

For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Dolutegravir Dispersible Tablets

10mg

FDA-
APPROVED
TREATMENT
FOR (HIV-1)
INFECTION.

DOLUTEGRAVIR OF (DISPERSIBLE TABLETS) IS AN ANTIRETROVIRAL MEDICATION CONTAINING DOLUTEGRAVIR (10MG), USED IN COMBINATION WITH OTHER ANTIRETROVIRAL DRUGS TO TREAT HIV-1 INFECTION IN ADULTS, ADOLESCENTS, AND CHILDREN WHO DO NOT HAVE OTHER FORMS OF HIV-1 INFECTION. IT BELONGS TO THE INTEGRASE STRAND TRANSFER INHIBITOR (INSTI) CLASS, INHIBITING VIRAL REPLICATION.

Package leaflet: Information for the patient Dolutegravir Dispersible Tablets 10mg

Read all of this leaflet carefully before you (or your child, if you are the patient) 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 (or your child, if they are the patient) 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.

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What is in this leaflet

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1. What Dolutegravir Dispersible Tablets is and what it is used for

Dolutegravir Dispersible Tablets is prescription medicines used to treat Human Immunodeficiency Virus-1 (HIV-1) infection together with:

- other HIV-1 medicines in adults who have not received HIV-1 medicines in the past or to replace their current HIV-1 medicines.
- other HIV-1 medicines in children, aged at least 4 weeks and weighing at least 6.6 pounds (3 kg), who have not received HIV-1 medicines in the past or to replace their current HIV-1 medicines when their healthcare provider determines that they meet certain requirements. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if Dolutegravir Dispersible Tablets is safe and effective in children who are less than 4 weeks of age and weigh less than 6.6 pounds (3 kg) or in children who have received certain types of medicine for HIV-1 infection

2. What you need to know before you take Dolutegravir Dispersible Tablets

Do not take Dolutegravir Dispersible Tablets if you:

- have ever had an allergic reaction to a medicine that contains dolutegravir.
 - take dolutegravir
- Before you take Dolutegravir Dispersible 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.
 - are pregnant or plan to become pregnant. Dolutegravir Dispersible Tablets may harm your unborn baby.

- Your healthcare provider may prescribe a different medicine than Dolutegravir Dispersible Tablets 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 Dispersible Tablets.

- If you can become pregnant, you should consistently use effective birth control (contraception) during treatment with Dolutegravir Dispersible Tablets.

- 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 Dispersible Tablets.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take Dolutegravir Dispersible Tablets.
- You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

- It is not known if Dolutegravir Dispersible Tablets can pass to your baby in your breast milk.

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

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

Some medicines interact with Dolutegravir Dispersible 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 Dispersible Tablets

Do not start taking a new medicine without telling your healthcare provider.

Your healthcare provider can tell you if it is safe to take Dolutegravir Dispersible Tablets with other medicines. Formulation contains mannitol which may have a mild laxative effect.

3. How to take Dolutegravir Dispersible Tablets

- Take Dolutegravir Dispersible Tablets exactly as your healthcare provider tells you to take it.

- Take Dolutegravir Dispersible Tablets with or without food.
- The tablet can be divided into two equal halves.
- Dolutegravir 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 tablet)

Swirl or stir until the tablets disperse completely.

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

- Dolutegravir tablets are not the same as Dolutegravir 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 Dolutegravir Dispersible Tablets without talking with your healthcare provider first.
- If you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines, Dolutegravir Dispersible 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 Dispersible Tablets:

- If you take Dolutegravir Dispersible Tablets with food, you may take these supplements at the same time that you take Dolutegravir Dispersible Tablets.
- If you do not take Dolutegravir Dispersible Tablets with food, take Dolutegravir Dispersible Tablets at least 2 hours before or 6 hours after you take these supplements.
- Do not miss a dose of Dolutegravir Dispersible Tablets.
- If you miss a dose of Dolutegravir Dispersible Tablets, take it as soon as you remember.
- Do not take 2 doses at the same time or take more than your prescribed dose.
- Stay under the care of a healthcare provider during treatment with Dolutegravir Dispersible Tablets.

- Do not run out of Dolutegravir Dispersible 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 Dispersible Tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

4. Possible side effects

- Dolutegravir Dispersible Tablets can cause serious side effects including:
 - Allergic reactions. Call your healthcare provider right away if you develop a rash with Dolutegravir Dispersible Tablets. Stop taking Dolutegravir Dispersible Tablets 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
 - 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
 - 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 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 Dolutegravir Dispersible Tablets.
- The most common side effects of Dolutegravir Dispersible Tablets include:
 - trouble sleeping
 - tiredness
 - headache

5. How to store Dolutegravir Dispersible Tablets

- Store Dolutegravir Dispersible Tablets dispersible tablets at room temperature below 86°F (30°C) in the original bottle. Keep the bottle tightly closed and protected from moisture.
- Keep out of the reach and sight of children.

2. Contents of the pack and other information

What Dolutegravir Dispersible Tablets contains
Active ingredient: Dolutegravir. Core Tablet Mannitol, Microcrystalline cellulose, Sodium starch glycolate, Povidone, Silicified Microcrystalline cellulose, Crospovidone and Sucralose.

HDPE Bottle pack of 30's, 60's, 90's, 180's and 270's*
* Not all pack sizes may be marketed.

The Product is not for administration to anyone other than Child Patients.
Any other use is not authorized.
Not all pack sizes may be marketed.
Marketing authorization holder and manufacturer

POM

TAJ GROUP

Manufactured By: **Taj Pharma India Ltd.**
PLOT NO.1019, SARIGAM G.I.D.C.,
ROAD NO. 10, DIST. - VALSAD,
GUJARAT 396155, INDIA.
(WHO-cGMP CERTIFIED COMPANY)
Mfg. Lic. No.: G/25/2700
Visit us at: www.tajpharma.in

Note: Patients receiving dolutegravir are advised to take it concomitantly with food.

This leaflet was last revised in Feb 2026.

TREATMENT OF HIV-1 INFECTION IN ADULTS AND CHILDREN, USED AS A COMPLETE TWO-DRUG REGIMEN WITH RILPIVIRINE (AS JALUCA) FOR CERTAIN ADULTS.

Dolutegravir 10mg Dispersible Tablets is an antiretroviral medication used in combination with other agents to treat HIV-1 in adults, adolescents, and children (at least 4 weeks old and weighing 3 kg). As an integrase Strand Transfer Inhibitor (INSTI), it inhibits HIV replication.

THE PRODUCT IS NOT FOR ADMINISTRATION TO WHO/OTHERS THINK CHILD PATIENTS. ANY OTHER USE IS NOT AUTHORIZED.

Also treat human immunodeficiency virus (HIV) infection in children 4 weeks of age and older who weigh at least 6.6 lbs (3 kg).

Take this medicine at least 2 hours before or 6 hours after you take antacids, laxatives, or other medicines that contain aluminum, magnesium, or buffered medicines. You may take calcium or iron supplements together with this medicine if you take them with food.

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TAJ PHARMA



Thank God I Said NO to AIDS



I AM DRIVING STRAIGHT HOME TO MY WIFE

Dolutegravir DT (dispersible tablets) is an antiretroviral medication containing Dolutegravir (10mg), used in combination with other anti-HIV medicines to treat HIV-1 infection in adults, adolescents, and children at least 4 weeks old and weighing at least 3 kg. It belongs to the integrase Strand Transfer Inhibitor (INSTI) class, inhibiting viral replication.

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DO NOT CHEW, CUT, OR CRUSH TABLET FOR ORAL SUSPENSION.



Dolutegravir Dispersible Tablets

10mg

Dolutegravir dispersible tablets is an antiretroviral medication containing Dolutegravir (10 mg), used in combination with other anti-HIV medicines to treat HIV-1 infection in adults, adolescents, and children (at least 4 weeks old and weighing at least 3 kg). It belongs to the integrase Strand Transfer Inhibitor (INSTI) class, inhibiting viral replication. Key Details: About Dolutegravir DT: Primary Use: Treatment of HIV-1 infection in combination with other antiretroviral agents. Formulation: Dispersible tablets (DT) are designed to dissolve in water, facilitating ease of administration for pediatric patients or those with difficulty swallowing.

FDA-APPROVED TREATMENT FOR (HIV-1) INFECTION.

Dolutegravir is available in various forms, including a dispersible tablet formulation, which is often used for pediatric patients. The appropriate form and strength are determined based on factors like the patient's weight. Administration: It can be taken with or without food. Side Effects: Common side effects may include insomnia, headache, diarrhea, nausea, dizziness, fatigue, and muscle pain. Important Considerations: Dolutegravir is not a cure for HIV and does not prevent its transmission. Usage in Children: Dolutegravir is a component of modern HIV regimens for children due to its tolerability and effectiveness. The specific formulation and amount used for children are determined based on their weight and treatment history.

Note: This information is for educational purposes only. Always consult a healthcare professional for diagnosis and treatment.

Take pills in risky behaviours such as drink driving or unprotected sex. Changes in behaviour such as mood swings or increased aggression toward others. Effects on sleep or experiencing insomnia. Cognitive/memory problems. Reduced appetite or not eating a balanced diet.

Increased risk of neuropsychiatric adverse events during dolutegravir-based antiretroviral therapy during pregnancy. Dolutegravir tablets are not interchangeable. Do not chew or crush tablet for oral suspension, but can be split on the breakline.

Dolutegravir is not a cure for HIV and does not prevent its transmission.

Side effects that you should report to your care team as soon as possible: Allergic reactions such as rash, hives, or swelling of the face, lips, tongue, or throat. Heart attack - pain or tightness in the chest. Stomach pain, nausea, vomiting, or diarrhea. Shortness of breath, cold or clammy skin, feeling faint or lightheaded. Overall, body weight increased by 4.6 kg (95% CI: 4.06-5.15 kg) at 12 months and 6.3 kg (95% CI: 5.65-6.94 kg) at 24 months. At 24 months, participants who started with a BMI gained a mean of 8.6 kg (95% CI: 7.35-9.92 kg) compared to 4.95 kg (95% CI: 3.87-6.02 kg) gain in the NRTI-based arm (p < 0.0001).