

# TIVICAY

## Patient Information Leaflet

### SCHEDULING STATUS:

S4

**TIVICAY 5 mg** Dispersible film-coated tablets

**TIVICAY 10 mg** Film-coated tablets

**TIVICAY 25 mg** Film-coated tablets

**TIVICAY 50 mg** Film-coated tablets

Dolutegravir

TIVICAY 5 mg: Contains Sugar mannitol: 14,54 mg/tablet:

Contains Sweetener: Sucralose: 0,60 mg per tablet

TIVICAY 10 mg: Contains sugar (mannitol: 48,3 mg/tablet) and sodium (1 mg/tablet).

TIVICAY 25 mg: Contains sugar (mannitol: 72,7 mg/tablet) and sodium (2 mg/tablet).

TIVICAY 50 mg: Contains sugar (mannitol: 145,4 mg/tablet) and sodium (4 mg/tablet).

### 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, pharmacist, nurse or other healthcare provider.
- 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 is in this leaflet:

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

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

## **1. WHAT TIVICAY IS AND WHAT IT IS USED FOR:**

TIVICAY is used to treat HIV (human immunodeficiency virus) infection in adults and in children, 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).

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TIVICAY:**

### **Do not take TIVICAY:**

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

### **Warnings and Special Precautions:**

#### **Take special care with TIVICAY:**

- if you or your child if they are the patient 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 section 4.

### **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 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.

### **Children.**

Do not use TIVICAY film-coated tablets if your child is under 6 years old or if your child weighs less than 15 kg.

### **Other medicines and TIVICAY:**

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

Do not take TIVICAY with any of the following medicines:

- Dofetilide or pilsicainide, to treat heart conditions.

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

- metformin, to treat **diabetes**
- 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** and other **bacterial infections**
- phenytoin and phenobarbital, to treat **epilepsy**
- 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 or your child\_are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

#### **TIVICAY with food and drink and alcohol:**

TIVICAY can be taken with or without food.

#### **Pregnancy and Breastfeeding and fertility:**

Safe use during pregnancy and lactation has not been established.

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

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.

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

→ **Talk to your doctor immediately**, if you are breastfeeding, or thinking about breastfeeding.

#### **Driving and using machines:**

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.

### **3. 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.

#### **Adults:**

##### **Film-coated tablets:**

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

For people with **HIV infection that is 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.

##### **Dispersible film-coated tablets:**

The usual dose of TIVICAY is 30 mg (taken as 6 dispersible tablets), once a day; or

For HIV infection that is resistant to other medicines similar to TIVICAY, the usual dose of TIVICAY is 30 mg (taken as 6 dispersible tablets), twice a day.

**Children:**

Your doctor will decide on the correct dose of TIVICAY for your child, depending on the weight and age of the child.

**How to take:**

TIVICAY can be taken with or without food.

**TIVICAY film-coated tablets:**

Swallow the tablets with some liquid. To reduce the risk of choking, children should not swallow more than one tablet at a time.

**TIVICAY Dispersible film-coated tablets:**

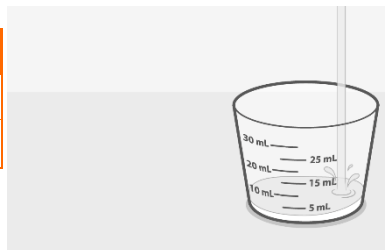
The dispersible tablets may be swallowed whole with drinking water or dispersed in drinking water. When dispersed, the amount of water will depend on the number of tablets prescribed. The tablet(s) should be fully dispersed before swallowing. Do not chew, cut or crush the tablets (see Instructions for Use).

**Instructions for Use:**

If your child is able and prefers to swallow the tablets, then you may skip the following steps

***Pour water:***

Water Volume Guide						
Number of tablets	1	2	3	4	5	6
Volume of water	5 mL			10 mL		



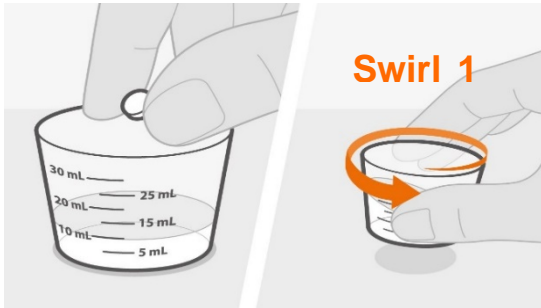
- Pour clean drinking water into the cup.

The water volume guide above shows the amount of water needed for the prescribed dose.

**Use drinking water only.**

**Do not** use any other drink or food to prepare the dose.

**How to prepare the medicine:**



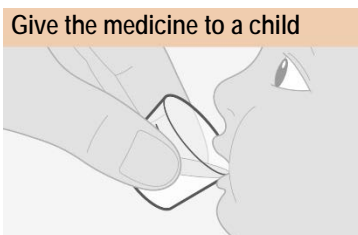
- Add the prescribed number of tablet(s) to the water.
- Swirl the cup gently for 1 to 2 minutes to disperse the tablet(s). The medicine will become cloudy. Take care not to spill any of the medicine.
- Check that the medicine is ready. If there are any lumps of tablet swirl the cup until they are gone.

If you spill any medicine, clean up the spill.

Throw away the rest of the prepared medicine and make a new dose.

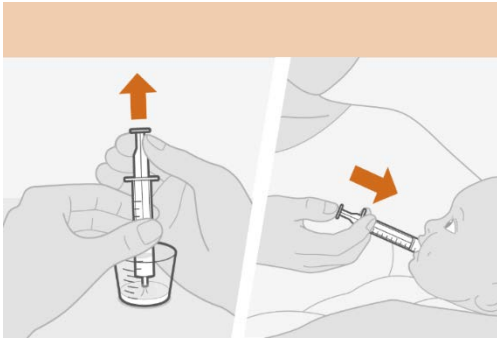
**You must give the dose of medicine within 30 minutes of preparing the dose.** If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.

**Giving the medicine:**



- Make sure that the child is upright. Give all the prepared medicine to the child.
- Add another 5 ml of drinking water to the cup, swirl and give it all to the child.
- Repeat if any medicine remains to make sure the child gets the full dose.

**Give the medicine to the infant:**



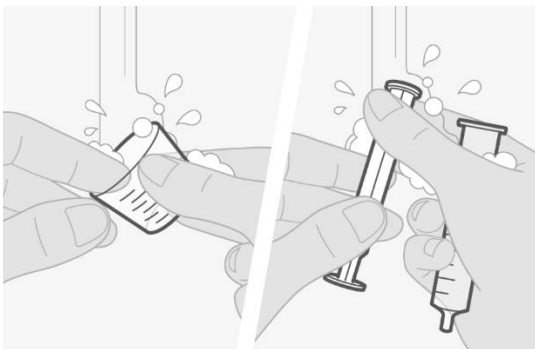
- Place the tip of the syringe into the prepared medicine and draw up all the medicine into the syringe by pulling up on the plunger.
- Place the tip of the syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another 5 mL of drinking water to the cup and swirl. Draw up the remaining medicine into the syringe and give it all to the infant.

**Repeat if any medicine remains to make sure the infant gets the full dose.**

**Allow time for the medicine to be swallowed.**

***Cleaning:***

**Clean the dosing items:**



- Wash the cup with water.
- Pull the plunger out of the syringe and wash the syringe parts separately in water.  
Allow parts to dry completely before reassembling and storing.

**All used parts will need to be clean before preparing the next dose.**

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, tell your doctor or pharmacist.

Children should keep scheduled doctor's visits because their TIVICAY dosage should be adjusted as they get older or gain weight. TIVICAY is available as film-coated and dispersible tablets. Film-coated tablets and dispersible tablets are not the same. Therefore, you should not switch between film-coated tablets and dispersible tablets without first talking to your doctor.

**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 or your child 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.

**If you stop taking TIVICAY:**

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

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

**As well as the effects listed below for TIVICAY**, other conditions can develop during combination therapy for HIV (see section 2, Take special care with TIVICAY).

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

**Allergic reactions:**

These are less frequent 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*), stomach discomfort
- difficulty in sleeping (*insomnia*)
- dizziness
- abnormal dreams
- depression (feeling of deep sadness and unworthiness)
- anxiety
- lack of energy (*fatigue*)
- wind (*flatulence*).

**Less frequent side effects:**

- inflammation of the liver (*hepatitis*)
- suicide thoughts (mainly in patients who have had depression or mental health problems before)
- an inflammatory condition which may develop as the immune system becomes stronger (*immune reconstitution inflammatory syndrome* or 'IRIS')
- allergic reaction (*hypersensitivity*) (see earlier in **this section** for more details).

**Other side effects:**

- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- joint pain
- muscle pain
- weight gain.

**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 or your child notice any side effects not listed in this leaflet.

### **Reporting of side effects:**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the '**6.04 Adverse Drug Reaction Reporting Form**,' found on line under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TIVICAY.

### **5. HOW TO STORE TIVICAY:**

Store all medicines out of reach of children.

TIVICAY 5 mg: Store at or below 30°C. in the original package in order to protect from moisture.

Keep the bottle tightly closed. Do not remove the desiccant.

TIVICAY 10 mg: Store at or below 30 °C. Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove desiccant.

TIVICAY 25 mg and 50 mg: 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).

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION:**

#### **What TIVICAY contains:**

The active substance is dolutegravir.

TIVICAY 5 mg: Each tablet contains 5 mg dolutegravir (as dolutegravir sodium).

Contains sugar (mannitol: 14,54 mg/ tablet)

Contains sweetener (sucralose 0,60 mg per tablet)

TIVICAY 10 mg: Each tablet contains 10 mg of dolutegravir (as dolutegravir sodium) Contains sugar (mannitol: 48,3 mg/tablet) and sodium (1 mg/tablet).

TIVICAY 25 mg: Each tablet contains 25 mg of dolutegravir (as dolutegravir sodium). Contains sugar (mannitol: 72,7 mg/tablet) and sodium (2 mg/tablet).

TIVICAY 50 mg: Each tablet contains 50 mg of dolutegravir (as dolutegravir sodium) Contains sugar (mannitol: 145,4 mg/tablet) and sodium (4 mg/tablet).

**Dispersible film-coated tablets: Other ingredients:**

Tablet core: Mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate, sodium stearyl fumarate, silicified microcrystalline cellulose, crospovidone (Type B), calcium sulfate dihydrate, sucralose, strawberry cream flavor, permaseal PHS-132963, sodium stearyl fumarate

Film-coating: Hypromellose, polyethylene glycol/ macrogol, titanium dioxide(E171)

**Film-coated tablets:**

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 (for 25 mg and 50 mg tablets), macrogol/polyethylene glycol, polyvinyl alcohol-part hydrolysed, talc and titanium dioxide in the tablet coating.

**What TIVICAY looks like and contents of the pack:**

TIVICAY 5 mg: White, round, biconvex film-coated tablets debossed with 'SV H7S' on one side and '5' on the other side.

TIVICAY 10 mg: White, round, biconvex tablets debossed with 'SV 572' on one side and '10' on the other side.

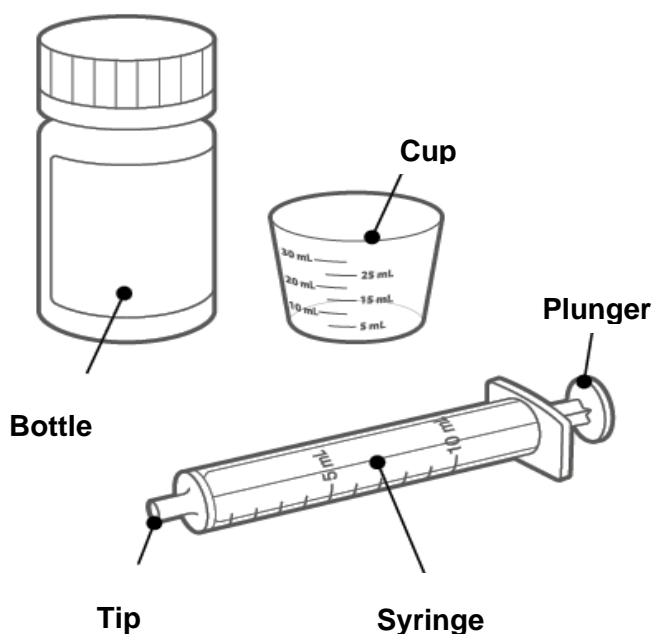
TIVICAY 25 mg: Pale yellow, round, biconvex tablets debossed with 'SV 572' on one side and '25' on the other side.

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

**Tivicay 5 mg Dispersible film-coated tablets:**

**Your pack contains:**

- A bottle containing 60 tablets.
- Dosing kit:
  - **Cup:** use this to prepare and give the medicine to **children.**
  - **Syringe:** use this to give the medicine to **infants.**



TIVICAY film coated 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 10 mg tablet bottles contain a desiccant.

**Holder of Certificate of Registration:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

**Registration Number:**

TIVICAY 5 mg: 56/20.2.8/0131

TIVICAY 10 mg: 51/20.2.8/0370

TIVICAY 25 mg: 51/20.2.8/0371

TIVICAY 50 mg: 48/20.2.8/0403

**This leaflet was last revised in:**

29 April 2022