

1.6.3 Patient Information Leaflet

The Patient Information Leaflet for Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg is enclosed after this page.

PATIENT INFORMATION LEAFLET (PIL) TEMPLATE

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg

{Dolutegravir Sodium}

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for your child.

- 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 your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of your child.
- If your child gets any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg and what it is used for
2. What you need to know before your child takes Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg
3. How to take Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg
4. Possible side effects
5. How to store Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg
6. Contents of the pack and other information

1. WHAT DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10mg ARE AND WHAT IT IS USED FOR

Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg are prescription medicines used to treat Human Immunodeficiency Virus-1 (HIV-1) infection together with:

- 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 Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg 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.

This medicine is intended for use in children. Safety information on use in adults is also provided.

2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD TAKES DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10mg

Your Child should not be given Dolutegravir Sodium Tablet For Oral Suspension (Dispersible Tablets) 10mg:

- if he/she is allergic to Dolutegravir or any of the other ingredients of this medicine.
- If he/she is taking another medicine called dofetilide (to treat heart conditions).

→If you think any of these apply to your child, tell your doctor.

Tell your health care provider about all, of your child's medical conditions, including if your child:

- has ever had an allergic reaction to Dolutegravir like rash associated with any of the following symptoms, as it may be a sign of a more serious reaction such as severe hypersensitivity: fever; generally ill feeling; extreme tiredness; muscle or joint aches; blisters or peeling of the skin; oral blisters or lesions; eye inflammation; facial swelling; swelling of the eyes, lips, tongue, or mouth; breathing difficulty; and/or signs and symptoms of liver problems (e.g., yellowing of the skin or whites of the eyes, dark or tea-colored urine, pale-colored stools or bowel movements, nausea, vomiting, loss of appetite, or pain, aching, or sensitivity on the right side below the ribs).
- has or has had Hepatotoxicity (liver problems), including hepatitis B or C infection.

Tell your healthcare provider about all, of your child's medical conditions, including if your child:

- Has ever had an allergic reaction to Dolutegravir.
- Has or have had liver problems, including hepatitis B or C infection.

Other medicines and Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg

Tell your child's health care provider if your child is taking, has recently taken or is planning to take any other medicines.

Your child should not take Dolutegravir Sodium Tablet For Oral Suspension (Dispersible Tablets) 10mg with the following medicine:

- dofetilide, used to treat **heart conditions**

Some medicines can affect how Dolutegravir Sodium Tablet For Oral Suspension (Dispersible Tablets) 10mg works, or make it more likely that your child will have side effects.

Dolutegravir can also affect how some other medicines work.

Tell your child's health care provider if your child is taking any of the medicines in the following list:

- metformin, to treat **diabetes**
- Medicines called **antacids**, to treat **indigestion** and **heartburn**. **Do not give an antacid** during the 6 hours before your child take Dolutegravir, or for at least 2 hours after your child takes it.
- Calcium supplements, iron supplements and multivitamins. **Do not give a calcium supplement, iron supplement or multivitamin** during the 6 hours before your child takes Dolutegravir, or for at least 2 hours after your child takes it.
- Etravirine, Efavirenz, fosamprenavir/ritonavir, Nevirapine or Tipranavir/ritonavir, to treat **HIV infection**
- rifampicin, to treat tuberculosis (TB) and other **bacterial infections**
- phenytoin and phenobarbital, to treat **epilepsy**
- Oxcarbazepine and carbamazepine, to treat **epilepsy** or **bipolar disorder**
- St. John's wort (*Hypericum perforatum*), a herbal remedy to treat **depression**
- Dalfampridine to treat multiple sclerosis

Tell your child's doctor or pharmacist if your child is taking any of these. Your child's doctor may decide to adjust your child's dose or that your child needs extra checkups.

Pregnancy and Breastfeeding

- Your healthcare provider may prescribe a different medicine than Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg, if adolescents (child-bearing age) are planning to become pregnant or if pregnancy is confirmed during the first 12 weeks of pregnancy
- If adolescents (child-bearing age) can become pregnant, your healthcare provider will perform a pregnancy test before starting treatment with Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.
- If adolescents (child-bearing age) can become pregnant, they should consistently use effective birth control (contraception) during treatment with Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.
- Tell your healthcare provider right away if adolescents (child-bearing age) are planning to become pregnant, become pregnant, or think they may be pregnant during treatment with Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.**
- 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 Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg can pass to your baby in your breast milk.

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

Driving and using machines

Dolutegravir 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 SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10MG

Always give this medicine as your child's healthcare provider has told you.

- Give your child Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg with or without food.
- For children who cannot swallow tablets, read the Instructions for Use at the end of this patient information for detailed instructions on how to prepare a dose of Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.
- Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg should be dispersed in drinking water and should not be chewed, cut, or crushed.
- **Dolutegravir Sodium Tablets are not the same as Dolutegravir Sodium 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.**
- Do not change your child's dose, switch medicines or stop giving Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg to your child, without talking with your child's healthcare provider first.
- If your child is taking antacids, laxatives, or other medicines that contain aluminium, magnesium, or buffered medicines, Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg should be given at least 2 hours before or 6 hours after you give these medicines to your child.
- If your child is taking iron or calcium supplements by mouth during treatment with Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg:
 - If you are giving Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg with food to your child, you can give these supplements at the same time that you give Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg to your child.
 - If you are not giving Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg with food to your child, give Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg at least 2 hours before or 6 hours after you give these supplements to your child.

- Do not miss a dose of Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.
- **If you miss giving a dose of Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg to your child**, give it as soon as you remember. Do not give 2 doses at the same time or give more than prescribed dose.
- Keep your child under the care of a healthcare provider during treatment with Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg.
- Do not run out of Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg. The virus in your child's blood may increase and the virus may become harder to treat. When your child's tablet supply starts to run low, get more from your child's healthcare provider or pharmacy.
- **If you give too much Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg to our child**, call your child's healthcare provider or go to the nearest hospital emergency room right away.

INSTRUCTIONS FOR USE DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION

Your Pack contains:

- A bottle containing 90 Dolutegravir dispersible tablets
- If provided by your healthcare worker, you may use a medicine cup or an oral syringe to aid dosing. This is not provided from the manufacturer.

You will also need:

- Clean drinking water
- A small cup or bowl your child can drink from
- A spoon (measuring spoon or teaspoon)

Step 1. Pour water:

- Measure clean drinking water into cup or bowl
- If your child's dose is $\frac{1}{2}$ tablet or $1\frac{1}{2}$ tablets use 1 spoonful of water. If your child's dose is 2, $2\frac{1}{2}$, or 3 tablets, use 2 spoonfuls of water.

Step 2. Prepare the medicine:

- Add the prescribed number of tablets to the water.
- If your child's dose includes a $\frac{1}{2}$ -tablet, you will need to split one of the tablets to give the right dose.
- Hold the tablet between your two thumbs and press along the score (break line). The tablet should split evenly along the score. Put the unused $\frac{1}{2}$ -tablet back in the bottle to use for another dose.
- Swirl the cup or bowl gently for 1 to 2 minutes to allow the tablets to dissolve. The medicine will become cloudy. Take care not to spill any of the medicine.

- Check that the medicine is ready. If there are any lumps of tablet, swirl the cup until they are gone.

If you spill any medicine, clean up the spill.

Throw away the rest of the prepared medicine and make a new dose.

You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes, wash away all the dose in the cup using water and prepare a new dose of medicine

Step 3. Give the medicine:

- Make sure that the child is upright.
- Give all the prepared medicine to the child to drink.
- Add another small amount of water to the cup, swirl, and give it all to the child.
- Repeat if any medicine remains in the cup to make sure the child gets the full dose.
- If your child is an infant, it may be easier to give the medicine with a syringe (with no needle). Ask your health care provider, pharmacist, or clinic if they have a medicine syringe to help you.
- Place the tip of the syringe into the prepared medicine and draw up all the medicine into the syringe by pulling up on the plunger (the inside piece).
- Place the tip of the syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another spoonful of water to the cup and swirl. Draw up the remaining medicine and give it all to the infant.
- Repeat if any medicine remains in the syringe to make sure your infant gets the full dose.
- Allow time for the medicine to be swallowed.

Step 4. Clean the dosing items

- Wash the cup with water.
- If you used a syringe, pull the plunger out of the syringe and wash both the syringe parts with water.

Allow parts to dry completely before putting the syringe back together and storing.

- All parts need to be clean before preparing the next dose

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, but not everybody gets them.

Allergic reactions

These are uncommon in people taking Dolutegravir. Signs include:

- skin rash
- a high temperature (fever)
- lack of energy (fatigue)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- Muscle or joint aches.

Very common side effects

These may affect **more than 1 in 10 people**:

- headache
- diarrhea
- feeling sick (nausea).

Common side effects

These may affect **up to 1 in 10 people**:

- rash
- itching (pruritus)
- being sick (vomiting)
- stomach pain (abdominal pain)
- stomach (abdominal) discomfort
- insomnia
- dizziness
- abnormal dreams
- depression (feelings of deep sadness and unworthiness)
- lack of energy (fatigue)
- wind (flatulence)
- increase in the level of liver enzymes
- increase in the level of enzymes produced in the muscles (creatine phosphokinase).

Uncommon side effects

These may affect **up to 1 in 100 people**:

- inflammation of the liver (hepatitis)
- suicidal attempt*
- suicidal thoughts*
- joint pain
- muscle pain

Other possible side effects

People taking medicines for HIV may get other side effects described below.

Infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems and they are more likely to develop serious infections (opportunistic infections). Such infections may have been 'silent' before starting HIV treatment. After starting treatment, the immune system becomes stronger, and may attack

the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, headache, stomach ache, and breathing difficulty.

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. Symptoms may include palpitations (rapid or irregular heartbeat), tremor, excessive restlessness and movement, weakness beginning in the hands and feet and moving up towards the trunk of the body.

Speak to your health care provider **immediately** if you get any symptoms of infection and inflammation. Do not take other medicines for the infection without checking with your health care provider.

Reporting of side effects

If your child gets any side effects, talk to your child's health care provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOLUTEGRAVIR SODIUM TABLET FOR ORAL SUSPENSION (DISPERSIBLE TABLETS) 10MG

Store below 30°C, Store in the original package to protect from moisture.

Keep the bottle tightly closed.

Keep this medicine out of the sight and reach of children.

Do not remove desiccant.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle.

This medicine does not require any special storage conditions.

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. FURTHER INFORMATION

What Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg contains

- The active pharmaceutical ingredient(s) is Dolutegravir Sodium
- The other ingredient(s) is (are)

Mannitol, Microcrystalline Cellulose, Sodium Starch Glycolate, Povidone, Silicified Microcrystalline Cellulose, Crospovidone, Calcium Sulphate Dihydrate, Strawberry Cream Flavor, Sucralose, Sodium Stearyl Fumarate, Opadry Pink (Hypromellose, Titanium dioxide, Macrogol and Iron oxide red).

What Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg looks like and contents of the pack

Pink colored, caplet shaped; film coated tablets, debossed "K" and "1" separated by breakline on one side and breakline on other side.

Dolutegravir Sodium Tablet for Oral Suspension (Dispersible Tablets) 10mg will be packed in

Container Pack: 90's Tablet with Silica Gel

90 tablets packed in 60cc white, round HDPE container with 33 mm neck finish with 33 mm Closure, child resistant with pulp and white printed heat seal liner with 1g Silica gel sachet (2x1gm) along with pack insert.

Container Pack: 90's Tablet without Silica Gel

90 tablets packed in 60cc white, round HDPE container with 33 mm neck finish with 33 mm Closure, child resistant with pulp and white printed heat seal liner along with pack insert.

Supplier and Manufacturer

Supplier

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Manufacturer

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This leaflet was last approved on {MM/YYYY}.

Detailed information on this medicinal product is available on PQTm's website (see: <http://www.who.int/prequal>).