

## PATIENT INFORMATION LEAFLET

### TIVICAY 5 mg dispersible tablets

#### Dolutegravir

**Read all of this leaflet carefully before you start taking this medicine.**

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

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

#### In this leaflet

- 1. What TIVICAY is and what it is used for**
- 2. Before you take TIVICAY**
- 3. How to take TIVICAY**
- 4. Possible side effects**
- 5. How to store TIVICAY**
- 6. Further information**
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### 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 aged at least 4 weeks, who weigh at least 3 kg.**

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).

TIVICAY does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. TIVICAY also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

TIVICAY is used, in combination with other anti-retroviral medicines (*combination therapy*), to treat HIV infection in adults and children. To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

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## 2. Before you take TIVICAY

### Don't take TIVICAY

- if you (or your child, if they are the patient) are allergic (*hypersensitive*) to **dolutegravir** or to any of the other ingredients of TIVICAY (listed in Section 6).
- if you (or your child) are taking another medicine called **dofetilide** or **pilsicainide** (to treat heart conditions), or **fampridine** (also known as dalfampridine; used in multiple sclerosis).

➔ If you think any of these apply to you, **don't take TIVICAY** until you have checked with your doctor.

### Conditions you need to look out for

TIVICAY can cause serious side effects. You must look out for certain symptoms while you (or your child, if they are the patient) are taking TIVICAY, and tell your doctor.

#### Allergic reaction

Contact your doctor promptly if you (or your child) develop a rash. Some people taking TIVICAY have had allergic reactions. See '*Allergic reactions*' in **Section 4**.

#### Symptoms of infection and inflammation

See '*Conditions you need to look out for*' in **Section 4**.

### Other medicines and TIVICAY

**Tell your doctor or pharmacist if you (or your child) are taking any other medicines**, if you've taken any recently, or if you start taking new ones. TIVICAY can also affect how some other medicines work. This includes herbal medicines and other medicines bought without a prescription.

Don't take TIVICAY with these medicines:

- dofetilide or pilsicainide, to treat **heart conditions**
- fampridine (also known as dalfampridine), used in **multiple sclerosis**

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

**Tell your doctor** if you (or your child) are taking any of the medicines *in the following list*:

- 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 (*see also Section 3*).
- 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. If you take food with your medicine you can take a calcium or iron supplement at the same time as TIVICAY (*see also Section 3*).

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- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat **HIV infection**
  - rifampicin, to treat tuberculosis (TB) 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.

## Pregnancy and breast-feeding

If you are **pregnant**, or **think you could be**, or if you are **planning to have a baby**, **don't take TIVICAY** without checking with your doctor. **Your doctor** will consider the benefit to you and the risk to your baby of taking TIVICAY while you're pregnant.

If you **could get pregnant** while receiving TIVICAY, you need to use a reliable method of **contraception**, to prevent pregnancy.

Taking TIVICAY at the time of becoming pregnant, or during the first twelve weeks of pregnancy, may increase the risk of a type of birth defect, called neural tube defect, such as spina bifida (malformed spinal cord).

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

A small amount of the ingredients in TIVICAY can also pass into your breast milk.

- ➔ **Talk to your doctor immediately**, if you're breast-feeding, or thinking about breast-feeding.

## Driving and using machines

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

- ➔ **Don't drive or use machines** unless you are sure you're not affected.

## While you're taking TIVICAY

### You will need regular blood tests

For as long as you (or your child) are taking TIVICAY, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in **Section 4** of this leaflet.

### Stay in regular contact with your doctor

TIVICAY helps to control your condition, but it is not a cure for HIV infection. You (or your child) need to keep taking it every day to stop your illness from getting worse. Because TIVICAY does not cure HIV infection, you (or your child) may still develop other infections and illnesses linked to HIV infection.

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- ➔ **Keep in touch with your doctor, and don't stop taking TIVICAY** without your doctor's advice.

### **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). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

## **3. How to take TIVICAY**

### **How much to take**

**Always take TIVICAY exactly as your doctor has told you to.** Check with your doctor or pharmacist if you're not sure.

#### **Adults**

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

#### **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.

The dispersible tablets may be swallowed whole with drinking water or dispersed in drinking water. When swallowed whole, children should not swallow more than one dispersible tablet at a time to reduce the risk of choking. When dispersed, the amount of water will depend on the number of tablets prescribed. The tablet(s) should be fully dispersed before swallowing (*see Instructions for Use*). Do not chew, cut or crush the tablets.

Children should keep scheduled doctor's visits because their TIVICAY dosage should be adjusted as they get older or gain weight.

TIVICAY is also available as film-coated 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.**

### **Antacid medicines**

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

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

### **Calcium or iron supplements**

Calcium or iron supplements can stop TIVICAY 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 TIVICAY, or for at least 2 hours after you take it. If you take food with TIVICAY, then you can take calcium and iron supplements at the same time as TIVICAY.

### **If you forget to take TIVICAY**

If you (or your child) miss a dose, take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

**Don't take a double dose** to make up for a missed dose.

### **If you take too much TIVICAY**

If you (or your child) take too many tablets of TIVICAY, **contact your doctor or pharmacist for advice**. If possible, show them the TIVICAY pack.

### **Don't stop TIVICAY without advice**

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

## **4. Possible side effects**

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of TIVICAY 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 (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.

- ➔ **It is important to read the information** in '*Conditions you need to look out for*', later in this section.

### **Allergic reactions**

These are uncommon in people taking TIVICAY. Signs include:

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- 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 TIVICAY.

## Very common side effects

These may affect **more than 1 in 10** people:

- headache
- diarrhoea
- feeling sick (*nausea*)

## Common side effects

These may affect **up to 1 in 10** people:

- rash
- itching (*pruritus*)
- being sick (*vomiting*)
- stomach pain (*abdominal pain*)
- stomach (*abdominal*) discomfort
- difficulty in sleeping (*insomnia*)
- dizziness
- abnormal dreams
- depression (feelings of deep sadness and unworthiness)
- anxiety
- lack of energy (*fatigue*)
- wind (*flatulence*)

## Uncommon side effects

These may affect **up to 1 in 100** people:

- inflammation of the liver (*hepatitis*)
- suicidal thoughts\*
- suicide attempt\*
- joint pain
- muscle pain
- weight gain

\* mainly in patients who have had depression or mental health problems before

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## Rare side effects

These may affect **up to 1 in 1000 people**

- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)

## Other side effects that may show up in blood tests

Other side effects have occurred in some people but their exact frequency is unknown:

- increase in *bilirubin* (a substance produced by the liver) in the blood
  - an increase in the level of enzymes produced in the muscles (*creatinine phosphokinase*)
  - an increase in a kidney function blood test result (*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.

## Conditions you need to look out for

Some other conditions may develop during HIV treatment.

### 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 (*autoimmune disorders*)

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

Symptoms may 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 (or your child) get any symptoms of infection** or if you notice any of the symptoms above:

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

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## 5. How to store TIVICAY

Keep out of the sight and reach of children.

Do not take TIVICAY after the expiry date shown on the pack.

The storage conditions are detailed on the packaging. Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove desiccant.

Don't throw away any medicines in wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. This will help to protect the environment.

## 6. Further information

### What TIVICAY contains

The active substance is dolutegravir (as dolutegravir sodium). Each tablet contains 5 mg, dolutegravir (as dolutegravir sodium).

The other ingredients are:

Tablet Core: Mannitol (E421), Microcrystalline cellulose, Povidone (K29/32), Sodium starch glycolate, Silicified microcrystalline cellulose, crospovidone, Sodium stearyl fumarate, Purified water, Calcium sulfate dihydrate, Sucralose, Strawberry cream flavour permaseal PHS-132963.

Tablet coating: Titanium dioxide (E171), Hypromellose, Polyethylene glycol.

### WHAT TIVICAY looks like and contents of the pack

TIVICAY dispersible tablets are supplied in HDPE (high density polyethylene) bottles, with polypropylene (PP) child resistant closures. A desiccant is included in the bottle.

A dosing cup and syringe are supplied with the pack.

## 7. Step-by-step Instructions

Read this Instructions for use before giving a dose of medicine.  
Follow the steps, using clean drinking water to prepare and give a dose to an infant or a child who cannot swallow the tablets.

### Important information

Always give this medicine exactly as your healthcare provider tells you. Talk to your healthcare provider if you are not sure.

**Do not** chew, cut, or crush the tablets.

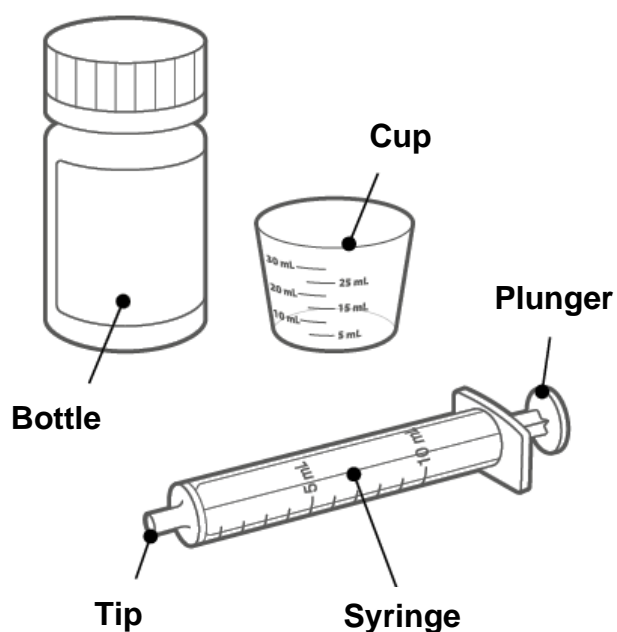


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If you forget to give a dose of medicine, give it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before. Do not give 2 doses at the same time or give more than your healthcare provider has prescribed.

If you give too much medicine, get emergency medical help right away.

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



### 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**.

### You will also need:

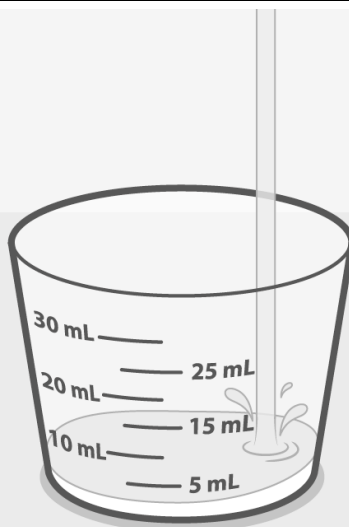
- Clean drinking water.

## Getting ready

### 1. Pour water

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

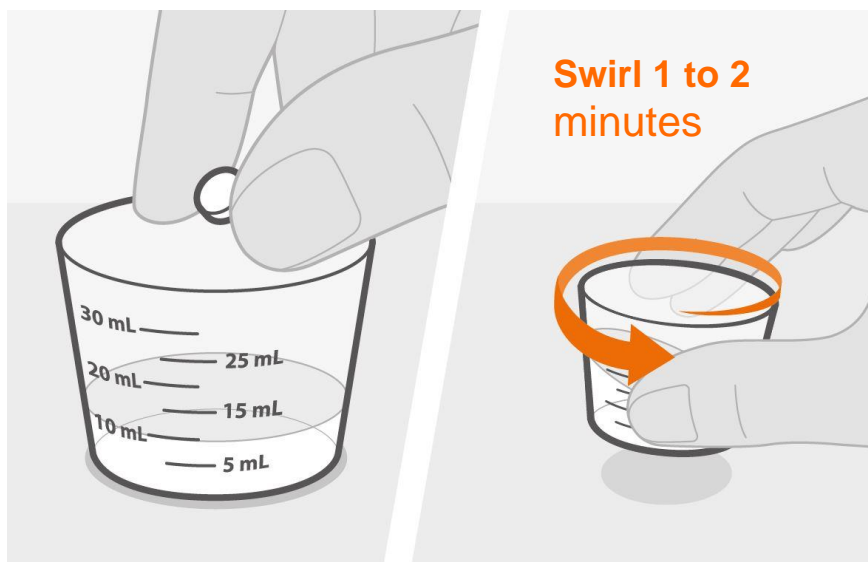


- Pour clean drinking water into the cup.  
The Water Volume Guide above shows the amount of water needed for the prescribed dose.

**Use drinking water only.**

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

## 2. 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.

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If you spill any medicine, clean up the spill.  
Throw away the rest of the prepared medicine and make a new dose.

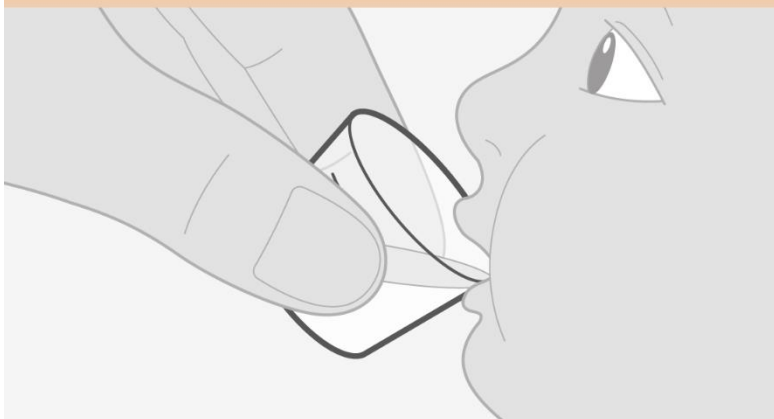
**You must give the dose of medicine within 30 minutes of preparing the dose.** If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.

## Giving the medicine

### 3. Give the medicine

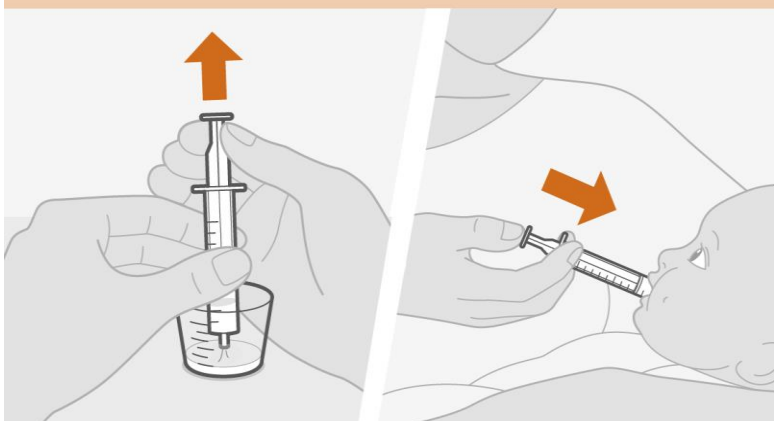
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### Give the medicine to a Child



- 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 an Infant



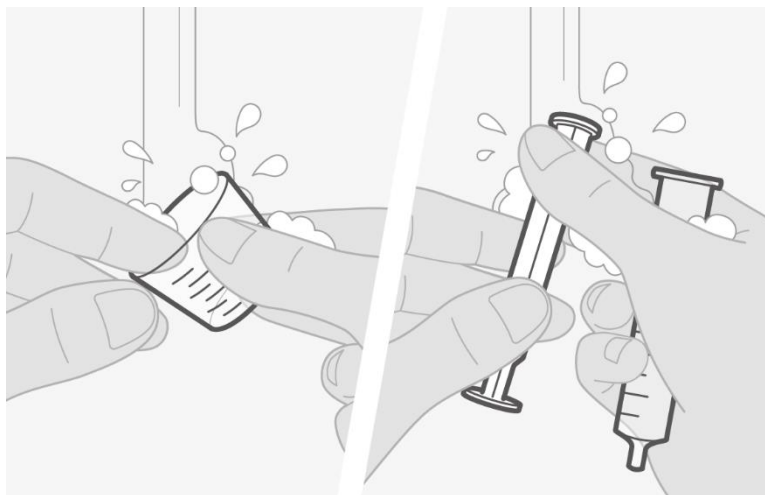
- Place the tip of the syringe into the prepared medicine and draw up all the medicine into the syringe by pulling up on the plunger.
- Place the tip of the syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another 5 mL of drinking water to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

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## Cleaning

### 4. 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.

## Storage information

Keep the tablets in the bottle. Keep the bottle tightly closed.

The bottle contains a desiccant canister which helps to keep the tablets dry. **Do not** eat the desiccant. **Do not** remove the desiccant.

**Keep all medicines out of reach of children.**

## Disposal information

When all the tablets in the bottle have been taken or are no longer needed, throw away the bottle, cup and syringe. Dispose of them using your local household waste guidelines.

You will get a new cup and syringe in your next pack.

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