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Dolutegravir

pronounced as (doe" loo teg' ra vir)

Why is this medication prescribed?

Dolutegravir is used with other medications to treat human immunodeficiency virus (HIV) infection in adults and children 4 weeks of age and older who weigh at least 6.6 lbs (3 kg). It is also used in combination with rilpivirine (Edurant) to treat HIV in certain adults to replace their current HIV medication(s) that has been taken for at least 6 months. Dolutegravir is in a class of medications called HIV integrase inhibitors. It works by decreasing the amount of HIV in your blood and increasing the number of immune cells that help fight infections in your body. Although dolutegravir does not cure HIV, using it along with other medications may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other lifestyle changes may decrease the risk of transmitting (spreading) the HIV virus to other people.

How should this medicine be used?

Dolutegravir comes as a tablet and as a tablet for suspension (a tablet to dissolve in liquid) to take by mouth. It is usually taken once or twice a day with or without food. Take dolutegravir at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take dolutegravir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Do not chew, cut, or crush the tablets for oral suspension. You can swallow the tablet whole, one at a time, or mix them with drinking water before use.

If you mix the tablets for oral suspension in drinking water, add the prescribed number of tablet(s) to a dosing cup. If taking 1 or 3 tablet(s) for oral suspension, add 1 teaspoon (5 mL) of drinking water to the cup. If taking 4, 5, or 6 tablets for oral suspension, add 2 teaspoons (10 mL) of drinking water to the cup. Do not use any other liquid to dissolve the tablet. Swirl the cup for 1 or 2 minutes or until the mixture is completely dissolved; the mixture will appear cloudy. When the tablet(s) for suspension completely dissolve, drink the mixture right after mixing it. If it has been more than 30 minutes after mixing the mixture, discard the mixture.

If giving the tablets for suspension mixture to a child, make sure that he or she is upright when taking it. If there is remaining mixture in the cup, add another 1 teaspoon (5 mL) of drinking water to the cup,

swirl, and give it all to the child to make sure the child gets the full dose.

If giving the tablets for suspension mixture to an infant, use the oral syringe provided to measure and give the dose. Place the tip of the syringe into the dosing cup with the prepared mixture to draw it up into the syringe. Place the tip of the oral syringe into the child's mouth against the inside of the cheek. Gently push down on the plunger to give the dose slowly. Allow time for the infant to swallow the mixture. Add another 1 teaspoon (5 mL) of drinking water to the cup and swirl. Draw up the remaining mixture into the syringe and give it all to the infant. Repeat if any of the mixture remains in the syringe to make sure the infant gets the full dose. The mixture should be given to the baby within 30 minutes of mixing. After the dose, wash the cup and syringe parts separately with water. Allow parts to dry completely before reassembling and storing.

Do not switch from tablets to tablet(s) for suspension without first talking to your doctor.

Continue to take dolutegravir even if you feel well. Do not stop taking dolutegravir without talking to your doctor. When your supply of dolutegravir runs low, get more from your doctor or pharmacist. If you stop taking dolutegravir or miss doses, your condition may become worse and more difficult to treat with medication.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking dolutegravir,

- tell your doctor and pharmacist if you are allergic to dolutegravir, any other medications, or any of the ingredients in dolutegravir tablets. Ask your pharmacist or check the manufacturer's patient information for a list of the ingredients.
- tell your doctor if you are taking dofetilide (Tikosyn). Your doctor will probably tell you not to take dolutegravir if you are taking this medication.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements, you are taking or plan to take. Be sure to mention any of the following: dalfampridine (Ampyra); other medications for HIV including efavirenz (Sustiva, in Atripla), etravirine (Intelence), fosamprenavir (Lexiva) taken with ritonavir (Norvir), nevirapine (Viramune), and tipranavir (Aptivus) taken with ritonavir (Norvir); certain medications for seizures including carbamazepine (Carbatrol, Equetro, Tegretol), oxcarbazepine (Oxtellar XR, Trileptal), phenobarbital, and phenytoin (Dilantin, Phenytek); metformin (Glumetza, Glucophage, Riomet); and rifampin (Rifadin, Rimactane, in Rifamate, in Rifater). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- if you are taking antacids, laxatives, or multivitamins that contain aluminum, magnesium, or calcium; calcium supplements; iron supplements; sucralfate (Carafate); or buffered medications such as buffered aspirin, take them 2 hours after or 6 hours before you take dolutegravir. However, if you take dolutegravir with food, you may take these supplements at the same time that you take dolutegravir.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had kidney disease or are receiving dialysis treatments or liver disease including hepatitis B or hepatitis C.
- tell your doctor if you are pregnant or plan to become pregnant. You will need to take a pregnancy test before you start treatment. Talk to your doctor about effective birth control methods that you can use during your treatment. If you become pregnant while taking dolutegravir, call your doctor immediately. Dolutegravir may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed if you are infected with HIV or if you are taking dolutegravir.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms after starting treatment with dolutegravir, be sure to tell your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Dolutegravir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- difficulty falling asleep or staying asleep
- headache
- stomach pain
- gas
- diarrhea
- weight gain

Some side effects can be serious. If you experience any of these symptoms or those listed in the SPECIAL PRECAUTIONS section, stop taking dolutegravir and call your doctor immediately or get emergency medical attention:

- rash
- fever
- feeling sick
- excessive tiredness
- muscle or joint pain

- blistering or peeling skin
- blisters or sores in the mouth
- red or swollen eyes
- swelling of the eyes, face, lips, mouth, tongue, or throat
- difficulty breathing or swallowing
- yellow of eyes or skin
- dark urine
- pale colored bowel movements
- nausea
- vomiting
- loss of appetite
- pain in the upper right part of the stomach

Dolutegravir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Do not remove the desiccant (small packet that contains a substance that absorbs moisture to keep the medication dry) from the bottle.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to dolutegravir.

Keep a supply of dolutegravir on hand. Do not wait until you run out of medication to refill your prescription.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Tivicay[®]
- Tivicay[®] PD
- Juluca[®] (as a combination product containing dolutegravir, rilpivirine)

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