

TIVICAY 50 mg PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TIVICAY 50 mg Film-coated tablets

Dolutegravir

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

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

WHAT TIVICAY CONTAINS:

The active substance is 50 mg of dolutegravir (as dolutegravir sodium).

Contains sugar (mannitol: up to 145,4 mg/tablet).

The other ingredients are: D-mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate and sodium stearyl fumarate in the tablet core; iron oxide yellow, macrogol/polyethylene glycol, polyvinyl alcohol-part hydrolysed, talc and titanium dioxide in the tablet coating.

WHAT TIVICAY IS USED FOR:

TIVICAY is used to treat HIV (human immunodeficiency virus) infections in adults in combination with other anti-retroviral medicines (combination therapy).

The active ingredient in TIVICAY is dolutegravir. TIVICAY is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called integrase inhibitors (INIs).

BEFORE YOU TAKE TIVICAY:

Do not take TIVICAY:

- if you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of **TIVICAY**
- if you are taking another medicine called dofetilide or pilsicainide (to treat heart conditions)
- if you are taking a medicine called metformin (to treat diabetes)
- if you have moderate or severe liver disease
- if you are in your first trimester of pregnancy.

Take special care with TIVICAY:

- if you develop a rash. Some people taking **TIVICAY** have had allergic reactions.
- if you get any symptoms of infection while you are taking TIVICAY:

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (*opportunistic infections*). When these people start treatment, they may find that old, hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

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

HIV can still be transmitted despite taking TIVICAY.

TIVICAY does not cure HIV infection; it reduces the amount of virus in your body.

While you are taking TIVICAY, you will need regular blood tests.

For as long as you are taking TIVICAY, 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.

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). TIVICAY will not stop you passing an 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.

Taking TIVICAY with food and drink:

TIVICAY can be taken with or without food.

Pregnancy and Breastfeeding:

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

If you are of the age of falling pregnant, you should have a negative pregnancy test before you start taking TIVICAY.

While you are taking TIVICAY you must use a reliable method of contraception, to prevent pregnancy.

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

Where possible, **women who are HIV-positive should not breastfeed their babies**, because HIV infection can be passed on to the baby in breast milk.

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

Driving and using machinery:

TIVICAY 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 TIVICAY:

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

Do not take TIVICAY with these medicines:

- Dofetilide or pilsicainide, to treat **heart conditions**
- Metformin, to treat **diabetes**.

Some medicines can affect how TIVICAY works or make it more likely that you will have side effects. These include:

- medicines called **antacids**, to treat **indigestion** and **heartburn**: **Do not take an antacid** during the 6 hours before you take TIVICAY, or for at least 2 hours after you take it
- calcium and iron supplements: **Do not take a calcium or iron supplement** during the 6 hours before you take TIVICAY, or for at least 2 hours after you take it
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat **HIV infection**
- rifampicin, to treat **tuberculosis**
- phenytoin and phenobarbitone, to treat **epilepsy**
- oxcarbamazepine and carbamazepine, to treat **epilepsy** and **bipolar disorder**
- St. John's wort, (*Hypericum perforatum*), a herbal remedy used for **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 check-ups.

HOW TO TAKE TIVICAY:

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

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

The usual dose of TIVICAY is one 50 mg tablet, **once a day**.

For people with HIV infection resistant to other medicines similar to TIVICAY, the usual dose of TIVICAY is one 50 mg tablet, **twice a day**.

Your doctor will decide on the correct dose of TIVICAY for you.

Swallow the tablet with some liquid.

TIVICAY can be taken with or without food.

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

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

If you take more TIVICAY than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. If possible, show them the TIVICAY pack.

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

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 TIVICAY is stopped:

Take TIVICAY for as long as your doctor recommends. Don't stop unless your doctor advises you to. If you stop taking TIVICAY without your doctor's recommendation, your HIV infection will flare up much stronger than before, and your HIV medicines might not work anymore.

POSSIBLE SIDE EFFECTS:

TIVICAY can have side effects.

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

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 TIVICAY. If you get any of these effects and if they are severe, your doctor may advise you to stop taking TIVICAY.

As well as the effects listed below for TIVICAY, other conditions can develop during combination therapy for HIV (see Take special care with TIVICAY).

If any of the following happens, see a doctor immediately:

Allergic reactions:

These appear less frequently in people taking TIVICAY. 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.

➔ **These are all very serious side effects. 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 TIVICAY.

Frequent side effects:

- headache
- diarrhoea
- feeling sick (*nausea*)
- rash
- itching (*pruritus*)
- being sick (*vomiting*)
- stomach pain (*upper abdominal pain*)

- difficulty in sleeping (*insomnia*)
- dizziness
- abnormal dreams
- lack of energy (*fatigue*)
- wind (*flatulence*).

Less frequent side effects:

- inflammation of the liver (*hepatitis*)
- an inflammatory condition which may develop as the immune system becomes stronger (*immune reconstitution syndrome* or 'IRIS')
- allergic reaction (*hypersensitivity*) (see earlier in **this section** for more details)
- stomach (*abdominal*) discomfort.

Side effects that may show up in blood tests:

- increase in *bilirubin* (a substance produced by the liver) in the blood
- an increase in the level of enzymes produced in the muscles (*creatine phosphokinase*, *creatinine*)

➔ **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 TIVICAY:

Store all medicines out of reach of children.

- Store at or below 30 °C
- 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 TIVICAY:

TIVICAY Tablets are packed in opaque, white round high density polyethylene (HDPE) bottles with a polypropylene child-resistant closure that includes a polyethylene faced induction seal liner.

The HDPE bottle is packed into an outer cardboard carton. Pack sizes of 30 tablets.

IDENTIFICATION OF TIVICAY:

Yellow, round, biconvex film-coated tablets debossed with 'SV 572' on one side and '50' on the other side.

REGISTRATION NUMBER:

48/20.2.8/0403

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

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