SCHEDULING STATUS S4

Myltega 10 mg Dispersible Tablets

Dolutegravir

Contains sugar: mannitol

Read all of this leaflet carefully before you start taking Myltega 10 mg Dispersible Tablets

- 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 10 mg Dispersible Tablets 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 10 mg Dispersible Tablets is and what it is used for
2. What you need to know before you give Myltega 10 mg Dispersible Tablets
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1. What Myltega 10 mg Dispersible Tablets is and what it is used for

Myltega 10 mg Dispersible Tablets is used to treat HIV (human

immunodeficiency virus) infection in adults and in children, in combination with other anti-retroviral medicines (combination therapy).

The active ingredient in Myltega 10 mg Dispersible Tablets is dolutegravir. Myltega 10 mg Dispersible Tablets is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called integrase inhibitors (INIs).

2. What you need to know before you give or receive Myltega 10 mg Dispersible Tablets

Do not take Myltega 10 mg Dispersible Tablets:

- if you or your child are allergic (hypersensitive) to dolutegravir or any of the other ingredients of Myltega 10 mg Dispersible Tablets (listed in section 6).
- if you or your child are taking another medicine called dofetilide or pilsicainide (to treat heart conditions).
- if you have severe liver disease.
- if you are in the first trimester of your pregnancy and if you are breastfeeding.

Warnings and precautions

Take special care with Myltega 10 mg Dispersible Tablets:

- if you get any rash as it may be an indication that you are having an allergic reaction. You should stop taking Myltega 10 mg Dispersible Tablets 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.

Keep in touch with your doctor, and do not stop taking Myltega 10 mg Dispersible Tablets without your doctor's advice.

HIV can still be transmitted despite taking Myltega 10 mg Dispersible Tablets.

Myltega 10 mg Dispersible Tablets does not cure HIV infection; it reduces the amount of virus in your body.

While you are taking Myltega 10 mg Dispersible Tablets, you will need regular blood tests.

For as long as you are taking Myltega 10 mg Dispersible Tablets, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in this leaflet. See section 4.

Protect other people.

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). Myltega 10 mg Dispersible Tablets will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

- **Use a condom** when you have oral or penetrative sex.
- **Do not risk blood transfer** - for example, don't share needles.

Other medicines and Myltega 10 mg Dispersible Tablets

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

Do not take Myltega 10 mg Dispersible Tablets with the following medicines:

- Dofetilide or pilsicainide used to treat heart conditions,

Myltega 10 mg Dispersible Tablets may have an effect on other medicines or other medicines may have an effect on Myltega 10 mg Dispersible Tablets thus causing you to have side effects.

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

- Metformin, which is used to treat diabetes.
- Medicines used to treat indigestion and heartburn called antacids should only be taken at least 6 hours before you take Myltega 10 mg Dispersible Tablets or 2 hours after taking Myltega 10 mg Dispersible Tablets.
- Calcium and iron supplements should also only be taken at least 6 hours before you take Myltega 10 mg Dispersible Tablets or 2 hours after taking Myltega 10 mg Dispersible Tablets.
- 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.

Tell your doctor or pharmacist if you or your child are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

Myltega 10 mg Dispersible Tablets with food and drink

Myltega 10 mg Dispersible Tablets may be taken with or without food.

Pregnancy, breast-feeding and fertility

Safe use during pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Myltega 10 mg Dispersible Tablets.

If you are of the age of falling pregnant, you should have a negative pregnancy test before you start taking Myltega 10 mg Dispersible Tablets.

While you are taking Myltega 10 mg Dispersible Tablets you must use a reliable method of contraception, to prevent pregnancy.

Women who are HIV-positive should not breastfeed their babies, because HIV infection can be passed on to the baby in breast milk.

Talk to your doctor immediately, if you are breastfeeding, or thinking about breastfeeding.

Driving and using machines

Myltega 10 mg Dispersible Tablets can make you dizzy and have other side effects that make you less alert.

Do not drive or use machines unless you are sure you are not affected.

3. How to give or receive Myltega 10 mg Dispersible Tablets

Do not share medicines prescribed for you with any other person.

Always take Myltega 10 mg Dispersible Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will determine th correct dose for you or your child which will depend on your weight.

- The tablet can be divided into two equal halves.
- Myltega 10 mg Dispersible Tablets may be swallowed whole or dispersed in drinking water and should not be chewed or crushed.
- Swallow the dispersible tablet whole (if more than one tablet is required, swallow one tablet at a time to reduce the risk of choking),

or

- Fully disperse the dispersible tablet in 5 ml of drinking water (if using ½ or 1½ dispersible tablet) or 10 ml (if using 2, 2 ½, or 3 dispersible tablets).

  Swirl or stir until the tablets disperse completely.

After full dispersion, administer or drink the oral suspension within 30 minutes of mixing.

- **Dolutegravir tablets are not the same as Myltega 10 mg Dispersible Tablets and cannot be substituted for each other. Check to make sure you receive the correct form of Dolutegravir each time you or your child's prescription is filled to avoid using the wrong medicine.**
- Do not change your dose, switch medicines or stop taking Myltega 10 mg Dispersible Tablets without talking with your healthcare provider first.

If you take more Myltega 10 mg Dispersible Tablets 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 or give Myltega 10 mg Dispersible Tablets

If you miss a dose of Myltega 10 mg Dispersible Tablets, take or give it as soon as you remember. Do not take 2 doses at the same time or take more than your prescribed dose.

Effects when treatment with Myltega 10 mg Dispersible Tablets is stopped:

Do not stop taking Myltega 10 mg Dispersible Tablets before taking to your doctor. The virus in your blood may increase and the virus may become harder to treat.

4. Possible side effects

Myltega 10 mg Dispersible Tablets can have side effects.

Not all side effects reported for Myltega 10 mg Dispersible Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Myltega 10 mg Dispersible Tablets, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Myltega 10 mg Dispersible Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to Myltega 10 mg Dispersible Tablets. 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:

- Liver problems. People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with Myltega 10 mg Dispersible Tablets.

  Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver. Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:

  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or “tea-colored” urine
  - light-colored stools (bowel movements)
  - nausea or vomiting
  - loss of appetite
  - pain, aching, or tenderness on the right side of your stomach area

- 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 start having new symptoms after you start taking Myltega 10 mg Dispersible Tablets.

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

Tell your doctor if you notice any of the following:

Frequent

- headache
- diarrhoea
- feeling sick (*nausea*)
- rash
- itching (*pruritus*)

- vertigo
- being sick (*vomiting*)
- stomach pain (*upper abdominal pain*), stomach discomfort
- difficulty in sleeping (*insomnia*)
- dizziness
- abnormal dreams
- depression (feeling of deep sadness and unworthiness)
- anxiety
- lack of energy (*fatigue*)
- wind (*flatulence*).

Less frequent

- inflammation of the liver (*hepatitis*)
- suicide thoughts (mainly in patients who have had depression or mental health problems before)
- an inflammatory condition which may develop as the immune system becomes stronger (*immune reconstitution inflammatory syndrome or 'IRIS'*)
- allergic reaction (*hypersensitivity*) (see earlier in **this section** for more details).

Other side effects:

- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- joint pain
- muscle pain
- weight gain.

Side effects that may show up in blood tests:

- increase in *bilirubin* (a substance produced by the liver) in the blood.
- an increase in the level of enzymes produced in the muscles (*creatine phosphokinase, creatinine*).

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wpcontent/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
By reporting side effects, you can help provide more information on the safety of Myltega 10 mg Dispersible Tablets.

5. How to store Myltega 10 mg Dispersible Tablets

Store all medicines out of reach of children.

- Store at or below 30 °C in the original container.
- Keep the bottle tightly closed and protected from moisture.
- 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 10 mg Dispersible Tablets contains

The active substance is dolutegravir.

Each dispersible tablet contains 10 mg dolutegravir.

Contains sugar: mannitol (29,080 mg) per dispersible tablet.

The other ingredients are:

Tablet Core:

Calcium sulfate, crospovidone, mannitol (E421), microcrystalline cellulose, povidone, silicified microcrystalline cellulose, sodium starch glycolate, sodium stearyl fumarate, strawberry cream flavour, sucralose.

Film Coat:

Black iron oxide (E172), Hypromellose, polyethylene glycol, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

What Myltega 10 mg Dispersible Tablets looks like and contents of the pack

Myltega 10 mg Dispersible Tablets is a pink coloured, film-coated, oval shape, biconvex tablet debossed with D on the left side and T on the right side of the score line on one side and M on the left side of the score line on other side.

Contents of the pack:

Available in HDPE Bottle pack of 28's, 30's, 60's, 84's, 90's,180's and 270's*

* Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

4 Brewery street

Isando

Gauteng

Republic of South Africa

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Access to the corresponding Professional Information

To be confirmed.