Patient information leaflet for DALIDUO

Scheduling status:

S4

DALIDUO (50/ 25 film coated tablets)

Dolutegravir sodium and rilpivirine hydrochloride

Contains sugar and sweetener such as 145 mg mannitol and 52 mg lactose monohydrate.

Read all of this leaflet carefully 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, pharmacist or nurse.
- DALIDUO 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 is DALIDUO and what is used for:
2. What you need to know before you take DALIDUO.
3. How to take DALIDUO.
4. Possible side effects
5. How to store DALIDUO
6. Contents of the pack and other information.

1. What is DALIDUO and what is used for

DALIDUO is indicated for the treatment of immunodeficiency virus-1(HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/ml), for at least 6 months on a stable PI, NI or NNRTI plus NRTI based regimens, without known or suspected resistance to either antiretroviral component. Co- administration with any other NNRTI medicines is not recommended.

2. What you need to know before you take DALIDUO.

Do not take DALIDUO:

- If you are hypersensitive (allergic) to rilpivirine, dolutegravir or any of the excipients
- with other medicines used to treat HIV which fall under the class of Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) such as delavirdine, efavirenz, etravirine, nevirapine
- in combination with carbamazepine, oxcarbazepine, phenobarbitone, phenytoin, systemic dexamethasone (except as a single dose treatment) rifabutin, rifampicin, rifapentine, St. Johns Wort, proton-pump inhibitors (PPIs) such as lansoprazole, omeprazole, rabeprazole, pantoprazole and esomeprazole as co-administration may result in loss of therapeutic effect of DALIDUO.
- in combination with dofetilide and Pilsicainide
- If you have been diagnosed with moderate or severe liver disease
- in combination with fampridine (also known as dalfampridine)
- if you are pregnant, planning to be pregnant or breastfeeding your baby

Warnings and precautions

Tell your doctor or health care provider before taking DALIDUO**:**

- if you have pain in joints (osteonecrosis)
- If you have been diagnosed with liver disease
- If you have any other infections
- If you have hepatitis B or C
- If you have taken other medicines containing rilpivirine
- If you are taking medicines that may cause heart related side effects, ask your doctor or pharmacist if you are not sure

If any of these applies to you, tell your doctor or nurse before you start taking DALIDUO.

Tell your doctor or health care provider straight away if you develop any of the following symptoms when taking DALIDUO:

- any signs or symptoms of allergic reactions develop (including, but not limited to severe rash or rash accompanied by fever, feeling tired, muscle or joint aches, blisters, oral lesions, facial swelling, abnormal blood tests). Discontinue use of DALIDUO if these symptoms start.
- If you develop changes in body fat as such changes have been seen in some patients taking DALIDUO. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen.
- worsening of a known condition or the appearance of a new condition after initiating antiretroviral therapy (immune reconstitution syndrome)
- DALIDUO does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others. Even if you are receiving treatment for HIV, you are still

at risk of contracting other infections and other complications of the HIV infection. Therefore, you should remain under close observation by your doctor.

Children and adolescents

The safety of DALIDUO in children and adolescents younger than the age of 18 is not known. DALIDUO is therefore not recommended for patients younger than 18 years of age.

Important information about some of the ingredients of DALIDUO

DALIDUO contains sugar and sweeteners in the form of 145 mg mannitol and 52 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tell your doctor or healthcare professional if you are allergic or intolerant to mannitol or lactose so that alternate therapy may be recommended. Mannitol may have a mild laxative effect.

Other medicines with DALIDUO

Always tell your healthcare professional if you are taking any other medicines.

(This includes complementary or traditional medicines).

The following medicines or substances may increase or decrease blood levels and increase the risk of adverse events associated with DALIDUO, so please inform your doctor if you are taking any of the following medicines before you start treatment with DALIDUO:

- isoniazid (to treat tuberculosis),
- etravirine (to treat HIV),
- efavirenz (to treat HIV),
- nevirapine (to treat HIV),
- atazanavir (to treat HIV),

- atazanavir and ritonavir (to treat HIV),
- tipranavir and ritonavir (to treat HIV),
- fosamprenavir and ritonavir (to treat HIV),
- nelfinavir (to treat HIV),
- lopinavir and ritonavir (to treat HIV),
- darunavir and ritonavir (to treat HIV),
- tenofovir (to treat HIV),
- lopinavir, ritonavir and etravirine (to treat HIV),
- darunavir, ritonavir and etravirine (to treat HIV),
- dofetilide, Pilsicainide (to treat irregular heartbeat),
- oxcarbazepine (to treat seizures),
- phenytoin, phenobarbitone, carbamazepine, oxcarbazepine, (to treat seizures),
- St. Johns wort (to treat depression),
- antacids containing magnesium, aluminium or calcium (to treat heartburn and indigestion),
- calcium supplements (to build and maintain strong bones),
- iron supplements (to treat iron deficiency),
- metformin (to treat diabetes),
- delavirdine (to treat HIV),
- saquinavir (to treat HIV),
- tipranavir (to treat HIV),
- indinavir (to treat HIV),
- ketoconazole, fluconazole, itraconazole, posaconazole, voriconazole (to treat fungal infections),
- rifabutin, rifampicin, rifapentine (to treat tuberculosis),

- clarithromycin, erythromycin, troleandomycin (to treat bacterial infections),
- dexamethasone (to reduce inflammation and treat allergic reactions),
- omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole (to treat heartburn and ulcers),
- famotidine, cimetidine, nizatidine, ranitidine (to treat heartburn and acid reflux),
- paracetamol (to treat pain and fever).

Current antiretroviral therapy does not cure HIV and has not been proven to prevent the transmission of HIV to others through blood, other bodily secretion or sexual contact. Appropriate precautions to prevent transmission of HIV should continue to be employed.

DALIDUO may increase the effect of the following medicines:

- defetilide
- metformin
- Pilsicainide

DALIDUO may reduce the effect of the following medicines:

- Methadone

Pregnancy and breastfeeding

Safe use during pregnancy and lactation has not been established.

Adequate contraception is recommended for women of childbearing potential when taking DALIDUO.

Mothers should not breastfeed if they are receiving DALIDUO.

Driving and using machines

DALIDUO may affect your ability to drive and use machines.

Dizziness and drowsiness may occur.

3. How to take DALIDUO

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

Always take DALIDUO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of DALIDUO is one tablet once a day with meals.

If you take more DALIDUO you should

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

4. Possible side effects

DALIDUO can have side effects.

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

If any of the following happens, stop taking / using DALIDUO 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
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to DALIDUO. 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:

- Suicidal thoughts

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:

- difficulty falling asleep
- headache, dizziness, abnormal dreams,
- nausea, diarrhoea, vomiting, passing of gas, upper abdominal pain,
- feeling tired,
- abnormal blood results of the liver and pancreas,
- depression,
- increased blood triglycerides (fasting),
- anxiety,
- dry mouth

Less Frequent side effects:

- worsening of a known condition or the appearance of a new condition after initiating DALIDUO,
- stomach pain,
- inflammation of the liver,
- liver failure,
- abnormal blood tests,
- decreased appetite,

- sleep disorders, depressed mood,
- dizziness,
- joint pain,
- muscle pain

Side effects of which is frequency is unknown:

- increased creatinine blood levels,
- change in total cholesterol, LDL- cholesterol, HDL - cholesterol and triglycerides associated with redistribution of body fat,

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 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 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of DALIDUO.

5. How to store DALIDUO

Store at or below 25°C

Keep the bottle tightly closed.

Keep away from children.

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 DALIDUO contains

The active substances:

DALIDUO (film-coated tablet): Each tablet contains rilpivirine hydrochloride

equivalent to 25 mg rilpivirine and dolutegravir sodium equivalent to 50 mg dolutegravir

The other ingredients are:

mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, colloidal silicon dioxide, sodium stearyl fumarate, lactose monohydrate, polysorbate 20, croscarmellose sodium, ferric oxide yellow, silicified microcrystalline cellulose, magnesium stearate and opadry pink.

What DALIDUO looks like and contents of the pack

DALIDUO is packed in a 50 cc white round HDPE Bottle consisting of a Silica Gel Bag 2 gm Stripax (Multisorb) R/F and closed with a 33 mm Blue Child Resistant Cap. The HDPE bottle is packed into an outer cardboard carton. Pack sizes are 28 and 30 tablets

Holder of Certificate of Registration

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This leaflet was last revised in

20 February 2024

Application number

55/20.2.8/0301