

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DOLVIDIN 50 mg/600 mg/300 mg film-coated tablets

Dolutegravir/Abacavir/Lamivudine

DOLVIDIN contains 275,02 mg mannitol

Read all of this leaflet carefully before you start taking DOLVIDIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DOLVIDIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Hypersensitivity reactions

DOLVIDIN contains abacavir. Some people who take abacavir may develop a hypersensitivity reaction (a serious allergic reaction), which can be life-threatening if they continue to take abacavir.

You must carefully read all the information under ‘Hypersensitivity reactions’ in Possible Side Effects and ‘Take special care with DOLVIDIN’.

The DOLVIDIN pack includes an **Alert Card**, to remind you and medical staff about abacavir hypersensitivity.

Detach this card and keep it with you at all times.

What is in this leaflet

1. What DOLVIDIN is and what it is used for
2. What you need to know before you take DOLVIDIN

3. How to take DOLVIDIN
4. Possible side effects
5. How to store DOLVIDIN
6. Contents of the pack and other information

1. What DOLVIDIN is and what it is used for

DOLVIDIN is a medicine that contains three active ingredients used to treat HIV infection: abacavir, lamivudine and dolutegravir. Abacavir and lamivudine belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs), and dolutegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs).

DOLVIDIN is used to treat HIV (human immunodeficiency virus) infection in adults and adolescents over 18 years old.

DOLVIDIN does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level.

Not everyone responds to treatment with DOLVIDIN in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take DOLVIDIN

Do not take DOLVIDIN:

- if you are hypersensitive (allergic) to dolutegravir, abacavir (or any other medicine containing abacavir), or lamivudine, or any of the other ingredients of DOLVIDIN listed in section 6
- if you are taking a medicine called dofetilide (to treat heart conditions) or pilsicainide (to treat heart dysrhythmia)

- if you have moderate or severe liver problems
- if you are pregnant (three months before (preconception) to three months after conception and during the first trimester) or breastfeeding your baby
- if you have severe kidney problems
- if you are a diabetic, taking metformin and your doctor want to prescribe DOLVIDIN.

Warnings and precautions

Take special care with DOLVIDIN:

IMPORTANT — Hypersensitivity reactions

DOLVIDIN contains **abacavir**.

About 5 in every 100 people who take abacavir develop a hypersensitivity reaction (a serious allergic reaction), which can be life-threatening if they continue to take abacavir.

Who gets these reactions?

Anyone taking DOLVIDIN could develop a hypersensitivity reaction to abacavir.

You are more likely to develop such a reaction if you have a gene called HLA-B*5701 (but you can get a reaction even if you do not have this gene). If possible, you will have been tested for this gene before DOLVIDIN was prescribed for you. **If you know you have this gene, tell your doctor before you take DOLVIDIN.**

What are the symptoms?

The most common symptoms are:

- fever (high temperature) and skin rash.

Other common symptoms are:

- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain,
- severe tiredness, shortness of breath, cough, headache, muscle pain and discomfort.

Other less common symptoms can include:

- pains in the joints, swelling of the neck, serious breathing problems, sore throat occasionally, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

If you continue to take DOLVIDIN, the symptoms will get worse and may be life-threatening.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with DOLVIDIN but are more likely during the first 6 weeks of treatment.

Occasionally, reactions have developed in people who start taking abacavir again and had only one symptom on the Alert Card before they stopped taking it.

Very rarely, reactions have developed in people who start taking abacavir again, but who had no symptoms before they stopped taking it.

Contact your doctor immediately:

1. if you get a skin rash, OR

2. if you get symptoms from at least 2 of the following groups:

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting, diarrhoea or stomach pain
- severe tiredness or achiness, or generally feeling ill.

Your doctor may advise you to stop taking DOLVIDIN.

Always carry your Alert Card while you are taking DOLVIDIN.

If you have stopped taking DOLVIDIN because of a hypersensitivity reaction, you must NEVER AGAIN take DOLVIDIN, or any other medicine containing abacavir. If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

Hypersensitivity to dolutegravir:

Contact your doctor promptly if you develop a rash. Some people taking dolutegravir, one of the active substances in DOLVIDIN, have had allergic reactions. See ‘Conditions to look out for’ in Possible Side Effects.

Change in body shape:

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution. See “Possible Side effects”.

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). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (auto-immune disorders).

The symptoms of auto-immune disorders may develop many months after you start taking medicine to treat your HIV infection.

See ‘Conditions to look out for’ in Possible Side Effects.

Protect other people:

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). DOLVIDIN will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

Use a condom when you have oral or penetrative sex.

Do not risk blood transfer - for example, do not share needles.

Keep in touch with your doctor and do not stop taking DOLVIDIN without your doctor’s advice.

Lactic acidosis:

A condition that is caused by build-up of lactic acid in the body. It is more likely to develop in people who have liver disease, especially in women. It can be life-threatening, causing failure of internal organs.

Risk of cardiovascular events:

Some studies have shown an increase in the risk of having a heart attack in people taking abacavir, one of the active substances in DOLVIDIN.

It cannot be excluded that abacavir as contained in DOLVIDIN may increase the risk of having cardiovascular events.

Tell your doctor if you have heart and blood vessel problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, or diabetes. Do not stop taking DOLVIDIN unless your doctor advises you to do so.

Some people taking DOLVIDIN or other combination treatments for HIV are more at risk of serious side effects than others. You need to be aware of the extra risks:

- if you have a kidney problem
- if you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop DOLVIDIN without your doctor's advice, as your hepatitis may come back)

Talk to your doctor if any of these apply to you before using DOLVIDIN. You may need extra check-ups, including blood tests, while you are taking your medicine. See Section 4 for more information.

While you are taking DOLVIDIN:

You will need regular blood tests:

For as long as you are taking DOLVIDIN, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in this leaflet. See Possible Side Effects.

Stay in regular contact with your doctor:

DOLVIDIN helps to control your condition. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

Children and adolescents

DO NOT TAKE DOLVIDIN if you are under 18 years of age.

Other medicines and DOLVIDIN

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take DOLVIDIN with the following medicine:

- dofetilide (to treat heart conditions) or pilsicainide (to treat heart dysrhythmia)
- metformin, to treat diabetes.
- Zalcitabine or emtricitabine (to treat HIV infection)

Some medicines can affect how DOLVIDIN works or make it more likely that you will have side effects.

DOLVIDIN can also affect how some other medicines work.

Tell your doctor if you are taking any of the medicines in the following list:

- medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take DOLVIDIN, or for at least 2 hours after you take it (See Section 3)
- calcium supplements, iron supplements and multivitamins. Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take DOLVIDIN or for at least 2 hours after you take it (see Section 3)
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection

- rifampicin, to treat tuberculosis (TB) and other bacterial infections
- co-trimoxazole, an antibiotic used to treat – *Pneumocystis jiroveci (carinii)* pneumonia or toxoplasmosis
- phenytoin and phenobarbitone, to treat epilepsy
- oxcarbazepine and carbamazepine, to treat epilepsy and bipolar disorder
- St. John's wort (*Hypericum perforatum*), a herbal remedy to treat depression
- methadone used as a heroin substitute. Abacavir increases the rate at which methadone is removed from the body. If you are taking methadone, you will be checked for any withdrawal symptoms. Your methadone dose may need to be changed.
- cladribine, used to treat hairy cell leukaemia
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking DOLVIDIN.

Do not take DOLVIDIN if you are pregnant or breastfeeding your baby. Women of childbearing potential should not use DOLVIDIN, unless they are on highly effective contraception.

Driving and using machines

DOLVIDIN can make you dizzy and have other side effects that make you less alert.

It is not always possible to predict to what extent DOLVIDIN may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which DOLVIDIN affects you.

3. How to take DOLVIDIN

Do not share medicines prescribed for you with any other person.

Always take DOLVIDIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents:

The usual dose is one tablet **once a day**.

Swallow the tablet with some liquid. DOLVIDIN can be taken with or without food.

Children: DOLVIDIN should not be used in patients younger than 18 years.

Do not take an antacid during the 6 hours before you take DOLVIDIN, or for at least 2 hours after you take it.

Other acid-lowering medicines like ranitidine and omeprazole can be taken at the same time as DOLVIDIN.

Talk to your doctor for further advice on taking antacid medicines with DOLVIDIN.

Do not take a calcium or iron supplement during the 6 hours before you take DOLVIDIN, or for at least 2 hours after you take it. Talk to your doctor for further advice on taking calcium supplements, iron supplements or multivitamins with DOLVIDIN.

Your doctor will tell you how long your treatment with DOLVIDIN will last. If you have the impression that the effect of DOLVIDIN is too strong or too weak, tell your doctor or pharmacist.

If you take more DOLVIDIN than you should

In the event of overdose, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of DOLVIDIN

Do not take a double dose to make up for forgotten individual doses.

If you stop taking DOLVIDIN

Take DOLVIDIN for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you have stopped taking DOLVIDIN for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting. In some cases, your doctor will ask you to restart DOLVIDIN in a place where you will be able to get ready access to medical care if needed.

If you have hepatitis B infection, do not stop DOLVIDIN without your doctor's advice, as your hepatitis may come back.

4. Possible side effects

DOLVIDIN can have side effects.

Not all side effects reported for DOLVIDIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOLVIDIN, please consult your healthcare provider for advice.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of DOLVIDIN or other medicines you are taking, or an effect of the HIV disease itself. So, it is very important to talk to your doctor about any changes in your health.

Some side effects may only be seen in your blood tests and may not appear immediately after you start taking DOLVIDIN. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking DOLVIDIN.

Hypersensitivity to abacavir:

About 5 in every 100 people who take abacavir develop a hypersensitivity reaction (a serious allergic reaction) **which can be life-threatening. It is very important that you read and understand the information about this serious reaction. See ‘Take special care with DOLVIDIN’.**

If any of the following happens, stop taking / using DOLVIDIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DOLVIDIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- symptoms of infection and inflammation such as muscle weakness and/or muscle pain joint pain or swelling, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations or tremor, hyperactivity (excessive restlessness and movement)
- lactic acidosis with signs such as deep, rapid, difficult breathing, drowsiness, numbness or weakness in the limbs, feeling sick (nausea), vomiting and stomach pain
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling (toxic epidermal necrolysis)

- body shape changes such as fat may be lost from the legs, arms or face, extra fat may build up around the stomach, or on the breasts or internal organs, fatty lumps (sometimes called buffalo hump) may appear on the back of the neck

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- loss of appetite
- difficulty in sleeping, abnormal dreams, depression, anxiety
- nightmares, sleep disorder
- headache, dizziness, sleepiness, lack of energy
- cough, nasal symptoms
- nausea, diarrhoea
- vomiting, wind (flatulence), stomach pain, stomach discomfort, indigestion
- reflux (heartburn)
- hair loss
- muscle pain and discomfort
- joint pain
- physical weakness, general feeling of being unwell, tiredness, fever
- increased liver enzymes

Less frequent side effects:

- decreased number of cells involved in blood clotting (thrombocytopenia).
- low red blood cell count (anaemia) or low white blood cell count (neutropenia)

- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).
- increase in sugar (glucose) in the blood
- increase in triglycerides (type of fat) in the blood
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)
- numbness, tingly, pain feelings in the skin (pins and needles) of the hands and feet
- inflammation of the pancreas
- inflammation of the liver
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)
- muscle weakness, pain and vomiting
- increased liver enzymes especially amylase

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/documents/adverse-drug-reactions-and-quality-problem-reporting-form>. By reporting side effects, you can help provide more information on the safety of DOLVIDIN.

5. How to store DOLVIDIN

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use DOLVIDIN after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DOLVIDIN contains

The active substances are dolutegravir, abacavir and lamivudine. Each tablet contains dolutegravir sodium equivalent to 50 mg dolutegravir, 600 mg abacavir (as sulphate) and 300 mg lamivudine.

The other ingredients are mannitol (E421), microcrystalline cellulose, povidone, sodium starch glycollate, purified water. Opadry II White 85F18422 (containing macrogol/PEG, polyvinyl alcohol – part hydrolysed, talc, titanium dioxide and purified water).

What DOLVIDIN looks like and contents of the pack

DOLVIDIN are white to off white, oval shaped, biconvex, film-coated tablets and debossed with “N” on one side and with “17” on other side.

DOLVIDIN tablets are packed in round wide mouth white opaque 100 ml HDPE container closed with white opaque polypropylene 38 mm – 400 continuous thread closure with wad having TEKNIPLEX HS 123 induction sealing liner. The HDPE container also contains 2 g of silica gel sachet. The HDPE bottles is further packed in a carton.

Pack size: 30's - One HDPE container contains 30 tablets.

Holder of Certificate of Registration

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