

TIVICAY DISPERSIBLE TABLETS

Dolutegravir 5mg

What is in this leaflet

1. What TIVICAY is used for
2. How TIVICAY works
3. Before you use TIVICAY
4. How to use TIVICAY
5. While you are using it
6. Side effects
7. Storage and Disposal of TIVICAY
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What TIVICAY is used for

Tivicay is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and children of at least 4 weeks of age or older, and who weigh at least 3 kg.

How TIVICAY works

Tivicay contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral 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. As a result of that, it 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.

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

Tivicay is always used in combination with other anti-retroviral medicines (*combination therapy*). 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.

Before you use TIVICAY

- When you must not use it

Don't take Tivicay:

- if you (or your child, if they are the patient) are allergic to

dolutegravir or any of the other ingredients of this medicine.

- if you (or your child) are taking another medicine called fampridine (also known as dalfampridine; used in multiple sclerosis).
- ➔ If you think any of these apply to you (or your child), tell your doctor.

- Before you start to use it

Warnings and precautions

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you (or your child, if they are the patient) are taking Tivicay.

Children

Do not give this medicine to children under 4 weeks of age, weighing less than 3 kg or with HIV infection that is resistant to other medicines similar to Tivicay. The use of Tivicay dispersible tablets in children under 4 weeks or weighing less than 3 kg has not yet been studied.

Children must **keep planned doctor's appointments**.

Pregnancy

If you are pregnant, think you may be pregnant, or if you are planning to have a baby:

- **Talk to your doctor** about the risks and benefits of taking Tivicay.

Tell your doctor immediately if you become pregnant or are planning to become pregnant. Your doctor will review your treatment. Do not stop taking Tivicay without consulting your doctor, as this may harm you and your unborn child.

Breast-feeding

Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredient in Tivicay can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

- Taking other medicines

Tell your doctor if you (or your child) are taking, have recently taken or are planning to take any other medicines.

Don't take Tivicay with the following medicine:

- 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.

Tivicay can also affect how some other medicines work.

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.
- supplements or multivitamins containing calcium, iron or magnesium. **If you take Tivicay with food**, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Tivicay. **If you do not take Tivicay with food, do not take a supplement or multivitamin containing calcium, iron or magnesium** 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 (TB) and other **bacterial infections**
- phenytoin and phenobarbital, to treat **epilepsy**
- oxcarbazepine and carbamazepine, to treat **epilepsy** or **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.

Antacid medicines

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

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.

Supplements or multivitamins containing calcium, iron or magnesium

Supplements or multivitamins containing calcium, iron or magnesium can stop Tivicay being absorbed into your body and make it less effective.

If you take Tivicay with food, you can take supplements or multivitamins containing calcium, iron or magnesium at the same time as Tivicay. **If you do not take Tivicay with food, do not take a supplement or multivitamin containing calcium, iron or magnesium** during the 6 hours before you take Tivicay, or for at least 2 hours after you take it.

➔ Talk to your doctor for further advice on taking supplements or multivitamins containing calcium, iron or magnesium with Tivicay.

How to use TIVICAY

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

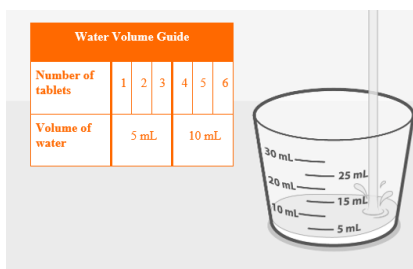
How to take the dispersible tablets

- The dispersible tablets may be dispersed in drinking water or swallowed whole with 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.
See the separate instructions for use regarding how to disperse and administer the tablets using the dosing cup and oral syringe provided in this pack.
- **Do not** chew, cut or crush the tablets.

Read this Instructions for use before giving a dose of medicine.

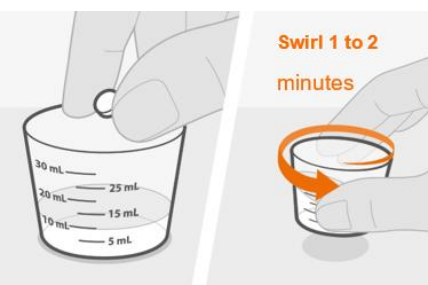
Getting ready

1. Pour water



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

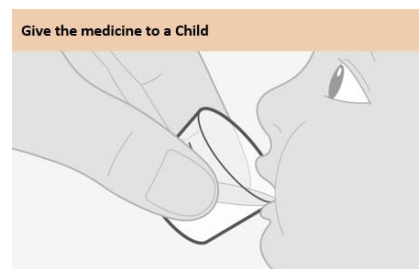
cloudy. Take care not to spill any of the medicine.

- Check that the medicine is ready. If there are any lumps of tablet swirl the cup until they are gone.

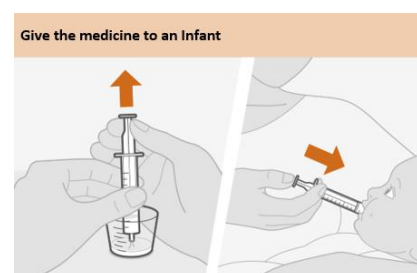
You must give the dose of medicine within 30 minutes of preparing the dose. If it has been more than 30 minutes wash the dose away and prepare a new dose of medicine.

Giving the medicine

3. Give the medicine



- 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.



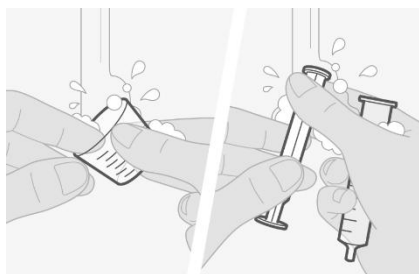
- Place the tip of the oral syringe into the prepared medicine and draw up all the medicine into the oral syringe by pulling up on the plunger.
- Place the tip of the oral syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another 5 mL of drinking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

remaining medicine into the oral 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

4. Clean the dosing items



- Wash the cup with water.
- Pull the plunger out of the oral syringe and wash the oral 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.

- How much to use

Adults

- **The usual adult dose** is 30 mg (taken as six 5 mg dispersible tablets) **once a day**.
- If you are taking **certain other medicines**, the dose is 30 mg (taken as six 5 mg dispersible tablets) **twice a day**.
- For HIV that is resistant to other medicines similar to Tivicay, the usual dose is 30 mg (taken as six 5 mg dispersible tablets), **twice a day**.

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

Children and adolescents

- **Children's dose** of Tivicay needs to be adjusted as they get older or gain weight.

- It is important therefore that children **keep planned doctor's appointments**.
- Children and adolescents weighing at least 20 kg can take the adult dose of 30 mg, once a day or 15 mg twice a day. Your doctor will decide how Tivicay should be given.
- For children aged at least 4 weeks and weighing between 3 and 20 kg, your doctor will decide on the correct dose of Tivicay, depending on the weight and age of your child.
- If swallowing tablets whole with water, children **must not swallow more than one tablet at a time** to reduce the risk of choking.
- Tivicay should **not** be used in children and adolescents with **HIV infection that is resistant** to other medicines similar to Tivicay.

- When to use it

- Tivicay can be taken **with or without food**. When Tivicay is taken twice a day, your doctor may advise you to take with food.

Tivicay is also available as **film-coated tablets**. Film-coated tablets and dispersible tablets are not the same, therefore **do not switch** between film-coated tablets and dispersible tablets without first talking to your doctor.

- How long to use it

Don't stop taking Tivicay without advice from your doctor

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

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 use too much (overdose)

If you take more Tivicay than you should

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.

While you are using TIVICAY

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using TIVICAY.

Tell your doctor immediately if you become pregnant while using this medication.

Take TIVICAY only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give TIVICAY to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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

➔ **Don't drive or operate machinery** unless you are sure you're not affected.

Tivicay contains less than 1 mmol sodium (23 mg) per tablet, that is to say is essentially 'sodium-free.'

Side effects

Like all medicines, TIVICAY can cause side effects, although not everybody gets them.

Allergic reactions

These are uncommon 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.

➔ **See a doctor straight away.** 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
- weight gain
- insomnia
- dizziness
- abnormal dreams
- depression (feelings of deep sadness and unworthiness)
- anxiety
- lack of energy (*fatigue*)
- wind (*flatulence*)
- increase in the level of liver enzymes
- increase in the level of enzymes produced in the muscles (*creatine phosphokinase*).

Uncommon side effects

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

- inflammation of the liver (hepatitis)
- suicide attempt*
- suicidal thoughts*
- panic attack
- joint pain
- muscle pain

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

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)

- increase in bilirubin (a test of liver function) in your blood.
- suicide (particularly in patients who have had depression or mental health problems before)

➔ **Tell your doctor immediately** if you experience any mental health problems (see also other mental health problems above).

Frequency not known

Cannot be estimated from the available data:

- a condition where red blood cells do not form properly (*sideroblastic anaemia*).

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*). Such infections may have been “silent” and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include **fever**, plus some of the following:

- headache
- stomach ache
- difficulty breathing

In rare cases, as the immune system becomes stronger, it can also attack 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:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.

If you (or your child) get any symptoms of infection and inflammation 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.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

➔ **Tell your doctor.**

Weight, blood lipid and blood glucose effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and lifestyle, and sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers ➔ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TIVICAY

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant. Do not swallow the desiccant.

The storage conditions are detailed on the packaging.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

What Tivicay looks like and contents of the pack

Tivicay 5 mg dispersible tablets are white, round, biconvex tablets marked with the code 'SV H7S' on one side and '5' on the other side. The bottle contains a desiccant to reduce moisture. Once the bottle has been opened keep the desiccant in the bottle, do not remove it.

The dispersible tablets are provided in bottles containing 60 tablets.

A dosing cup and oral syringe are supplied with the pack.

- Ingredients

The active substance is dolutegravir.

Each tablet contains dolutegravir sodium equivalent to 5 mg dolutegravir.

The other ingredients are mannitol (E421), microcrystalline cellulose, povidone, sodium starch glycolate, colloidal silicon dioxide and microcrystalline cellulose, crospovidone, sodium stearyl fumarate, calcium sulfate dihydrate, sucralose, strawberry cream flavour, titanium dioxide (E171), hypromellose and macrogol.

- MAL number:

MALxxx

Manufacturer

Manufactured by:

Glaxo Operations UK Ltd*
(trading as Glaxo Wellcome Operations)
Priory Street, Ware
Hertfordshire SG12 0DJ
United Kingdom

Packed by:

Glaxo Wellcome, S.A.*
Avda. Extremadura, 3
09400 Aranda de Duero
Burgos
Spain

*Member of GSK group of companies.

Product Registration Holder

GlaxoSmithKline (GSK) Pharmaceutical
Sdn. Bhd.
HZ.01, Horizon Penthouse, 1
Powerhouse,
1, Persiaran Bandar Utama, Bandar
Utama

Date of revision

22/04/2026

Serial Number

NPRA (R1) 25/020