TRELAVUE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TRELAVUE Film-coated tablets

Fixed dose combination of 50 mg of dolutegravir, 600 mg of abacavir and 300 mg of lamivudine.

Read all of this leaflet carefully before you start taking TRELAVUE:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TRELAVUE 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.

IMPORTANT — Hypersensitivity reactions

- **TRELAVUE 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 TRELAVUE'.**

The TRELAVUE 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 TRELAVUE CONTAINS:

The active substances are 50 mg of dolutegravir as dolutegravir sodium, 600 mg of abacavir as abacavir sulphate and 300 mg of lamivudine.

The other ingredients are: D-mannitol, magnesium stearate, microcrystalline cellulose, povidone K29/32, sodium starch glycolate in the tablet core; polyvinyl alcohol – part hydrolysed, titanium oxide, macrogol/PEG, talc, iron oxide black, iron oxide red in the tablet coating.

WHAT TRELAVUE IS USED FOR:

TRELAVUE is used to treat HIV (human immunodeficiency virus) infection in adults and adolescents aged 18 years and older.

Dolutegravir belongs to a group of antiretroviral medicines called *integrase inhibitors* (INIs). Abacavir and lamivudine belong to a group of antiretroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

TRELAVUE 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 TRELAVUE in the same way. Your doctor will monitor the effectiveness of your treatment.

BEFORE YOU TAKE TRELAVUE:

Do not take TRELAVUE:

- if you are **allergic** (hypersensitive) to abacavir or any other medicine containing abacavir, lamivudine, or dolutegravir, or any other ingredients of TRELAVUE.

Carefully read all the information about abacavir hypersensitivity reactions in POSSIBLE SIDE EFFECTS and 'Take special care with TRELAVUE'.

- if you're taking another medicine called **dofetilide** or **pilsicanide** (to treat heart conditions) or **metformin** (to treat diabetes)
- if you have moderate to severe liver disease
- if you are pregnant, intend to become pregnant or if you are breastfeeding your baby
- if you have moderate to severe renal disease.

Take special care with TRELAVUE:

- if you have mild liver disease or have ever had liver disease, including hepatitis B or C.

Talk to your doctor if this applies to you. You may need extra check-ups, including blood tests, while you're taking your medication. See POSSIBLE SIDE EFFECTS for more information.

Hypersensitivity reactions:

***Hypersensitivity to abacavir*:**

TRELAVUE 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 TRELAVUE 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 don't have this gene). If possible, you will have been tested for this gene before TRELAVUE was prescribed for you. **If you know you have this gene, tell your doctor before you take TRELAVUE.**

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 TRELAVUE, 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 TRELAVUE 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 TRELAVUE.

Always carry your Alert Card while you are taking TRELAVUE.

If you have stopped taking TRELAVUE because of a hypersensitivity reaction, you must NEVER AGAIN take TRELAVUE, 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 TRELAVUE, have had allergic reactions. See 'Conditions to look out for' in POSSIBLE SIDE EFFECTS.

Heart Disease:

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

Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, or diabetes. Don't stop taking TRELAVUE unless your doctor advises you to do so.

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 you need 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 'Conditions you need to look out for' in POSSIBLE SIDE EFFECTS.

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.

See 'Conditions you need to look out for' in POSSIBLE SIDE EFFECTS.

While you are taking TRELAVUE:

You will need regular blood tests:

For as long as you are taking TRELAVUE, 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:

TRELAVUE 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.

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). TRELAVUE 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, don't share needles.

➔ **Keep in touch with your doctor and do not stop taking TRELAVUE** without your doctor's advice.

Taking TRELAVUE with food and drink:

TRELAVUE can be taken with or without food.

Pregnancy and breastfeeding:

TRELAVUE is not for use during pregnancy or by mothers who are breastfeeding their babies.

If you are pregnant or breastfeeding your baby while taking TRELAVUE, please consult your doctor, pharmacist or other healthcare professional for advice before taking TRELAVUE.

The ingredients of TRELAVUE can pass into breast milk and harm your baby.

Driving and using machinery:

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

➔ **Do not drive or use machines** unless you are sure you are not affected.

Taking other medicines with TRELAVUE:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Don't take TRELAVUE with these medicines:

- dofetilide or pilsicainide, to treat **heart conditions**
- metformin, to treat **diabetes**

These medicines should not be used with TRELAVUE:

- zalcitabine or emtricitabine, to treat **HIV infection**

Tell your doctor if you're being treated with either of these.

Methadone and TRELAVUE:

If you are taking methadone, your doctor may need to adjust your methadone dose, as abacavir (one of the active substances in TRELAVUE) increases the rate at which methadone leaves your body. This is unlikely to affect most methadone users.

Tell your doctor if you are taking:

- medicines called **antacids**, to treat **indigestion** and **heartburn. Do not take an antacid** during the 6 hours before you take TRELAVUE, or for at least 2 hours after you take it (see also 'HOW TO TAKE TRELAVUE').
- calcium and iron supplements. **Do not take a calcium or iron supplement** during the 6 hours before you take TRELAVUE, or for at least 2 hours after you take it. If you take food with your medicine you can take a calcium or iron

supplement at the same time as TRELAVUE (see also 'HOW TO TAKE TRELAVUE').

- 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 phenobarbital, to treat **epilepsy**
- oxcarbamazepine and carbamazepine, to treat **epilepsy** and **bipolar disorder**
- **St. John's wort**, (*Hypericum perforatum*), a herbal remedy to treat **depression**

➔ **Tell your doctor or pharmacist** if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra checkups.

HOW TO TAKE TRELAVUE:

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

Always take TRELAVUE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of TRELAVUE in adults and in adolescents weighing more than 40 kg is one combined tablet (50 mg dolutegravir, 600 mg abacavir, 300 mg lamivudine) taken **once a day**.

If you weigh less than 40 kg, you cannot take TRELAVUE, because the dose of each component of this medicine cannot be adjusted to your weight. Your doctor might prescribe the components separately for you.

Swallow the tablet with some liquid.

TRELAVUE can be taken with or without food.

Antacid medicines:

Antacids, to treat **indigestion** and **heartburn,** can stop TRELAVUE being absorbed into your body and make it less effective.

Do not take an antacid during the 6 hours before you take TRELAVUE, 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 TRELAVUE. Talk to your doctor for further advice on taking acid-lowering medicines with TRELAVUE.

Calcium or iron supplements:

Calcium or iron supplements can stop TRELAVUE being absorbed into your body and make it less effective.

Do not take a calcium or iron supplement during the 6 hours before you take TRELAVUE, or for at least 2 hours after you take it. If you take food with TRELAVUE, then you can take calcium and iron supplements at the same time as TRELAVUE.

Your doctor will tell you how long your treatment with TRELAVUE will last. Do not stop treatment unless your doctor advises you to.

If you have the impression that the effect of TRELAVUE is too strong or too weak, tell your doctor or pharmacist.

If you take more TRELAVUE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. If possible, show them the TRELAVUE pack.

If you forget to take or missed a dose of TRELAVUE:

If you miss a dose, take it as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

Do not take a double dose to make up for a missed dose.

Effects when treatment with TRELAVUE is stopped:

Take TRELAVUE for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you have stopped taking TRELAVUE 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 TRELAVUE in a place where you will be able to get ready access to medical care if needed.

If you have hepatitis B infection, don't stop TRELAVUE without your doctor's advice, as your hepatitis may come back.

POSSIBLE SIDE EFFECTS:

TRELAVUE can have side effects.

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

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of TRELAVUE 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 TRELAVUE. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking TRELAVUE.

Conditions to look out for:

Hypersensitivity reactions:

If you notice any of these symptoms stop taking TRELAVUE and contact a doctor immediately or go to the casualty department of the nearest hospital.

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 TRELAVUE'.**

Hypersensitivity to dolutegravir:

TRELAVUE contains dolutegravir, some people taking dolutegravir have allergic reactions. 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.

➔ **See a doctor as soon as possible**. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking TRELAVUE.

Symptoms of infection and inflammation:

Symptoms of infection and inflammation may develop and include:

- **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).

If you get any symptoms of infection while you're taking TRELAVUE:

➔ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

See 'Take special care with TRELAVUE'.

Your body shape may change:

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- 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.

If you notice changes in your body shape tell your doctor immediately.

Lactic acidosis is a serious side effect:

Some people taking TRELAVUE, develop a condition called lactic acidosis, together with an enlarged liver.

Signs of lactic acidosis include:

- **deep, rapid, difficult breathing**
- **drowsiness**
- **numbness or weakness** in the limbs
- **feeling sick** (nausea), **being sick** (vomiting)
- **stomach pain.**

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above or any other symptoms that worry you:

➔ **See your doctor immediately.**

As well as the conditions listed above, other side effects can develop:

Frequent side effects:

- abacavir hypersensitivity reaction (See ‘Take special care with TRELAVUE’)
- high temperature (fever)
- skin rash, itching (pruritus)
- joint pain, muscle pain and discomfort
- headache

- diarrhoea, feeling sick (nausea), being sick (vomiting), stomach pains (abdominal pain) and bloating (abdominal distension), stomach (abdominal) discomfort, wind (flatulence), indigestion (dyspepsia), gastro-oesophageal reflux disease, loss of appetite
- feeling drowsy, tiredness, lack of energy, general feeling of being unwell
- dizziness
- nightmares and abnormal dreams, sleep disorder, difficulty in sleeping (insomnia), depression
- hair loss.

Frequent side effects that may show up in blood tests are:

- increase in triglycerides (type of fat) in the blood
- increase in glucose (sugar) in the blood.

Less frequent side effects:

- dolutegravir allergic reaction (see 'Hypersensitivity reactions' earlier in this section)
- inflammation of the liver (hepatitis)
- lactic acidosis (see 'Lactic acidosis is a serious side effect' earlier in this section)
- inflammation of the pancreas (pancreatitis)
- breakdown of muscle tissue
- tingling or numbness of the hands and feet (paraesthesiae)
- numbness, tingling or weakness of the arms and legs (peripheral neuropathy)
- 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)
- 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 in more than 30 % of the body surface (toxic epidermal necrolysis).

If you notice any of these symptoms contact a doctor immediately.

Less frequent side effects that may show up in blood tests are:

- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- an increase in the level of liver enzymes
- increase in an enzyme called amylase
- failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

STORING AND DISPOSING OF TRELAVUE:

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package to protect from moisture.
- Keep the bottle tightly closed.
- Do not remove the dessicant.
- Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF TRELAVUE:

TRELAVUE is packaged in opaque, white high density polyethylene (HDPE) bottles with a fill count of 30 tablets per bottle and closed with a heat sealed liner and a white child-resistant closure. A silica gel desiccant is included in each bottle.

IDENTIFICATION OF TRELAVUE:

Purple, biconvex, oval, film-coated tablets, debossed with “572 Trı” on one side.

REGISTRATION NUMBER:

49/20.2.8/0097

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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