

PATIENT INFORMATION LEAFLET
Dobataf-3
(Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets
50 mg / 200 mg / 25 mg)

Read all of this leaflet carefully before you start taking this medicine 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets is and what it is used for

Dolutegravir, emtricitabine and tenofovir alafenamide tablets is a prescription medicine that is used as a complete regimen to treat human immunodeficiency virus (HIV-1) infection in adults and children who weigh at least 25 kg (55 pounds).

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

Dolutegravir, emtricitabine and tenofovir alafenamide tablets contain 3 prescription medicines dolutegravir, emtricitabine and tenofovir alafenamide.

It is not known if dolutegravir, emtricitabine and tenofovir alafenamide tablets for treatment of HIV-1 infection is safe and effective in children who weigh less than 25 kg (55 pounds).

2. What you need to know before you take Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets

Do not take dolutegravir, emtricitabine and tenofovir alafenamide tablets if you:

- have ever had an allergic reaction to a medicine that contains dolutegravir, emtricitabine, or tenofovir alafenamide
- take dofetilide

Before taking dolutegravir, emtricitabine and tenofovir alafenamide tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems, including hepatitis B or C infection
- have kidney problems
- are pregnant or plan to become pregnant. Dolutegravir, one of the medicines in dolutegravir, emtricitabine and tenofovir alafenamide tablets, may harm your unborn baby.
 - o Your healthcare provider may prescribe a different medicine than dolutegravir, emtricitabine and tenofovir alafenamide tablets if you are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy.
 - o If you can become pregnant, your healthcare provider may perform a pregnancy test before you start treatment with dolutegravir, emtricitabine and tenofovir alafenamide tablets.
 - o If you can become pregnant, you and your healthcare provider should talk about the use of effective birth control (contraception) during treatment with dolutegravir, emtricitabine and tenofovir alafenamide tablets.
 - o Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with dolutegravir, emtricitabine and tenofovir alafenamide tablets.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take dolutegravir, emtricitabine and tenofovir alafenamide tablets**
 - o You should not breastfeed if you have HIV-1 because the risk of passing HIV-1 to your baby.

- o At least two of the medicines in dolutegravir, emtricitabine and tenofovir alafenamide tablets (dolutegravir and emtricitabine) pass into your breast milk. It is not known if the other medicine in dolutegravir, emtricitabine and tenofovir alafenamide tablets can pass into your breast milk.
- o Talk with your healthcare provider about the best way to feed your baby during treatment with dolutegravir, emtricitabine and tenofovir alafenamide tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with dolutegravir, emtricitabine and tenofovir alafenamide tablets. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with dolutegravir, emtricitabine and tenofovir alafenamide tablets.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take dolutegravir, emtricitabine and tenofovir alafenamide tablets with other medicines.

Pregnancy

If you are pregnant, if you become pregnant, or if you are planning to have a baby:

- **Talk to your doctor** about the risks and benefits of taking dolutegravir, emtricitabine and tenofovir alafenamide tablets.

Advise adolescents and adults of childbearing potential, including those actively trying to become pregnant, of the potential risk of neural tube defects with use of dolutegravir.

Pregnancy testing is recommended in adolescents and adults of childbearing potential before initiation of dolutegravir.

In adolescents and adults of childbearing potential currently on dolutegravir who are actively trying to become pregnant or if pregnancy is confirmed in the first trimester, assess the risks and benefits of continuing dolutegravir and discuss with the patient if an alternative treatment should be considered.

Breast-feeding

Women who are HIV-positive must not breast feed because HIV infection can be passed on to the baby in breast milk.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take dolutegravir tablets.**
 - o You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - o It is not known if dolutegravir, emtricitabine and tenofovir alafenamide can pass to your baby in your breast milk.

Talk with your healthcare provider about the best way to feed your baby.

Driving and using machines

Dolutegravir, emtricitabine and tenofovir alafenamide tablets can make you dizzy and have other side effects that make you less alert.

- Don't drive or operate machinery unless you are sure you're not affected.

3. How to take Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets

- **Take dolutegravir, emtricitabine and tenofovir alafenamide tablets exactly as your healthcare provider tell you.**
- Take dolutegravir, emtricitabine and tenofovir alafenamide tablets with or without food.
- Do not change your dose or stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets without first talking with your healthcare provider. Stay under a healthcare provider's care when taking dolutegravir, emtricitabine and tenofovir alafenamide tablets. Do not miss a dose of dolutegravir, emtricitabine and tenofovir alafenamide tablets.
- If you miss a dose of dolutegravir, emtricitabine and tenofovir alafenamide tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than your prescribed dose.
- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, dolutegravir, emtricitabine and tenofovir alafenamide tablets should be taken at least 2 hours before or 6 hours after you take these medicines.
- If you need to take iron or calcium supplements by mouth during treatment with dolutegravir, emtricitabine and tenofovir alafenamide tablets:
 - o If you take dolutegravir, emtricitabine and tenofovir alafenamide tablets with food, you may take these supplements at the same time that you take dolutegravir, emtricitabine and tenofovir alafenamide tablets.
 - o If you do not take dolutegravir, emtricitabine and tenofovir alafenamide tablets with food, take dolutegravir, emtricitabine and tenofovir alafenamide tablets at least 2 hours before or 6 hours after you take these supplements.

- Do not run out of dolutegravir, emtricitabine and tenofovir alafenamide tablets. The virus in your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much dolutegravir, emtricitabine and tenofovir alafenamide tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

4. Possible side effects

What are the possible side effects of dolutegravir, emtricitabine and tenofovir alafenamide tablets

- Dolutegravir, emtricitabine and tenofovir alafenamide tablets can cause serious side effects, including:**
- Allergic reactions. Call your healthcare provider right away if you develop a rash with dolutegravir, emtricitabine and tenofovir alafenamide tablets. Stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets and get medical help right away if you develop a rash with any of the following signs or symptoms:**

o fever	o blisters or peeling of the skin
o generally ill feeling	o redness or swelling of the eyes
o tiredness	o swelling of the mouth, face, lips, or to tongue
o muscle or joint aches	o blisters or sores in mouth
o problems breathing	

- 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 dolutegravir, emtricitabine and tenofovir alafenamide 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.

Tell your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:

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

- Worsening of hepatitis B virus (HBV) infection. Your healthcare provider will test you for HBV infection before or when you start treatment with dolutegravir, emtricitabine and tenofovir alafenamide tablets. If you have HBV infection and take dolutegravir, emtricitabine and tenofovir alafenamide tablets, your HBV may get worse (flare-up) if you stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.**
 - Do not run out of dolutegravir, emtricitabine and tenofovir alafenamide tablets. Refill your prescription or talk to your healthcare provider before your dolutegravir, emtricitabine and tenofovir alafenamide tablets is all gone.
 - Do not stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets without first talking to your healthcare provider.
 - If you stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver, and may give you a medicine to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets.
- Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking medicines to treat HIV-1 infection. 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 any new symptoms after starting your HIV-1 medicine.
- New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and while taking dolutegravir, emtricitabine and tenofovir alafenamide tablets. Your healthcare provider may tell you to stop taking dolutegravir, emtricitabine and tenofovir alafenamide tablets if you develop new or worse kidney problems.
- Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or

fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

- Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

The most common side effects of dolutegravir, emtricitabine and tenofovir alafenamide tablets include:

- o trouble sleeping
- o nausea
- o tiredness
- o headache
- o diarrhea

These are not all of the possible side effects of dolutegravir, emtricitabine and tenofovir alafenamide tablets.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet, please report it immediately via following e-mail address: pharmacovigilance@aurobindo.com. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets

- Store dolutegravir, emtricitabine and tenofovir alafenamide tablets below 30°C.
- Keep dolutegravir, emtricitabine and tenofovir alafenamide tablets in their original container.
- Keep the container tightly closed.
- The bottle of dolutegravir, emtricitabine and tenofovir alafenamide tablets contains desiccant packets to help keep your medicine dry (protect it from moisture). Do not remove the desiccant packets from the bottle.

Keep dolutegravir, emtricitabine and tenofovir alafenamide tablets and all medicines out of the reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets contains

- The active substance is Dolutegravir, Emtricitabine and Tenofovir Alafenamide. Each film-coated tablet contains Dolutegravir sodium equivalent to 50 mg of Dolutegravir, Emtricitabine 200 mg, Tenofovir Alafenamide 25 mg equivalent to 28 mg of Tenofovir Alafenamide Fumarate.
- The other ingredients in the tablet core are Mannitol, Microcrystalline Cellulose, Povidone, Ferric Oxide, Sodium Starch Glycolate, Sodium Stearyl Fumarate, Croscarmellose sodium and Magnesium stearate.
- The other ingredients in the tablet film coating are Polyvinyl alcohol, Talc, Titanium dioxide and Polyethylene glycol.

What Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets looks like and contents of the pack

Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets are White to off-white colored, modified capsule shaped, film-coated tablets debossed with "DET" on one side and plain on other side.

The film-coated tablets are provided in bottles containing 30 & 90 tablets.

Marketing Authorization Holder

Aurobindo Pharma Limited,
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AUROBINDO

Manufactured By

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