfeeding and fertility

Women of childbearing potential

Women of childbearing potential should be counselled about the potential risk of birth defects of the brain and spine with dolutegravir, including consideration of using effective contraceptive measures.

Perform pregnancy testing before start of MYLTEGA in women of childbearing potential to exclude unintentional use of MYLTEGA during the first trimester of pregnancy.

If a woman plans pregnancy, the benefits and the risks of starting or continuing treatment with dolutegravir versus using another antiretroviral medicine should be discussed with her.

Pregnancy:

Use of dolutegravir during pregnancy was associated with a small increase in the birth defects of the brain and spine.

If a pregnancy is confirmed in the first trimester while on dolutegravir, the benefits and risks of continuing dolutegravir versus switching to another antiretroviral medicine should be discussed with the patient.

Dolutegravir may be used during the second and third trimester of pregnancy when the expected benefit outweighs the potential risk to the foetus.

Breast-feeding:

HIV infected women should not breast-feed their infants in order to avoid transmission of HIV or follow appropriate guidelines.

Dolutegravir is excreted in human breast milk, and there is significant exposure to the neonate/infants due to slow removal. There is insufficient information on the effects of dolutegravir in neonates/infants.

Fertility:

There are no data on the effects of dolutegravir on human male or female fertility. Animal studies indicate no effects of dolutegravir on male or female fertility.

Driving and using machines

Do not operate machines or drive if you feel dizzy after taking MYLTEGA.

Important information about some of the ingredients of MYLTEGA:

MYLTEGA contains mannitol which may cause loose bowels.

3. How to take MYLTEGA

Do not share medicines prescribed for you with any other person.
Always take MYLTEGA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and Adolescents:

The usual dose is one MYLTEGA tablet (50 mg) once a day.
Your doctor will determine whether you need to take more MYLTEGA or not depending on the antiretroviral medicine that you have been taking or have taken in the past.
You must not use this medicine if you have mild or severe liver disease or liver damage.
Do not take more than the recommended dose.

Your doctor will tell you how long your treatment with MYLTEGA will last.

If you have the impression that the effect of MYLTEGA is too strong or too weak, tell your doctor or pharmacist.

If you take more MYLTEGA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MYLTEGA :

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MYLTEGA :

Take MYLTEGA for as long as your doctor recommends. Don’t stop unless your doctor advises you to.

4. Possible side effects

MYLTEGA can have side effects.

Not all side effects reported for MYLTEGA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYLTEGA , please consult your health care provider for advice.

If any of the following happens, stop taking MYLTEGA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction MYLTEGA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- skin rash,
- fever,
- lack of energy,
- swelling of the face and mouth causing difficulty in breathing,
- muscle or joint aches,
- IRIS (development of other inflammatory reactions or infections when you begin treatment with MYLTEGA.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- insomnia (difficulty in sleeping),
- headache,

- dizziness,
- abnormal dreams,
- nausea,
- diarrhoea (frequent and watery bowel movements),
- vomiting,
- flatulence (excessive gas/ wind),
- upper abdominal pain,
- pruritus (an intense itching sensation),
- fatigue (temporary loss of strength and energy),
- depression.

Less frequent side effects:

- abdominal pain,
- abdominal discomfort,
- allergic reactions,
- inflammation of the liver usually noticed by yellowing of your skin and nails,
- suicide attempts or thoughts about suicide.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of MYLTEGA.

5. How to store MYLTEGA

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the tablets in the original container until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLTEGA contains

The active substance is dolutegravir. MYLTEGA contains 50 mg of dolutegravir per tablet.

The other ingredients of MYLTEGA are:

Tablet core: Microcrystalline cellulose, povidone, sodium starch glycolate, sodium stearyl fumarate.

Tablet coating: Black iron oxide/ferrosoferric oxide, iron oxide red, macrogol, polyvinyl alcohol, talc, titanium dioxide.

Contains sugar: mannitol 145,4 mg.

What MYLTEGA looks like and contents of the pack

MYLTEGA tablets are packed in blue opaque, high-density polyethylene (HDPE) bottles with a blue opaque polypropylene cap.

The HDPE bottle is packed into an outer cardboard carton.

Pack size:

30’s – One HDPE container contains 30 tablets.

Holder of Certificate of Registration

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