

# TIVICAY PD 5 mg dispersible tablets

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## 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.

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- ▼ 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 PD?

TIVICAY PD contains the active ingredient dolutegravir. TIVICAY PD 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 PD?](#) in the full CMI.

## 2. What should I know before I use TIVICAY PD?

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).

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**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 PD?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with TIVICAY PD 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 PD?**

- For children, your doctor will decide on the correct dose of TIVICAY PD for your child, depending on their weight and age.
- For adults, the usual dose of TIVICAY PD dispersible tablets is 30 mg (taken as 6 dispersible tablets), once a day.
- For HIV infection that is resistant to other medicines similar to TIVICAY PD, the usual dose of TIVICAY PD dispersible tablets is 30 mg (taken as 6 dispersible tablets) twice a day.
- The dispersible tablets can be dispersed in clean drinking water using the supplied dosing kit (cup and syringe) for those cannot swallow the tablets (i.e. infant or child).

- Film-coated tablets and dispersible tablets are not interchangeable.

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

## 5. What should I know while using TIVICAY PD?

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

<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● TIVICAY PD can make you dizzy and have other side effects that make you less alert.</li> <li>● Don't drive or use machines if you are affected.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Keep your tablets in a cool dry place where the temperature stays below 30°C.</li> <li>● Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccant.</li> </ul>

For more information, see Section [5. What should I know while using TIVICAY PD?](#) 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](http://www.tga.gov.au/reporting-problems).

# TIVICAY PD 5 mg dispersible tablets

Dolutegravir

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using TIVICAY PD. **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 PD.**

**Where to find information in this leaflet:**

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

## **1. Why am I using TIVICAY PD?**

**TIVICAY PD 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 combination with other antiretroviral agents in adults and in children of at least 4 weeks in age or older weighing 3 kg or more.**

TIVICAY PD does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. TIVICAY PD 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 PD is used, in combination with other anti-retroviral medicines (combination therapy), to treat HIV infection in adults and children. 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 PD?

### Warnings

#### Do not use TIVICAY PD 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 PD while you're pregnant.

If you could get pregnant while taking TIVICAY PD, 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. It is not known whether the ingredients of TIVICAY PD can pass into breast milk and harm your baby.

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.

## **Different formulations**

TIVICAY PD dispersible tablets are not the same as TIVICAY film-coated tablets and cannot be substituted for each other. Check to make sure you receive the correct form of TIVICAY each time you or your child's prescription is filled to avoid using the wrong medicine.

### **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 PD with dofetilide or pilsicainide, to treat heart conditions.**

**Some medicines may interfere with TIVICAY PD 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 PD 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 PD being absorbed into the body and make it less effective.

Do not take an antacid during the 6 hours before taking TIVICAY PD, 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 PD.

Talk to your doctor for further advice on taking acid-lowering medicines with TIVICAY PD.

## **Calcium or iron supplements**

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

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 PD?

TIVICAY PD is available as dispersible tablets and TIVICAY is available as film-coated tablets. Dispersible tablets and film-coated tablets are not the same. Therefore, you should not switch between film-coated tablets and dispersible tablets without first talking to your doctor.

### How much to use

- CHILDREN
- Your doctor will decide on the correct dose of TIVICAY PD for your child, depending on their weight and age.
- Children should keep scheduled doctor's visits because their TIVICAY PD dosage should be adjusted as they get older or gain weight.
- ADULTS
- The usual dose of TIVICAY PD dispersible tablets for adults is 30 mg (taken as 6 dispersible tablets), once a day; or
- For HIV infection that is resistant to other medicines similar to TIVICAY PD, the usual dose of TIVICAY PD dispersible tablets is 30 mg (taken as 6 dispersible tablets) twice a day.
- Your doctor will decide on the correct dose of TIVICAY PD for you.

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

## **When to use TIVICAY PD**

- 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.

## **How to prepare TIVICAY PD**

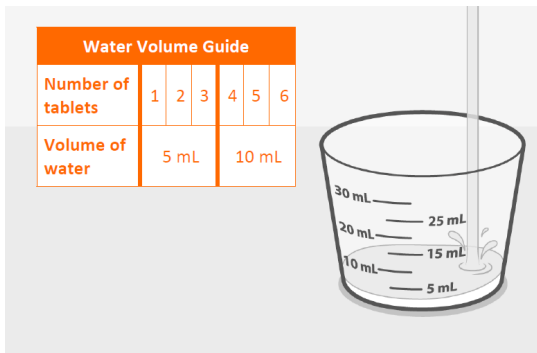
- Always take or give this medicine exactly as your healthcare provider tells you. Talk to your healthcare provider if you are not sure.
- The dispersible tablets may be swallowed whole with drinking water or dispersed in drinking water (see below).
- When swallowed whole, children should not swallow more than one dispersible tablet at a time to reduce the risk of choking.
- Do not chew, cut, or crush the tablets.

Follow these steps, using clean drinking water to prepare and give a dose to an infant or a child who cannot swallow the tablets. If your child is able and prefers to swallow the tablets then you may skip the following steps.

### **Getting ready**

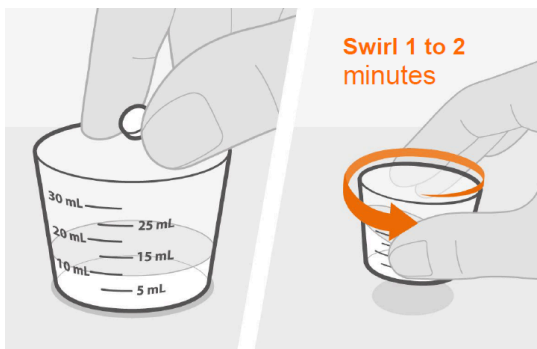
#### **1. Pour water**

- Pour clean drinking water into the cup.



- The Water Volume Guide above shows the amount of water needed for the prescribed dose.
- 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

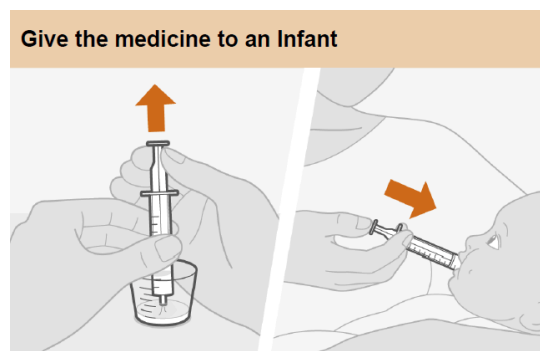
30 minutes wash the dose away and prepare a new dose of medicine.

## Getting ready

### 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.



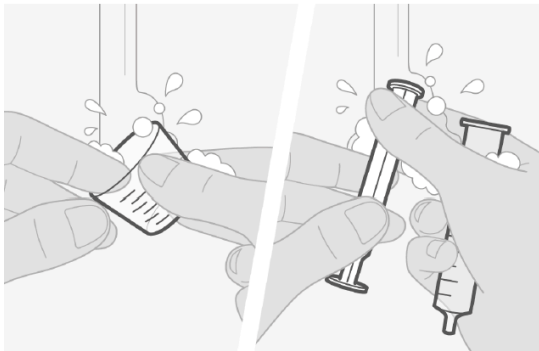
- Place the tip of the syringe into the prepared medicine and draw up all the medicine into the syringe by pulling up on the plunger.



- 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

### 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.

## If you forget to use TIVICAY PD

TIVICAY PD 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 PD**

If you think that you have used too much TIVICAY PD, 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 PD?**

### **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 PD, your doctor will arrange regular blood tests to check for side effects.

#### **Stay in regular contact with your doctor**

TIVICAY PD 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 PD 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 PD 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). TIVICAY PD 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.
- Don't risk blood transfer - for example, don't share needles.

Remind any doctor, dentist or pharmacist you visit that you are using TIVICAY PD.

## **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 PD affects you.**

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

Don't drive or use machines if you are 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.

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 PD.**

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 PD 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 PD. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking TIVICAY PD.

**As well as the effects listed below for TIVICAY PD, 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 PD. 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 PD.**

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 PD, 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

<b>General</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• headache</li><li>• weight gain.</li><li>• difficulty in sleeping (insomnia)</li><li>• dizziness</li></ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.
<b>Gastro-intestinal</b>	
<ul style="list-style-type: none"><li>• diarrhoea</li><li>• feeling sick (nausea).</li><li>• being sick (vomiting)</li><li>• stomach (abdominal) pain or discomfort</li></ul>	

General	What to do
<ul style="list-style-type: none"> <li>• wind (flatulence).</li> </ul>	
<b>Dermatological</b>	
<ul style="list-style-type: none"> <li>• rash</li> <li>• itching (pruritus)</li> </ul>	
<b>Psychological</b>	
<ul style="list-style-type: none"> <li>• abnormal dreams</li> <li>• depression (feelings of deep sadness and unworthiness)</li> <li>• anxiety</li> <li>• lack of energy (fatigue)</li> </ul>	
<b>Musculoskeletal</b>	
<ul style="list-style-type: none"> <li>• joint pain</li> <li>• muscle pain</li> </ul>	

## Serious side effects

Liver related	What to do
<ul style="list-style-type: none"> <li>• inflammation of the liver (hepatitis)</li> <li>• liver failure (signs may include yellowing of the skin and the whites of</li> </ul>	<p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p>



<b>Liver related</b>	<b>What to do</b>
the eyes or unusually dark urine.	
<b>Allergy related</b>	
<ul style="list-style-type: none"> <li>● an inflammatory condition which may develop as the immune system becomes stronger (immune reconstitution syndrome or 'IRIS')</li> <li>● allergic reaction (hypersensitivity) (see earlier in this section for more details)</li> </ul>	
<b>Psychological</b>	
<ul style="list-style-type: none"> <li>● suicidal thoughts*</li> <li>● suicidal attempt*</li> </ul> <p>* mainly in patients who have had depression or mental health problems before.</p>	

### **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](http://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 PD contains

<b>Active ingredient (main ingredient)</b>	dolutegravir (as dolutegravir sodium)
<b>Other ingredients (inactive ingredients)</b>	mannitol microcrystalline cellulose povidone sodium starch glycolate type A silicified microcrystalline cellulose crospovidone sodium stearyl fumarate purified water calcium sulfate dihydrate sucralose Strawberry Cream Flavour PHS-132963 titanium dioxide hypromellose polyethylene glycol

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

## **What TIVICAY PD looks like**

TIVICAY PD 5 mg dispersible tablets are white, round, biconvex tablets debossed with 'SV H7S' on one side and '5' on the other side.

TIVICAY PD dispersible tablets are available in bottles of 60 tablets with child-resistant closure.

(AUST R 340591).

## **Who distributes TIVICAY PD**

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston St,

Abbotsford, Victoria, 3067

Australia.

This leaflet was prepared in May 2021.

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