dolutegravir (Tivicay, Tivicay PD)

WHAT IS DOLUTEGRAVIR?

Dolutegravir, also known as dolutegravir sodium and DTG (brand name Tivicay, Tivicay PD), is a drug used as part of antiretroviral therapy (ART). The FDA approved dolutegravir in 2013 as an antiretroviral drug (ARV) for people with HIV infection. Dolutegravir is manufactured by ViiV Healthcare.

Dolutegravir is a type of drug called an integrase inhibitor. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating.

When used with other ARVs to treat HIV infection, dolutegravir may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Dolutegravir does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE DOLUTEGRAVIR?

Dolutegravir is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children 4 weeks old and older who weigh at least 6.6 pounds (3 kg):

- who have not received HIV medicines in the past
  OR
- to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements

Dolutegravir comes in two forms: Tivicay and Tivicay PD

- Tivicay is a prescription HIV medicine used with rilpivirine (Edurant) as a complete regimen to treat HIV infection in adults.
- Tivicay PD is a prescription HIV medicine used with other ARVs to treat HIV infection in children weighing at least 6.6 pounds (3 kg).

The safety and effectiveness of dolutegravir has not been established in children less than 4 weeks of age who weigh less than 6.6 pounds (3 kg). Dolutegravir has not been carefully studied in the elderly (65 years of age and older).

All people living HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE DOLUTEGRAVIR?

Do not take dolutegravir if you are allergic to dolutegravir or any of the ingredients in this product.

Do not take dolutegravir if you take dofetilide.

Dolutegravir is not recommended in people with severe liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING DOLUTEGRAVIR?

Before you take dolutegravir tell your healthcare provider about all of your medical conditions, and in particular if you have or have had liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with dolutegravir. Dolutegravir may harm your unborn baby. Your healthcare provider may prescribe a different medicine than dolutegravir if you are planning to become pregnant or if pregnancy is confirmed during the first 12

weeks of pregnancy. If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with dolutegravir and you should consistently use effective birth control (contraception) during treatment with dolutegravir.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with dolutegravir. It is not known if dolutegravir can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS DOLUTEGRAVIR TAKEN?

Dolutegravir is taken by mouth as a tablet or oral suspension. The recommended dosage of dolutegravir for adults who have not taken integrase inhibitors previously is one 50 mg tablet once daily, **in combination with one 25 mg tablet of rilpivirine (Edurant).** In adults who have used integrase inhibitors previously or who have suspected resistance to integrase inhibitors, the recommended dosage of dolutegravir is 100 mg daily taken as one 50 mg tablet twice daily, in combination with one 25 mg tablet of rilpivirine (Edurant).

The recommended dosage of dolutegravir for children varies based on the child's weight, age, and other medicines they are taking. Your healthcare provider will determine the correct dosage.

You should take dolutegravir at the same time each day with or without food.

If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, dolutegravir 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:

- If you take dolutegravir with food, you may take these supplements at the same time that you take dolutegravir.
- If you do not take dolutegravir with food, take dolutegravir at least 2 hours before or 6 hours after you take these supplements.

Tivicay tablets are not the same as Tivicay PD tablets for oral suspension 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.

Dolutegravir is also available in several combination medications. Combination HIV medicines contain two or more HIV medicines from one or more drug classes.

- Abacavir/dolutegravir/lamivudine (Triumeq)
- Dolutegravir/lamivudine (Dovato)
- Dolutegravir/rilpivirine (Juluca)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of dolutegravir are trouble sleeping, tiredness, and headaches.

Dolutegravir can cause serious side effects including:

Allergic reactions. Call your healthcare provider right away if you develop a rash with dolutegravir. Stop taking dolutegravir and get medical help right away if you develop a rash with any of the following signs or symptoms:

- Fever
- Generally ill feeling
- Tiredness
- Muscle or joint aches

- Trouble breathing
- Blisters or sores in mouth
- Blisters or peeling of the skin
- Redness or swelling of the eyes
- Swelling of the mouth, face, lips, or tongue

Liver problems. People with a history of HBV or HCV may have an increased risk of developing new or worsening changes in certain liver tests during treatment with dolutegravir. 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
- Itching

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting dolutegravir.

These are not all the possible side effects of dolutegravir. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES DOLUTEGRAVIR REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take dolutegravir with other medicines.

Dolutegravir should not be taken with the heart medication dofetilide.

MORE INFORMATION

Visit the Tivicay website.

Visit the Tivicay healthcare professional website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Check out the ViiV Healthcare Patient Assistance Program.

Get a ViiV Healthcare Savings Card.

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