

TIVICAY Film Coated Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using TIVICAY?

TIVICAY contains the active ingredient dolutegravir. TIVICAY is used to treat HIV (human immunodeficiency virus) infection in adults and in children. For more information, see Section [1. Why am I using TIVICAY?](#) in the full CMI.

2. What should I know before I use TIVICAY?

Do not use if you (or your child, if they are the patient) have ever had an allergic reaction to dolutegravir or any of the ingredients listed at the end of the CMI. Do not use if taking another medicine called dofetilide (to treat heart conditions).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use TIVICAY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TIVICAY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TIVICAY?

- For children, your doctor will decide on the correct dose of TIVICAY for your child, depending on their weight and age.
- For adults, the usual dose of TIVICAY film coated tablets is 50 mg, once a day.
- For HIV infection that is resistant to other medicines similar to TIVICAY, the usual dose of TIVICAY film coated tablets is 50 mg taken twice a day.
- Film-coated tablets and dispersible tablets are not interchangeable.

More instructions can be found in Section [4. How do I use TIVICAY?](#) in the full CMI.

5. What should I know while using TIVICAY?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TIVICAY.• If you become pregnant while taking this medicine, tell your doctor immediately.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not give your medicine to anyone else, even if they have the same condition.• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• TIVICAY can make you dizzy and have other side effects that make you less alert.

	<ul style="list-style-type: none"> • Don't drive or use machines if you are affected.
Looking after your medicine	<ul style="list-style-type: none"> • Keep your tablets in a cool dry place where the temperature stays below 30°C. • Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant. • 10 mg film coated tablets only - Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.

For more information, see Section [5. What should I know while using TIVICAY?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are headache, diarrhoea and feeling sick (nausea).

See a doctor as soon as possible if you develop a rash or if you notice anything that is making you feel unwell.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TIVICAY Film Coated Tablets

Dolutegravir

Consumer Medicine Information (CMI)

This leaflet provides important information about using TIVICAY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TIVICAY.**

Where to find information in this leaflet:

- [1. Why am I using TIVICAY ?](#)
- [2. What should I know before I use TIVICAY ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TIVICAY ?](#)
- [5. What should I know while using TIVICAY ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TIVICAY?

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

Dolutegravir is used to treat HIV (human immunodeficiency virus) infection in adults and in children over 6 years old.

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 over 6 years old. To control HIV infection, and to stop the illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

2. What should I know before I use TIVICAY?

Warnings

Do not use TIVICAY if:

- you (or your child, if they are the patient) has had an allergic reaction to are allergic to dolutegravir, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you (or your child, if they are the patient) are taking another medicine called dofetilide (to treat heart conditions).

Check with your doctor if you:

- have liver problems, including hepatitis B or C or any other medical conditions.
- take any medicines for any other condition.
- are not sure whether you (or your child, if they are the patient) should start taking this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. 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 taking TIVICAY, you need to use a reliable method of contraception to prevent pregnancy. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed. A small amount of the ingredients in TIVICAY can also pass into your breast milk.

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

Before starting

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 starting medicine to treat 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Don't take TIVICAY with dofetilide or pilsicainide, to treat heart conditions.

Some medicines may interfere with TIVICAY and affect how it works.

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 (see below).
- calcium and iron supplements (see below).
- 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.

These medicines may be affected by TIVICAY or may affect how well it works. Differing amounts of medicines or different medicines may be needed.

Antacid medicines

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

Do not take an antacid during the 6 hours before taking TIVICAY, or for at least 2 hours after taking 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 from being absorbed into your body and make it less effective.

Do not take a calcium or iron supplement during the 6 hours before taking TIVICAY, or for at least 2 hours after taking it. If you take food with TIVICAY, then you can take calcium and iron supplements at the same time as TIVICAY.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I use TIVICAY?

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.

Swallow the tablets whole with a full glass of water.

To reduce the risk of choking, children should not swallow more than one tablet at a time.

How much to use

ADULTS

- The usual dose of TIVICAY for adults is one 50 mg, tablet once a day; or
- For HIV infection that is resistant to other medicines similar to TIVICAY, the usual dose of TIVICAY is one 50 mg tablet, taken 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 their weight and age.
- Children should keep scheduled doctor's visits because their TIVICAY dosage should be adjusted as they get older or gain weight.

Follow the instructions provided and use TIVICAY until your doctor tells you to stop.

When to use TIVICAY

- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

If you forget to use TIVICAY

TIVICAY should be used regularly at the same time(s) each day. If you (or your child) miss a dose, take it as soon as you remember. But if it is less than 4 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much TIVICAY

If you think that you have used too much TIVICAY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TIVICAY?

Things you should do

Call your doctor straight away if you:

- have an allergic reaction to this medicine.

You (or your child) 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.

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.

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). While effective viral suppression with antiretroviral therapy has been proven to substantially reduce the risk of sexual

transmission, a residual risk cannot be excluded. To protect other people from becoming infected with HIV:

- Use a condom when you have oral or penetrative sex. Don't risk blood transfer - for example, don't share needles. Remind any doctor, dentist or pharmacist you visit that you are using TIVICAY.

Things you should not do

- Do not stop using this medicine or lower the dosage without checking with your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you (or your child).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TIVICAY affects you.

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

Don't drive or use machines if you are not affected.

Looking after your medicine

- Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.

- 10 mg tablets only - Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.

Follow the instructions in the carton on how to take care of your medicine properly.

Store away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you (or your child) do not feel well while you are taking TIVICAY.

This medicine helps most people with HIV, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You (or your child)

may need medical attention if you (or your child) get some of the side effects.

When being treated for HIV, it can be hard to tell whether a symptom is a side effect of TIVICAY or other medicines you (or your child) are taking, or an effect of the HIV disease itself. So, it is very important to talk to your doctor about any changes in 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 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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Allergic reactions

See a doctor as soon as possible if you develop a rash.

Allergic reactions 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.

Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking TIVICAY.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side Effects

As well as the effects listed below for TIVICAY, other conditions can develop during combination therapy for HIV.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

General	What to do
<ul style="list-style-type: none"> • headache • weight gain • difficulty in sleeping (insomnia) • dizziness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

General	What to do
Gastro-intestinal	
<ul style="list-style-type: none"> • diarrhoea • feeling sick (nausea) • being sick (vomiting) • stomach (abdominal) pain or discomfort • wind (flatulence) 	
Dermatological	
<ul style="list-style-type: none"> • rash • itching (pruritus) 	
Psychological	
<ul style="list-style-type: none"> • abnormal dreams • depression (feelings of deep sadness and unworthiness) • anxiety • lack of energy (fatigue) 	
Musculoskeletal	
<ul style="list-style-type: none"> • joint pain • muscle pain 	

Serious side effects

Liver related	What to do
<ul style="list-style-type: none">● inflammation of the liver (hepatitis)● liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)	Call your doctor straight away if you notice any of these serious side effects.
Allergy related	
<ul style="list-style-type: none">● 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)	
Psychological	
<ul style="list-style-type: none">● suicidal thoughts*● suicidal attempt*	

Liver related	What to do
* mainly in patients who have had depression or mental health problems before.	

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 (creatine phosphokinase, creatinine).

Speak to your doctor if you have any of these side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TIVICAY contains

Active ingredient (main ingredient)	10 mg, 25 mg or 50 mg of dolutegravir (as dolutegravir sodium)
Other ingredients (inactive ingredients)	mannitol microcrystalline cellulose povidone sodium starch glycolate Type A sodium stearyl fumarate polyvinyl alcohol titanium dioxide macrogol 3350 talc iron oxide yellow (25 mg and 50 mg tablets only)

Do not take this medicine if you are allergic to any of these ingredients.

What TIVICAY looks like

Film-coated tablets

10 mg - White, film-coated, round, biconvex tablets debossed with 'SV 572' on one side and '10' on the other side.

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

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

TIVICAY film-coated tablets are available in bottles of 30 tablets with child-resistant closure.

The 10 mg tablet bottles contain a desiccant to reduce moisture. Once the bottle has been opened, keep the desiccant in the bottle, do not remove it.

10 mg film-coated tablets - AUST R 312782

25 mg film-coated tablets - AUST R 312781

50 mg film-coated tablets - AUST R 205212

Who distributes TIVICAY

ViiV Healthcare Pty Ltd

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Abbotsford, Victoria, 3067
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