Information for the patient

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg

Dolutegravir (sodium)/lamivudine/tenofovir disoproxil fumarate

The warnings and instructions in this leaflet are intended for the person taking the medicine. If you are a parent or carer responsible for giving the medicine to someone else such as a child, you will need to apply the instructions accordingly .

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 questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is and what it is used for
2. What you need to know before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg
3. How to take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg
4. Possible side effects
5. How to store Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg
6. Contents of the pack and other information

1. What Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is and what it is used for

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is a medicine used to treat HIV (human immunodeficiency virus) infection in adults and adolescents who weigh at least 30 kg. It contains three active ingredients: dolutegravir, lamivudine and tenofovir disoproxil.
Dolutegravir belongs to a group of antiretroviral medicines called integrase inhibitors. Tenofovir is a nucleotide reverse transcriptase inhibitor, while lamivudine belongs to the group of the nucleoside analogue reverse transcriptase inhibitors.
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg reduces the amount of virus in your body and keeps it at a very low level. It is not a cure for HIV infection but if taken correctly it will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg does not work equally well in everybody. Your health care provider will check how well your treatment is working.
To control your HIV infection, and to stop your illness from getting worse, you must take all your HIV medicines regularly, unless your health care provider tells you to stop taking any.

2. What you need to know before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg

Do not take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg if you are:
- allergic to dolutegravir, tenofovir disoproxil, lamivudine or any of the other ingredients of this medicine (listed in section 6)
- taking medicines such as dofetilide (to treat heart conditions) or fampridine (also known as dalfampridine used in multiple sclerosis).

If you think any of these apply to you, tell your health care provider.

Warnings and precautions
Look out for important symptoms
Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:
- infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you are taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg.

Tell your healthcare provider about any flu-like illness – either in the month before starting Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, or at any time while taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg.
Read the information, „Other possible side effects" in Section 4 of this leaflet.

Kidney disease
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg may affect your kidneys. Before starting this medicine you may need blood tests to check how well your kidneys are working. Blood tests may also be required during treatment to check the health of your kidneys.
Tell your health care provider if you have had kidney disease or if tests have shown problems with your kidneys. If so, the dose of tenofovir disoproxil and lamivudine may need to be reduced. In such cases formulations of tenofovir disoproxil and lamivudine other than Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg should be used.

Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is not usually taken with other medicines that can damage your kidneys (see "Other medicines and Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg."). If this is unavoidable, you may need regular tests to check how well your kidneys are working.

Liver disease
Tell your health care provider if you have a history of liver disease, including hepatitis. HIV-infected patients with liver disease, including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you are infected with HIV and hepatitis B virus, your health care provider will carefully consider the best treatment for you. If you have a history of liver disease or chronic hepatitis B infection your health care provider may conduct blood tests to monitor your liver function.

Children
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is suitable only for adolescents who weigh at least 30 kg. Other medicines that contain smaller amounts of dolutegravir, tenofovir or lamivudine are needed for patients who weigh less than 30 kg.

Other medicines and Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg
Tell your health care provider if you are taking, have recently taken or are planning to take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

You **must not** take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg with dofetilide, which is used to treat heart conditions or fampridine (used in treatment of multiple sclerosis).

Some medicines can affect how Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg works or increase side effects. Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg can also affect how some other medicines work.

Tell your health care provider if you are taking any of the following:
- metformin, to treat diabetes
- antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, or for at least 2 hours after you take it
- calcium supplements, iron supplements and multivitamins. Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, or for at least 2 hours after you take it
- didanosine, etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin or rifapentine to treat tuberculosis 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 used for treating depression
- other medicines containing tenofovir disoproxil, emtricitabine, lamivudine or zalcitabine to treat HIV infection

It is very important to tell your health care provider if you are taking other medicines that may damage your kidneys. These include:
- aminoglycosides, pentamidine or vancomycin (for bacterial infection)
- amphotericin B (for fungal infection)
- foscarnet, ganciclovir, or cidofovir (for viral infection)
- adefovir dipivoxil (for hepatitis B virus infection)
- tacrolimus (for suppression of the immune system)
- interleukin-2 (to treat cancer)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains) such as aspirin and ibuprofen.

If you are taking any of these, your health care provider may adjust your dose or arrange extra check-ups.

Other medicines containing didanosine (for HIV infection):
Taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg with medicines that contain didanosine can increase the amount of didanosine in your blood. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), sometimes causing death, has been reported when medicines containing tenofovir disoproxil and didanosine were taken together. Combining tenofovir disoproxil with didanosine can also reduce the effects of antiretroviral therapy. Your health care provider will carefully consider whether to treat you with a combination of tenofovir disoproxil and didanosine.

If you are taking another antiviral medicine called a protease inhibitor to treat HIV, your healthcare provider may order blood tests to closely monitor your kidney function.

It is also important to tell your health care provider if you are taking ledipasvir/sofosbuvir, sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir to treat hepatitis C infection.

Pregnancy
If you are pregnant, if you become pregnant, or if you are planning to have a baby talk to your health care provider about the risks and benefits of taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg. Your health care provider will review your treatment.

Taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg around the time you become pregnant or during the first weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect (e.g. spina bifida).

Do not stop taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg without checking with your health care provider, as this may harm you and your unborn baby.

Breast-feeding
If you wish to breast-feed your baby, you should discuss the risks and benefits with your health care provider.

Driving and using machines
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg can make you dizzy and have other side effects that make you less alert. Do not drive or operate machinery until you are sure that you do not have side effects that affect driving or using machines.

Important information about some of the ingredients of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg contains mannitol which may have a mild laxative effect. This medicine also contains less than 1 mmoL sodium per tablet, that is to say, is essentially „sodium-free".

3. How to take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg

Always take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg exactly as your health care provider has told you. Do not stop taking it without checking with your health care provider. Check with the health care provider if you are not sure.
You can take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg with food or between meals.

The dose of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg in adults and adolescents weighing at least 30 kg is one tablet once a day.

Adults whose HIV infection is resistant to medicines similar to dolutegravir, one of the components of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, may be given additional doses of medicines containing the active substance dolutegravir only.

Adolescents whose HIV infection is resistant to medicines similar to dolutegravir, one of the components of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, should **not** take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg.

Children
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is not suitable for children weighing less than 30 kg and different formulations should be used.

Antacids, calcium supplements, iron supplements, multivitamins
Ask your health care provider for advice if you are taking:
- an antacid (a medicine used for treating indigestion and heartburn).
- calcium supplements
- iron supplements
- multivitamins.

Take these medicines at least 6 hours before you take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg or take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg at least 2 hours after taking an antacid, calcium or iron supplement, or multivitamins.

If you take more Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg than you should
If you take too many tablets of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, contact your health care provider for advice. If possible, show them the Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg pack.

If you forget to take or if you vomit after taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg
If you forget to take a dose, take the missed dose as soon as you remember on the same day. If you do not remember on the same day, take the normal dose on the next day. Do not take a double dose to make up for forgotten dose. If you are unsure about what to do, ask your health care provider.

If you vomit within 1 hour of taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg, then you should take an extra dose. If vomiting occurs more than an hour after taking the dose, then you do not need to take an extra dose and can take the next dose as usual when it is due.

Don't stop taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg without advice from your health care provider
Take Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg for as long as your health care provider recommends it. Don"t stop unless your health care provider advises you to. Taking the tablets regularly is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The infection may then become harder to treat.
If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

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

Talk to your health care provider if there is any worsening of your health. The changes could be caused by the medicine or the condition getting worse.

Allergic reactions
See a health care provider straightaway if you get an allergic reaction because the health care provider may decide that you should stop taking Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg.
The signs of allergic reactions are:
- skin rash
- fever
- tiredness (fatigue)
- swelling under the skin which can involve the face or mouth and difficulty in breathing
- muscle and joint ache

Very common side effects
These may affect more than 1 in 10 people
- rash
- headache
- lack of energy (asthenia)
- dizziness
- diarrhoea
- feeling sick (nausea) and vomiting

Tests may also show:
- abnormally low levels of phosphate in the blood

Common side effects
These may affect up to 1 in 10 people:
- cough, nasal symptoms
- tiredness
- hair loss
- fever
- itching (pruritus)
- muscle disorders and joint ache (arthralgia)
- abdominal (belly) pain and discomfort,
- wind (flatulence)
- difficulty sleeping (insomnia), abnormal dreams
- depression
- anxiety

Tests may also show:
- liver problems (increase in liver enzymes)
- increase in an enzymes produced in the muscle called creatine phosphokinase

Uncommon side effects
These may affect up to 1 in 100 people:
- yellow skin or eyes, itching, or pain in the abdomen (tummy) caused by inflammation of the liver (hepatitis)
- muscle pain (myalgia) and muscle weakness
- breakdown of muscle fibres (rhabdomyolysis)
- panick attack
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- allergic reactions
- appearance of symptoms of infection as part of the „immune reactivation syndrome" (see Warnings and precautions)

Tests may also show
- increased creatinine in your blood
- a decreased number of cells involved in blood clotting (thrombocytopenia)
- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)

Rare side effects
These may affect up to 1 in 1000 people:
- pain in the tummy (abdomen) caused by inflammation of the pancreas
- lactic acidosis (excess of lactic acid in the blood)
- liver failure
- fatty liver
- swelling under the skin (angioedema)
- inflammation of the kidney, passing a lot of urine and feeling thirsty
- changes to your urine and back pain caused by kidney problems, including kidney failure
- softening of the bones (with bone pain and sometimes resulting in fractures)
- muscle disease causing weakness (myopathy)

Tests may also show
- damage to kidneys
- increase in an enzyme called amylase (pancreas problems)

Lactic acidosis (excess lactic acid in the blood) is a **rare** but serious side effect that can be fatal. The following side effects may be signs of lactic acidosis:
- deep, rapid breathing
- drowsiness
- feeling sick (nausea), being sick (vomiting) and stomach pain

Very rare side effects
These may affect up to 1 in 10000 people
- nerve injury causing weakness and sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy)
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)

Tests may also show:
- damage to kidney tubule cells

Side effects with unknown frequency
- death of bone tissue (osteonecrosis)
- decreases in potassium in the blood

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Symptoms of infection and inflammation
People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). Such infections may have been „silent" and not detected by the weak immune system before treatment was started. 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, plus some of the following:
- headache
- stomach ache
- difficulty breathing.

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) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.

If you get any symptoms of infection and inflammation or if you notice any of the symptoms above, tell your healthcare provider immediately. Don"t take other medicines for the infection without your health care provider's advice.

Joint pain, stiffness and bone problems
Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:
- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:
- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms, tell your health care provider.

Weight, blood lipid and blood glucose effects
During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle, and in the case of blood lipids sometimes to the HIV medicines themselves. Your health care provider will test for these changes.
If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects,talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg

Keep this medicine out of the sight and reach of children. Do not store above 30ºC. Store in the original container.
Discard 90 days after first opening. *(This is applicable to pack sizes of 90 and 500*). Discard 180 days after first opening. *(This is applicable to pack sizes of 180*).

Do not use this medicine after the expiry date stated on the label, after "EXP". The expiry date refers to the last day of that month.
Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.
Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg contains

- The active ingredients are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.
- The other ingredients of Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg are mannitol, microcrystalline cellulose, sodium starch glycolate, povidone, croscarmellose sodium, magnesium stearate, hydroxypropyl methylcellulose, polyvinyl alcohol, talc, titanium dioxide, sodium lauryl sulfate, FD& C blue #2/indigo carmine and FD& C blue #1/brilliant blue FCF aluminium lake.

What Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg looks like and contents of the pack
Blue-coloured, capsule-shaped, biconvex, film-coated tablet debossed with "C" on one side and plain on the other side.
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is available in white HDPE bottle with two 2 gram silica gel bags and closed with white non-child resistant cap. Each bottle contains 30 or 90 tablets.
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is available in white HDPE bottle with four 5 gram silica gel bags and closed with white non-child resistant cap. Each bottle contains 500 tablets.
Dolutegravir (as sodium)/Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg is also available in white HDPE bottle with three 5 gram silica gel bags and closed with white non-child resistant cap. Each bottle contains 180 tablets.

Supplier and Manufacturer

Supplier	*Manufacturer*
Cipla Limited Cipla House, Peninsula Business Park, Ganpatrao, Kadam Marg, Lower Parel, Mumbai, Maharashtra 400013, India Tel. No.:+ 91222482600 Fax No.: +912224826120	Cipla Limited, Goa Unit VII Verna Industrial Estate Verna, Salcette Goa-403 722 India Cipla Limited Unit VII PD II Verna Industrial Estate Verna, Salcette Goa-403 722 India Tel. No.: +91 832 2889 000/199 Fax No.: +91-832-2782805 Cipla Quality Chemical Industries Ltd Plot No 1-7, 1st Ring Road Luzira Industrial Park P.O. Box 34871, Kampala Uganda

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in September 2022

- **This Product has been produced under a licence from the Medicines Patent Pool**
- **Any other use is not authorized**

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Dolutegravir (as sodium)/ Lamivudine/Tenofovir disoproxil fumarate tablets 50mg/300mg/300mg

Information for the patient

[Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de ténofovir disoproxil comprimés 50mg/300mg/300mg]

Dolutégravir (sodique)/Lamivudine/fumarate de Ténofovir disoproxil

Les avertissements et les instructions contenus dans cette notice sont destinés à la personne qui prend le médicament. Si vous êtes un parent ou un aidant responsable de l'administration du médicament à une autre personne, par exemple un enfant, vous devrez appliquer les instructions en conséquence

Veuillez lire attentivement l'intégralité de cette notice avant de prendre ce médicament car elle contient des informations importantes pour vous.
- Gardez cette notice. Vous pourriez avoir besoin de la relire.
- Si vous avez des questions au sujet du médicament, consultez votre professionnel de santé.
- Ce médicament vous a été personnellement prescrit. Ne le donnez pas à d'autres. Il pourrait leur être nocif, même si les signes de la maladie sont les mêmes que les vôtres.
- Si vous êtes préoccupé par un quelconque effet secondaire, parlez-en à votre professionnel de santé. Cela inclut les effets indésirables non mentionnés dans cette notice. Voir rubrique 4.

Que contient cette notice

1. Qu'est-ce que Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg et dans quel cas est-il utilisé
2. Quelles sont les informations à connaître avant de prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg
3. Comment prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg
4. Effets indésirables possibles
5. Comment conserver Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg
6. Contenu de l'emballage et autres informations

1. Qu'est-ce que Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg et dans quel cas est-il utilisé

Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg est un médicament utilisé pour traiter l'infection par le VIH (virus de l'immunodéficience humaine) chez les adultes et les adolescents pesant au moins 30 kg. Il contient trois ingrédients actifs : dolutégravir, ténofovir disoproxil et lamivudine. Dolutégravir appartient à un groupe de médicaments antirétroviraux appelés inhibiteurs de l'intégrase. Le Ténofovir est un inhibiteur nucléotidique de la transcriptase inverse, tandis que la lamivudine appartient au groupe des inhibiteurs nucléosidiques analogues de la transcriptase inverse.

Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg réduit la quantité de virus dans votre corps et la maintient à un niveau très bas. Il ne s'agit pas d'un remède contre l'infection au VIH, mais s'il est pris correctement, il améliorera votre système immunitaire et réduira le risque de développer des maladies liées à l'infection au VIH.

Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg ne fonctionne pas aussi bien chez tous les patients. Votre professionnel de santé vérifiera l'efficacité de votre traitement.
Pour contrôler votre infection à VIH et empêcher votre maladie de s'aggraver, vous devez prendre tous vos médicaments anti-VIH régulièrement, à moins que votre professionnel de santé ne vous dise d'arrêter de les prendre.

2. Quelles sont les informations à connaître avant de prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg

Ne prenez pas Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg si vous êtes enceinte :
- Si vous êtes allergique au dolutégravir, ténofovir disoproxil, lamivudine ou à l'un des autres composants contenus dans ce médicament (énumérés dans la rubrique 6)
- Si vous prenez médicaments tels que le dofétilide (pour traiter les problèmes cardiaques) ou la fampridine (également connue sous le nom de dalfampridine utilisée dans la sclérose en plaques).

Si vous pensez que l'une de ces conditions s'applique à vous, parlez-en à votre professionnel de santé.

Mises en garde et précautions d'emploi
Faites attention aux symptômes importants:
Certaines personnes prenant des médicaments contre l'infection par le VIH développent d'autres maladies qui peuvent être graves. Ceux-ci incluent :
- infections et inflammation
- douleurs articulaires, raideurs et problèmes osseux

Vous devez connaître les signes et les symptômes importants à surveiller pendant que vous prenez Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg.

Informez votre professionnel de santé de toute maladie pseudo-grippale - soit au cours du mois précédant l'administration de Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg, soit à tout moment pendant que vous prenez Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg.
Lisez les informations contenues dans «Autres effets indésirables» dans la rubrique 4 de cette notice.

Maladie rénale
Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg peut affecter vos reins. Avant de commencer ce médicament, vous pouvez avoir besoin d'analyses sanguines afin de vérifier si vos reins fonctionnent normalement. Des analyses sanguines peuvent être nécessaires pendant le traitement afin de vérifier l'état de vos reins.

Avertissez votre professionnel de santé si vous avez souffert d'une maladie rénale ou si des tests ont révélé des problèmes avec vos reins. Le cas échéant, les doses de ténofovir disoproxil et lamivudine peuvent nécessiter une réduction. Dans de tels cas, il sera nécessaire d'utiliser des préparations de ténofovir disoproxil et de lamivudine autres que Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg.

Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg n'est habituellement pas pris avec d'autres médicaments qui peuvent endommager vos reins (voir "Autres médicaments et Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg").
Si cela est inévitable, vous pouvez nécessiter des analyses régulières afin de vérifier si vos reins fonctionnent normalement.

Maladie hépatique
Informez votre professionnel de santé si vous avez des antécédents de maladies hépatiques, dont l'hépatite. Les patients infectés par le VIH présentant des maladies hépatiques dont l'hépatite B ou C chronique, qui sont traités par des antirétroviraux, ont un risque plus élevé de complications hépatiques sévères et potentiellement fatales. Si vous êtes infecté par les virus du VIH et de l'hépatite B, votre professionnel de santé envisagera soigneusement le meilleur traitement pour vous. Si vous avez des antécédents de maladie du foie ou d'une infection chronique à hépatite B, votre professionnel de santé peut vous prescrire des analyses sanguines afin de surveiller votre fonction hépatique.

Enfants
Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg convient uniquement aux adolescents pesants au moins 30 kg. D'autres médicaments qui contiennent de plus petites quantités de dolutégravir, de ténofovir ou de lamivudine sont nécessaires pour les patients qui pèsent moins de 30 kg.

Autres médicaments et Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg
Avertissez votre professionnel de santé si vous prenez, avez récemment pris ou prévoyez prendre d'autres médicaments. Cela comprend les médicaments que vous achetez sans ordonnance et les plantes médicinales.

Vous **ne devez pas** prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg avec le dofétilide, qui est utilisé pour traiter les maladies cardiaques ou la fampridine (utilisée dans la sclérose en plaques).
Certains médicaments peuvent affecter l'action de Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg ou augmenter les effets secondaires. Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg peut également affecter l'action de certains autres médicaments.

Avertissez votre professionnel de santé si vous prenez l'un des médicaments suivants :
- La metformine, pour traiter le diabète
- Antiacides, pour traiter l'indigestion et les brûlures d'estomac. Ne prenez pas d'antiacide pendant les 6 heures précédant la prise de Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg, ou pendant au moins 2 heures après l'avoir pris
- Suppléments de calcium, suppléments de fer et multivitamines. Ne prenez pas de supplément de calcium, de supplément de fer ou de multivitamine pendant les 6 heures précédant la prise de Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg, ou pendant au moins 2 heures après l'avoir pris
- didanosine, étravirine, éfavirenz, fosamprenavir/ritonavir, névirapine ou tipranavir/ritonavir, pour traiter une infection à VIH
- Rifampicine ou rifapentine, pour traiter la tuberculose et autres infections bactériennes
- Phénytoïne et phénobarbital, pour traiter l'épilepsie
- L'oxcarbazépine et la carbamazépine, pour traiter l'épilepsie ou le trouble bipolaire.
- Le millepertuis, (*Hypericum perforatum*) remède à base de plantes pour traiter la dépression.
- Autres médicaments contenant du ténofovir disoproxil, de l'emtricitabine, de la lamivudine ou de la zalcitabine pour traiter une infection à VIH

Il est très important d'informer votre professionnel de santé si vous prenez d'autres médicaments qui peuvent endommager les reins. Ceux-ci incluent :
- les aminosides, la pentamidine ou la vancomycine (pour une infection bactérienne)
- l'amphotéricine B (pour le une infection fongique)
- le foscarnet, le ganciclovir ou le cidofovir (pour le une infection virale)
- L'adéfovir dipivoxil (pour l'infection du virus de l'hépatite B)
- le tacrolimus (pour la suppression du système immunitaire)
- l'interleukine-2 (pour le traitement d'un cancer)
- les anti-inflammatoires non stéroïdiens (AINS, pour soulager les douleurs osseuses ou musculaires) comme l'aspirine et l'ibuprofène.

Si vous prenez l'un de ces médicaments, votre professionnel de santé peut ajuster votre dose ou vous faire subir des examens complémentaires supplémentaires.

Autres médicaments contenant de la didanosine (pour le infection par le VIH) :
Prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg avec des médicaments contenant de la didanosine peut augmenter le taux de didanosine dans votre sang. Dans des cas rares, l'inflammation du pancréas et l'acidose lactique (excès d'acide lactique dans le sang), qui ont parfois entraîné la mort, ont été signalées lorsque des médicaments contenant le ténofovir disoproxil et la didanosine ont été pris ensemble. L'association du ténofovir disoproxil avec la didanosine peut également réduire les effets du traitement antirétroviral. Votre professionnel de santé évaluera soigneusement s'il y a lieu de vous traiter avec une association de ténofovir disoproxil et de didanosine.

Si vous prenez un autre médicament antiviral appelé inhibiteur de protéase pour traiter le VIH, votre professionnel de santé peut demander des analyses sanguines pour surveiller étroitement votre fonction rénale.

Il est également important d'aviser votre professionnel de santé si vous prenez du ledipasvir/sofosbuvir, du sofosbuvir/velpatasvir ou du sofosbuvir/velpatasvir/voxilaprevir pour traiter l'infection à l'hépatite C.

Grossesse
Si vous êtes enceinte, si vous devenez enceinte ou si vous prévoyez avoir un bébé, parlez-en à votre professionnel de santé des risques et des bienfaits de la prise de Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg. Votre professionnel de santé examinera votre traitement.

Le fait de prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg au moment où vous devenez enceinte ou pendant les premières semaines de la grossesse peut augmenter le risque d'un type d'anomalie congénitale, appelée anomalie du tube neural (par exemple, le spina-bifida). N'arrêtez pas de prendre Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg sans en parler à votre professionnel de santé, car cela pourrait nuire à vous et à votre bébé à naître.

Allaitement
Si vous souhaitez allaiter votre bébé, vous devrez discuter des risques et des avantages avec votre professionnel de santé.

Conduite et utilisation des machines
Comprimés de Dolutégravir (sous forme de sodium)/Lamivudine/fumarate de Ténofovir disoproxil 50mg/300mg/300mg peut vous donner le vertige et avoir d'autres effets sec