

Package leaflet: Information for the patient

Tivicay 5 mg dispersible tablets dolutegravir

Read all of this leaflet carefully before you (or your child, if they are the patient) start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or your child, if they are the patient) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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. Contents of the pack and other information

Step-by-step instructions for use are also provided

1. What Tivicay is and what it is used for

Tivicay contains the active ingredient dolutegravir. Dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*.

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.

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.

2. What you need to know before you take Tivicay

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 (listed in section 6).
 - 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.

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.

→ **Read the information in Section 4 of this leaflet.**

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.

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** (see 'Children and adolescents' in Section 3 for more information).

Other medicines and Tivicay

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. (See also Section 3).
- calcium supplements, iron supplements and multivitamins. **Do not take a calcium supplement, iron supplement or multivitamin** during the 6 hours before you take Tivicay, or for at least 2 hours after you take it (see also Section 3).
- 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.

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.

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

If you could get pregnant while receiving Tivicay:

→ **Talk to your doctor** and discuss whether there is a need for contraception, such as condom or pills.

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

Women who are HIV-positive must not breast feed 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:

→ **Talk to your doctor immediately.**

Driving and using machines

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.'

3. How to take Tivicay

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

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.

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.

- 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.

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.

Calcium supplements, iron supplements or multivitamins

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

Do not take a calcium supplement, iron supplement or multivitamin 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 calcium supplements, iron supplements or multivitamins with Tivicay.

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.

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.

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, but 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
- 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*
- 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.

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 in the case of blood lipids 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 can also report side effects directly via Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tivicay

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. This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tivicay contains

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, silicified microcrystalline cellulose, crospovidone, sodium stearyl fumarate, calcium sulfate dihydrate, sucralose, strawberry cream flavour, titanium dioxide (E171), hypromellose and macrogol.

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.

Marketing Authorisation Holder

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Step-by-step instructions for use

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

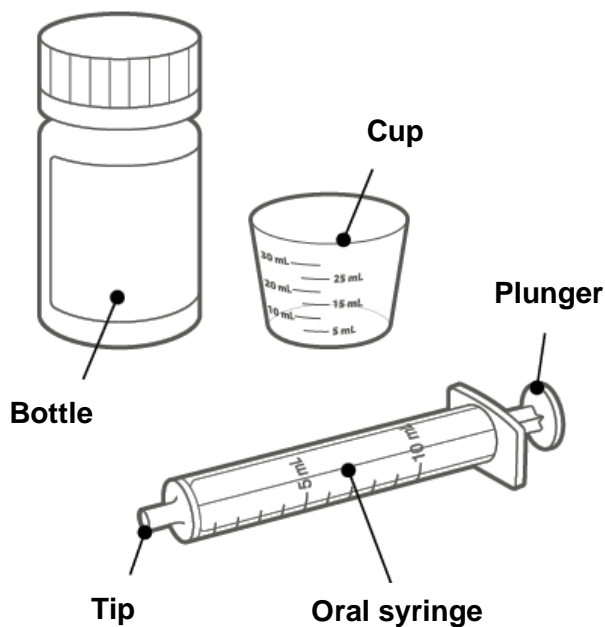
Always give this medicine exactly as your healthcare provider tells you. Talk to your healthcare provider if you are not sure.

Do not chew, cut, or crush the tablets.

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**.
 - **Oral syringe:** use this to give the medicine to **infants**.

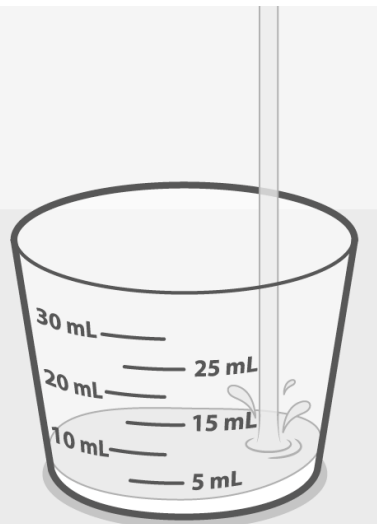
You will also need:

- Clean drinking water.

Getting ready

1. Pour water

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

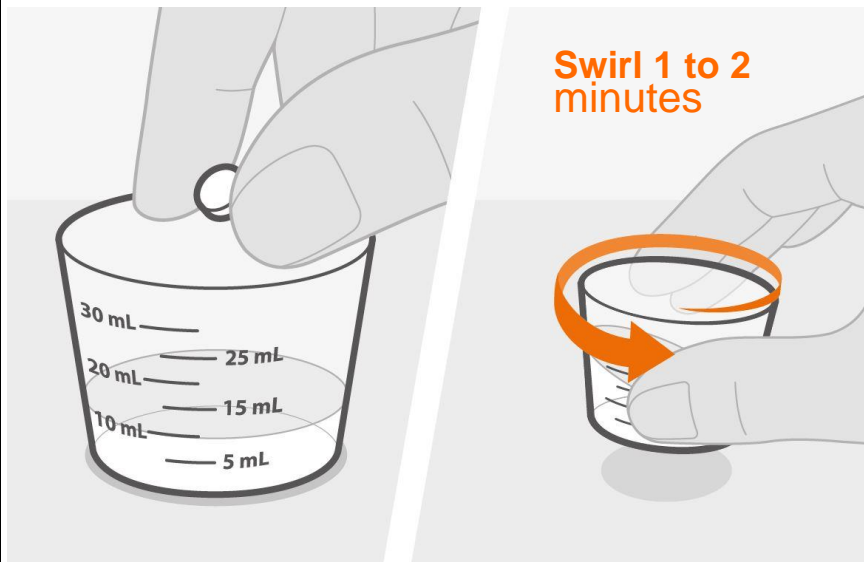


- Pour clean drinking water into the cup.
The Water Volume Guide above shows the amount of water needed for the prescribed dose.

Use drinking water only.

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

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.

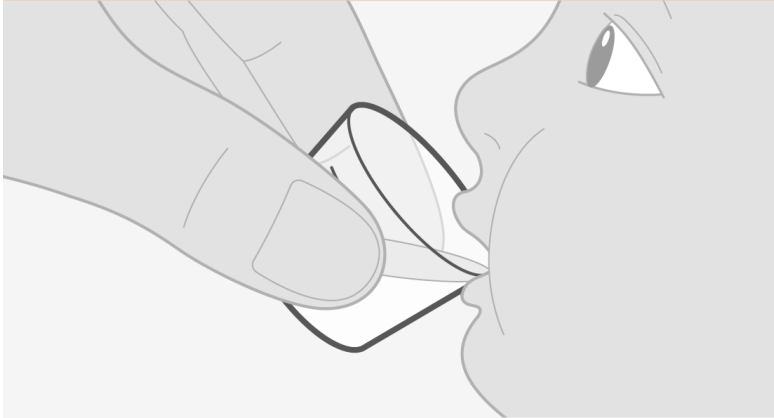
If you spill any medicine, clean up the spill.
Throw away the rest of the prepared medicine and make a new dose.

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

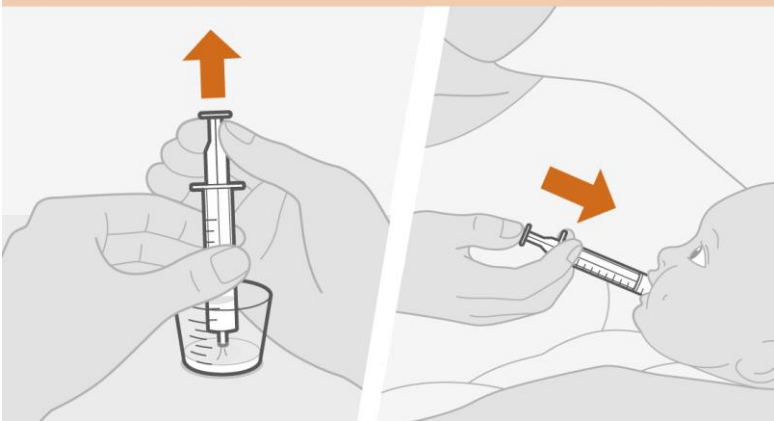
3. Give the medicine

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

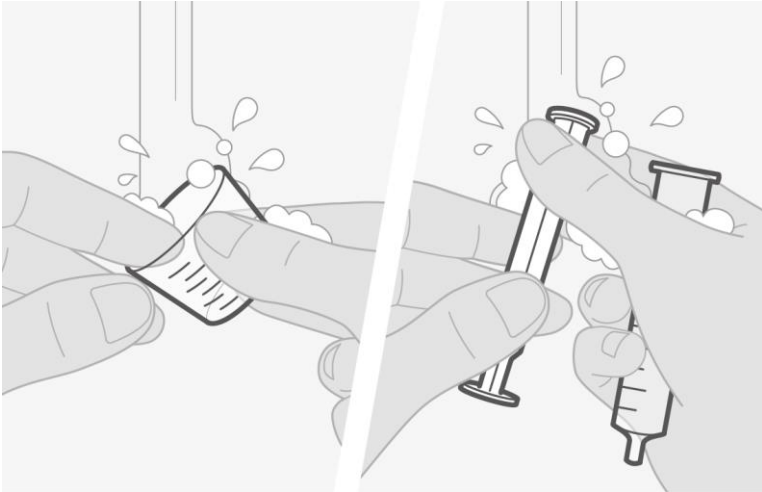


- Place the tip of the oral syringe into the prepared medicine and draw up all the medicine into the oral syringe by pulling up on the plunger.
- Place the tip of the oral syringe against the inside of the infant's cheek. Gently push down the plunger to give the dose slowly.
- Add another 5 mL of drinking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

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 oral syringe. Dispose of them using your local household waste guidelines.

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