

Package leaflet: Information for the user

Delstrigo® 100 mg/300 mg/245 mg film-coated tablets

doravirine/ lamivudine/ tenofovir disoproxil

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 any further questions, ask your doctor, pharmacist, or nurse.
- 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 are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Delstrigo is and what it is used for
2. What you need to know before you take Delstrigo
3. How to take Delstrigo
4. Possible side effects
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1. What Delstrigo is and what it is used for

What Delstrigo is

Delstrigo is used to treat HIV ('human immunodeficiency virus') infection. It belongs to a group of medicines called 'antiretroviral medicines'.

Delstrigo contains the active substances:

- Doravirine - a non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Lamivudine - a nucleoside analogue reverse transcriptase inhibitor (NRTI)
- Tenofovir disoproxil - a nucleoside analogue reverse transcriptase inhibitor (NRTI)

What Delstrigo is used for

Delstrigo is used to treat HIV infection in adults, and adolescents aged 12 years and older weighing at least 35 kg. HIV is the virus that causes AIDS ('acquired immune deficiency syndrome'). You should not take Delstrigo if your doctor has told you that the virus causing your infection is resistant to any of the medicines in Delstrigo.

How Delstrigo works

Delstrigo works by preventing HIV from making more viruses in your body. This will help by:

- reducing the amount of HIV in your blood (this is called your 'viral load')
- increasing the number of white blood cells called 'CD4+ T'. This can make your immune system stronger. This may reduce your risk of early death or catching infections because your immune system is weak.

2. What you need to know before you take Delstrigo

Do not take Delstrigo

- if you are allergic to doravirine, lamivudine or tenofovir disoproxil or any of the other ingredients of this medicine listed in section 6.
- if you are taking any of the following medicines:
 - carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines for seizure)
 - rifampicin, rifapentine (medicines for tuberculosis)
 - St. John's wort (*Hypericum perforatum*, a herbal remedy used for depression and anxiety) or products that contain it
 - mitotane (a medicine to treat cancer)
 - enzalutamide (a medicine to treat prostate cancer)
 - lumacaftor (a medicine to treat cystic fibrosis)

Do not take Delstrigo if the above applies to you. If you are not sure, talk to your doctor, pharmacist, or nurse before taking Delstrigo. See also the list in section "Other Medicines and Delstrigo".

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Delstrigo.

Severe skin reactions

Severe skin reactions, including Stevens-Johnson syndrome/toxic epidermal necrolysis, have been reported in association with Delstrigo treatment. Stop using Delstrigo and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Worsening of hepatitis B infection

If you have both HIV and hepatitis B virus infections, your hepatitis B may get worse if you stop taking Delstrigo. You may require blood tests for several months after stopping treatment. Discuss your hepatitis B therapy with your doctor.

New or worsening kidney problems, including kidney failure

This can happen in some people who take Delstrigo. Your doctor will do blood tests to check your kidney function before and during treatment with Delstrigo.

Bone problems

This can happen in some people who take Delstrigo. Tell your doctor if you suffer from osteoporosis, have a history of bone fracture or if you have problems with your bones. Bone problems (manifesting as persistent or worsening bone pain and sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 4, Possible side effects). Tell your doctor if you have bone pain or fractures.

Tenofovir disoproxil may also cause loss of bone mass. The most pronounced bone loss was seen in clinical studies when patients were treated with tenofovir disoproxil in combination with a boosted protease inhibitor.

Overall, the effects of tenofovir disoproxil on long-term bone health and future fracture risk in adult and paediatric patients are uncertain.

Immune reactivation syndrome

This can happen when you start taking any HIV medicine, including Delstrigo. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having any new symptoms after starting your HIV medicine.

Autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Children and adolescents

Do not give this medicine to children aged less than 12 years or weighing less than 35 kg. The use of Delstrigo in children aged less than 12 years or weighing less than 35 kg has not yet been studied.

Other medicines and Delstrigo

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines. This is because other medicines may affect how Delstrigo works, and Delstrigo might affect the way some other medicines work.

There are some medicines you must not take with Delstrigo. See list under "Do not take Delstrigo" section.

Talk to your doctor before taking the following medicines with Delstrigo as your doctor may need to change the dose of your medicines:

- bosentan (a medicine to treat lung disease)
- dabrafenib (a medicine to treat skin cancer)
- lesinurad (a medicine to treat gout)
- modafinil (a medicine to treat excessive sleepiness)
- nafcillin (a medicine to treat some bacterial infections)
- rifabutin (a medicine to treat some bacterial infections such as tuberculosis)
- telotristat ethyl (a medicine to treat diarrhoea in people with carcinoid syndrome)
- thioridazine (a medicine to treat psychiatric conditions such as schizophrenia)

If your doctor decides you should take these medicines with Delstrigo, your doctor will prescribe a 100 mg tablet of doravirine to be taken daily, approximately 12 hours after your dose of Delstrigo.

Your doctor may check your blood levels or monitor for side effects if you take the following medicines with Delstrigo:

- ledipasvir/sofosbuvir (medicines used to treat hepatitis C infection)
- sirolimus (a medicine used to control your body's immune response after a transplant)
- sofosbuvir/velpatasvir (medicines used to treat hepatitis C infection)
- tacrolimus (a medicine used to control your body's immune response after a transplant)
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, talk to your doctor about the risks and benefits of taking Delstrigo. It is preferable to avoid the use of Delstrigo during pregnancy. This is because it has not been studied in pregnancy and it is not known if Delstrigo will harm your baby while you are pregnant.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

Driving and using machines

Use caution when driving, riding a bicycle, or operating machines if you feel tired, dizzy, or sleepy after taking this medicine.

Delstrigo tablets contains lactose

If you have been told by your doctor that you have an intolerance to lactose, talk to your doctor before taking this medicine.

3. How to take Delstrigo

Always take this medicine exactly as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure. Delstrigo is a complete regimen taken as a single tablet for the treatment of HIV infection.

How much to take

The recommended dose is 1 tablet once a day. If you take certain medicines, your doctor may need to change the amount of doravirine you take. See "Other medicines and Delstrigo" section for a list of medicines.

Taking this medicine

- Swallow the tablet whole (do not crush or chew).
- This medicine can be taken with food or between meals.

If you take more Delstrigo than you should

Do not take more than the recommended dose. If you accidentally take more, contact your doctor.

If you forget to take Delstrigo

- It is important that you do not miss or skip doses of Delstrigo.
- If you forget a dose, take it as soon as you remember. But if your next dose is due within 12 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.
- Do not take two doses of Delstrigo at the same time to make up for a missed dose.
- If you are not sure what to do, call your doctor or pharmacist.

If you stop taking Delstrigo

Do not run out of Delstrigo. Refill your prescription or talk to your doctor before your Delstrigo is all gone.

If you stop taking Delstrigo, your doctor will need to check your health often and do blood tests regularly for several months to check your HIV infection. If you have HIV infection and hepatitis B infection, it is especially important not to stop your Delstrigo treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has worsened after stopping lamivudine or tenofovir disoproxil (two of the three active substances of Delstrigo). If Delstrigo is stopped your doctor may recommend that you resume hepatitis B treatment. You may need blood tests to check how your liver is working for 4 months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis, which may be life-threatening.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not stop taking this medicine without first talking to your doctor.

Stop using Delstrigo and seek medical attention immediately if you notice any of the following symptoms: reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome/toxic epidermal necrolysis). The frequency of these reactions cannot be estimated from the available data.

Other side effects that may occur

Common: may affect up to 1 in 10 people:

- abnormal dreams, difficulty in sleeping (insomnia)
- headache, dizziness, sleepiness
- cough, nasal symptoms
- feeling sick (nausea), diarrhoea, stomach pain, vomiting, wind (flatulence)
- hair loss, rash
- muscle symptoms (pain, stiffness)
- loss of bone mass
- feeling tired, fever

Blood tests may also show:

- increased levels in liver enzymes (ALT)

Uncommon: may affect up to 1 in 100 people:

- nightmares, depression, anxiety, irritability, confusion, suicidal thoughts
- trouble concentrating, memory problems, tingling of hands and feet, stiff muscles, poor quality of sleep
- high blood pressure
- constipation, stomach discomfort, swollen or bloated stomach (abdominal distension), indigestion, soft stools, stomach spasms, frequent bowel movements, inflammation of the pancreas (pancreatitis) (causing stomach pain, vomiting)
- itchiness
- joint pain, breakdown of muscle tissue, muscular weakness
- feeling weak, general feeling of being unwell

Blood tests may also show:

- decreased number of white blood cells in your blood (neutropenia)
- decreased number of red blood cells in your blood (anaemia)
- decreased levels of platelets in your blood (you may bleed more easily)
- decreased levels phosphate
- decreased levels of potassium in your blood
- increased levels of creatinine in your blood
- increased levels in liver enzymes (AST)
- increased levels of lipase
- increased levels of amylase
- decreased levels of haemoglobin

The muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.

Rare: may affect up to 1 in 1,000 people:

- aggression, hallucinations, difficulty adjusting to changes, mood changes, sleepwalking
- difficulty breathing, enlarged tonsils
- feeling of incomplete defecation
- enlarged liver or fatty liver, yellow skin or eyes, pain in the belly (abdomen) caused by inflammation of the liver
- inflammation of the skin due to allergy, redness on the cheeks, nose, chin or forehead, bumps or pimples on the face, swelling of the face, lips, tongue or throat
- muscle weakness, weakening of the bones (with bone pain and sometimes resulting in fractures)
- kidney damage, kidney stones, kidney failure, damage to kidney tubule cells, kidney injury, passing a lot of urine and feeling thirsty
- pain in the chest, feeling cold, pain, thirst

Blood tests may also show:

- decreased levels of magnesium
- lactic acidosis (excess lactic acid in the blood)
- increased levels of creatine phosphokinase

Very rare: may affect up to 1 in 10,000 people:

Blood tests may also show:

- failure of the bone marrow to produce new red blood cells (pure red cell aplasia)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Delstrigo

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle after EXP.
- The bottle contains desiccant protecting the tablets from moisture. There may be more than one in the bottle. Keep desiccant inside the bottle and do not throw away until you have finished taking all of the medicine.
- Keep the bottle tightly closed in order to protect from moisture.
- This medicinal product does not require any special temperature 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. Contents of the pack and other information

What Delstrigo contains

- The active substances are 100 mg of doravirine, 300 mg of lamivudine and 245 mg of tenofovir disoproxil (as fumarate)
- The other ingredients are croscarmellose sodium E468; hypromellose acetate succinate; magnesium stearate E470b; microcrystalline cellulose E460; silica, colloidal anhydrous E551; sodium stearyl fumarate. The tablets are film-coated with a coating material containing the following ingredients: carnauba wax E903, hypromellose E464; iron oxide yellow E172; lactose monohydrate; titanium dioxide E171; and triacetin E1518.

What Delstrigo looks like and contents of the pack

Delstrigo is available as a yellow, oval-shaped, film-coated tablet, and is debossed with the corporate logo and 776 on one side and plain on the other side.

The following pack sizes are available:

- 1 bottle with 30 film-coated tablets
- 90 film-coated tablets (3 bottles of 30 film-coated tablets)

Not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, UK.

Manufacturer: Merck Sharp & Dohme B.V., Waarderweg 39, Haarlem, 2031 BN, The Netherlands

Other sources of information

For any information about this medicine, please contact:

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