### Dolutegravir

#### Other NAMES: Tivicay<sup>®</sup>

#### WHY is this drug prescribed?

Dolutegravir is an antiretroviral (anti-HIV) that belongs to a class of drugs called integrase strand-transfer inhibitors (InSTIs). It is intended for treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least 40kg. It works by blocking the enzyme integrase. Dolutegravir is used together with other antiretrovirals to delay the progression of HIV-1 infection. By taking this drug in combination with other antiretroviral agents your doctor has prescribed, your immune system should improve (increase in CD4<sup>+</sup> count) better protecting you against infections and your viral load should decrease because the enzyme needed to produce more viruses is being blocked.

Dolutegravir does not cure AIDS or completely kill the HIV virus, but helps to prevent further damage by slowing down the production of new viruses. Treatment with dolutegravir does not reduce the risk of passing infection on to others. You will still be able to pass HIV by sexual contact, by blood transfer, or by sharing needles. You should always use appropriate precautions to prevent passing HIV on to others.

#### HOW should this drug be taken?

The usual dose of dolutegravir is 50 mg once or twice daily, with or without food. The drug must be taken in a combination regimen with other antiretrovirals. Your dosage is:

□ 50 mg (1 yellow tablet) **once** daily

□ 50 mg (1 yellow tablet) **twice** daily

# What should you do if you FORGET a dose?

If you miss a dose of dolutegravir, take it as soon as possible. However, if it is within 4 hours of your next dose, do not double the dose; just carry on with your regular schedule.

## Why should you not forget to take this drug?

If you miss doses of dolutegravir, the amount of HIV virus in your blood (known as the viral load) will start increasing again and your immune system will be further damaged. A few missed doses can be enough for dolutegravir to stop being active; this is a phenomenon known as **resistance**. When this happens, other antiretrovirals that work in a similar way as dolutegravir may also become inactive. **Therefore, missing doses of dolutegravir can decrease treatment options for the future.** Please do not stop dolutegravir without talking to your doctor first.

#### What SIDE EFFECTS can this drug cause? What should you do about them?

Some people taking dolutegravir will have symptoms such as diarrhea, headache, difficulty sleeping, or nausea. Other side effects may include rash, itching, vomiting, stomach discomfort, dizziness, abnormal dreams, lack of energy or intestinal gas. If these effects occur and bother you, please call the clinic or discuss them at your next visit.

Regular blood tests will be done to detect any changes in your liver or muscle function.

Hepatitis is a rare side effect of dolutegravir. Notify your doctor immediately if you develop yellowing of the skin or whites of the eyes, dark or tea-coloured urine, pale coloured stools/bowel movements, nausea or vomiting, or pain/tenderness on right side below ribs.

Rarely, an allergic or HYPERSENSITIVITY REACTION may occur. Notify your doctor immediately if you develop a skin rash, fever, lack of energy, swelling of the mouth or face causing difficulty in breathing, or muscle or joint aches.

It is important that you keep your doctor appointments and come for your laboratory tests so that your progress can be followed.

# What other PRECAUTIONS should you follow while using this drug?

Certain drugs can decrease the effect of dolutegravir. Also dolutegravir might influence the effect of other drugs you are taking. Inform your doctor and pharmacist of all prescribed and non-prescribed drugs you are taking. As well, you should inform them of natural products or recreational (street drugs) you may be taking. If you wish to start a new drug or natural product, please consult with your pharmacist before doing so.

# Do NOT take dofetilide (Tykosyn®) with dolutegravir.

Tell your doctor if you take:

- Metformin (to treat diabetes)
- Anticonvulsants (carbamazepine, oxcarbazepine, phenobarbital, phenytoin)
- St. John's wort
- Rifampin
- Antacids, calcium or iron supplements (see below)

Antacids and supplements containing calcium, magnesium, iron or aluminum can prevent your body from absorbing dolutegravir and make it less effective.

- <u>Take dolutegravir at least 2 hours</u> before or 6 hours after taking antacids.
- If you take dolutegravir with food, you may take calcium and iron supplements at the same time. Otherwise, <u>take dolutegravir</u> <u>at least 2 hours before or 6 hours after</u> <u>taking calcium or iron supplements.</u>

The safety of dolutegravir in pregnancy is not well known. Please inform your doctor if you believe you are pregnant or if you wish to become pregnant in the near future. A registry has been established to monitor patients on dolutegravir while pregnant. Please inform your doctor if you are pregnant, as he/she is able to register your exposure at 1-800-258-4263 and can recommend an appropriate treatment to help reduce the risk of passing the HIV virus on to your baby. Breastfeeding is NOT recommended if you have HIV as you can transmit the virus to your baby through your breast milk.

#### How should this drug be STORED?

Dolutegravir should be stored up to 30°C. Keep out of the reach of children. Ensure that the drug has not expired by checking the expiry date ("EXP") shown on the outside of the package.

If you have any questions or concerns about this drug or if you are experiencing adverse effects, please discuss them with your pharmacist, doctor or nurse.

Write questions or concerns down to ensure they are addressed.

The following pharmacist is available to answer questions:

Pharmacist: \_\_\_\_\_

Telephone: \_\_\_\_\_

References:

Product Monograph Tivicay<sup>®</sup> (dolutegravir). Laval, QC, Canada: Viiv Healthcare ULC, 2014.

Health Canada Summary Basis of Decision Tivicay  $\ensuremath{^{\text{TM}}}$  (dolute gravir).

Prepared by the Ontario HIV Pharmacy Professional Specialty Group, 2014. Additional medication fact sheets and updates may be found

at: www.hivclinic.ca

### DOLUTEGRAVIR (Tivicay<sup>®</sup>)

### **MEDICATION**

### FACT SHEET