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APPROVED PATIENT INFORMATION LEAFLET

S4

SCHEDULING STATUS

TAFORTRIP film-coated tablet

Emtricitabine/tenofovir alafenamide/dolutegravir

Contains sugar: mannitol 143.380 mg.

WARNING:

TOO MUCH LACTIC ACID IN YOUR BLOOD (LACTIC ACIDOSIS) IS A SERIOUS BUT RARE MEDICAL EMERGENCY THAT CAN LEAD TO DEATH. TELL YOUR HEALTHCARE PROVIDER RIGHT AWAY IF YOU GET THESE SYMPTOMS: WEAKNESS OR BEING TIRED MORE THAN USUAL, UNUSUAL MUSCLE PAIN, BEING SHORT OF BREATH OR FAST BREATHING, STOMACH PAIN WITH NAUSEA AND VOMITING, COLD OR BLUE HANDS AND FEET, FEEL DIZZY OR LIGHTHEADED, OR A FAST OR ABNORMAL HEARTBEAT.

IF YOU HAVE HEPATITIS B INFECTION, YOUR DOCTOR WILL CAREFULLY CONSIDER THE BEST TREATMENT REGIMEN FOR YOU. IF YOU HAVE HEPATITIS B INFECTION, LIVER PROBLEMS MAY BECOME WORSE AFTER YOU STOP TAKING TAFORTRIP. IT IS IMPORTANT NOT TO STOP TAKING TAFORTRIP. WITHOUT TALKING TO YOUR DOCTOR. YOU MUST REMAIN UNDER THE CARE OF YOUR DOCTOR WHILE TAKING TAFORTRIP.

Read all of this leaflet carefully before you start taking TAFORTRIP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TAFORTRIP** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1 What TAFORTRIP is and what it is used for

TAFORTRIP contains two active substances:

- **emtricitabine,** an antiretroviral medicine of a type known as a nucleoside reverse transcriptase inhibitor (NRTI)
- **tenofovir alafenamide,** an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI)
- **dolutegravir**, an antiretroviral medicine of a type known as an integrase strand-transfer inhibitor (INSTIs).

TAFORTRIP in combination with other medicines is for the **treatment of human immunodeficiency virus 1 (HIV-1) infection** in adults and adolescents 12 years of age and older, who weigh at least 40 kg.

2 What you need to know before you take TAFORTRIP

Do not take TAFORTRIP :

- If you are allergic (hypersensitive) to emtricitabine, tenofovir alafenamide or dolutegravir or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- If you take medicine containing dofetilide or pilsicainide, as taking them with **TAFORTRIP** can cause serious or life-threatening side effects.
- If you are taking medicine containing metformin.
- If you have moderate or severe hepatic impairment.
- If you have severe renal disease
- If your doctor has told you that your HIV-1 has the K65R mutation.
- If you are pregnant or breastfeeding.

Warnings and precautions

Too much lactic acid in your blood (lactic acidosis) is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. If you have hepatitis B infection, liver problems may become worse after you stop taking **TAFORTRIP** . It is important not to stop taking **TAFORTRIP** without talking to your doctor.

You must remain under the care of your doctor while taking **TAFORTRIP** .

You can still pass on HIV when taking **TAFORTRIP** . Discuss with your doctor the precautions needed to avoid infecting other people. **TAFORTRIP** is not a cure for HIV infection. While taking **TAFORTRIP** you may still develop infections or other illnesses associated with HIV infection.

During HIV therapy such as with **TAFORTRIP** 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.

Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as **TAFORTRIP** . Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:

- muscle weakness
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations, tremor or hyperactivity

Talk to your doctor before taking **TAFORTRIP** :

If you have liver problems or have suffered liver disease, including hepatitis.

- Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you.

- If you have hepatitis B liver problems it may become worse after you stop taking **TAFORTRIP** . Do not stop taking **TAFORTRIP** without talking to your doctor: see section 3, Do not stop taking **TAFORTRIP** .
- Your doctor may not prescribe **TAFORTRIP** to you if the virus has a K65R mutation.

While you are taking TAFORTRIP

Once you start taking **TAFORTRIP** , look out for:

- Signs of inflammation or infection
- Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak

immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment, such as with **TAFORTRIP** , is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

- Joint pain, stiffness or bone problems
- Bone problems. Some patients taking combination antiretroviral medicines such as **TAFORTRIP** may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:

- joint stiffness

- joint aches and pains (especially of the hip, knee and shoulder)
- difficulty with movement

If you notice any of these symptoms, tell your doctor immediately. For more information see section 4, Possible side effects.

Although kidney problems have not been observed with **TAFORTRIP** , there is a possibility that you may experience kidney problems when taking **TAFORTRIP** over a long period of time.

Children and adolescents

Do not give this medicine to children under 12 years of age or weighing less than 40 kg.

The use of **TAFORTRIP** in children under 12 years of age has not been studied.

Other medicines and TAFORTRIP

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. **TAFORTRIP** may interact with other medicines. As a result, the amounts of **TAFORTRIP** or other medicines in your blood may change. This may stop your medicines from working properly or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels.

Medicines containing dofetilide should not be taken with **TAFORTRIP** as blood levels are raised and increased side effects can result.

Metformin blood levels are increased by **TAFORTRIP** . You should not take **TAFORTRIP** if you are also taking metformin.

Other types of medicine:

Talk to your doctor if you are taking:

antibiotics, used to treat bacterial infections including tuberculosis, containing:

- rifabutin, rifampicin, and rifapentine

antiviral medicines used to treat HIV:

- emtricitabine and tipranavir

anticonvulsants, used to treat epilepsy, such as:

- carbamazepine, oxcarbazepine, phenobarbitone and phenytoin

herbal remedies used to treat depression and anxiety containing:

- St. John’s wort (Hypericum perforatum)

Tell your doctor if you are taking these or any other medicines. Do not stop your treatment without contacting your doctor.

Some antacids or laxatives containing magnesium or aluminium, sucralfate and oral calcium or iron supplements may be used if **TAFORTRIP** is taken 2 hours before or 6 hours after these medicines.

TAFORTRIP with food, drink and alcohol

TAFORTRIP may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **TAFORTRIP** .

TAFORTRIP is contraindicated in pregnancy and you must not take it if you are pregnant or are planning to become pregnant.

Use of dolutegravir during pregnancy was associated with a small increase in the birth defects of the brain and spine.

If a pregnancy is confirmed in the first trimester while on dolutegravir, the benefits and risks of continuing dolutegravir versus switching to another antiretroviral medicine should be discussed with the patient. Dolutegravir may be used during the second and third trimester of pregnancy when the expected benefit outweighs the potential risk to the foetus.

A urine pregnancy test should be carried out within 24 hours before commencing treatment with **TAFORTRIP** . Once treatment has started, pregnancy testing should be repeated every 4 weeks. Pregnancy testing and counselling should be performed if a woman misses her period or if there is any abnormality in menstrual bleeding.

Use effective contraception while taking TAFORTRIP

Women of childbearing potential should be counselled about the potential risk of birth defects of the brain and spine with dolutegravir, including consideration of using effective contraceptive measures.

Perform pregnancy testing before start of **TAFORTRIP** in women of childbearing potential to exclude unintentional use of **TAFORTRIP** during the first trimester of pregnancy.

If a woman plans pregnancy, the benefits and the risks of starting or continuing treatment with dolutegravir versus using another antiretroviral medicine should be discussed with her.

Do not breastfeed your baby during treatment with TAFORTRIP .

The active substances in **TAFORTRIP** pass into breast milk and possible harm to your baby cannot be excluded.

It is also recommended that you do not breastfeed your baby to avoid passing the HIV virus to the baby through your breast milk.

Driving and using machines

TAFORTRIP may affect your ability to drive and use machines. Do not drive and use machines until you know how treatment with **TAFORTRIP** affects you.

TAFORTRIP can cause dizziness and fatigue/tiredness. If you feel tired and/or dizzy when taking **TAFORTRIP** , do not drive and do not use any tools or machines.

TAFORTRIP contains mannitol

TAFORTRIP also contains mannitol and may have a laxative effect.

3 How to take TAFORTRIP

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

The recommended dose is:

Adults: one tablet each day, with or without food

Adolescents 12 years of age and older, who weigh at least 35 kg: one tablet each day with or without food

Do not chew, crush or split the tablet.

Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.
If you are on dialysis, take your daily dose of **TAFORTRIP** following completion of dialysis.

If you take more TAFORTRIP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take more than the recommended dose of **TAFORTRIP** you may be at higher risk of experiencing side effects (see section 4, Possible side effects).
Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can show what you have taken.

If you forget to take TAFORTRIP

Do not take a double dose to make up for forgotten individual doses.

It is important not to miss a dose of **TAFORTRIP** . If you do miss a dose:

If you notice this miss dose within 18 hours of the time you usually take **TAFORTRIP** , you must take the tablet as soon as possible. Then take the next dose as usual.

If you notice this miss dose, 18 hours or more after the time you usually take **TAFORTRIP** , then do not take the missed dose. Wait and take the next dose at your usual time.

If you vomit less than 1 hour after taking **TAFORTRIP** , you should take another tablet.

Do not stop taking TAFORTRIP

Do not stop taking **TAFORTRIP** without talking to your doctor. Stopping **TAFORTRIP** can seriously affect how well future treatment works. If **TAFORTRIP** is stopped for any reason, speak to your doctor before you restart taking **TAFORTRIP** tablets.

When your supply of **TAFORTRIP** starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if **TAFORTRIP** is stopped for even a short time. The disease may then become harder to treat.

If you have both HIV infection and hepatitis B, it is very important not to stop taking **TAFORTRIP** without talking to your doctor first. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment may lead to worsening of hepatitis, which may be life-threatening.

Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

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

4 Possible side effects

TAFORTRIP can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **TAFORTRIP** and tell your doctor immediately or go to the casualty department at your nearest hospital:

TAFORTRIP can cause some serious side effects.

Possible serious side effects: tell a doctor immediately

Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment such as with **TAFORTRIP** is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

Autoimmune disorders (the immune system attacks healthy body tissue) may also occur after you start taking medicines for HIV infection such as **TAFORTRIP** . Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:

- muscle weakness

- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations, tremor or hyperactivity

If you notice the side effects described above, tell your doctor immediately.

If any of the following happens, stop taking **TAFORTRIP** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Fever
- Generally ill feeling
- Tiredness
- Muscle or joint aches
- Blisters or sores in the mouth
- Blisters or peeling of the skin
- Redness or swelling of the eyes
- Swelling of the mouth, face, lips or tongue
- Difficulty in swallowing or breathing

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **TAFORTRIP** . You may need urgent medical attention or hospitalisation.

Worsening of hepatitis B virus infection: **TAFORTRIP** tablets are not for use to treat chronic hepatitis B virus (HBV) infection. If you have hepatitis B virus (HBV) infection and take **TAFORTRIP** tablets, your HBV may get worse (flare-up) if you stop taking

TAFORTRIP . A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following signs or symptoms of liver problems:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or “tea-coloured” urine
- Light coloured stools
- Nausea or vomiting
- Loss of appetite
- Pain, aching or tenderness on the right side of your stomach area.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following signs or symptoms of too much lactic acid in your blood:

- Weakness or being more tired than usual, unusual muscle pain
- Short of breath or fast breathing
- Stomach pain with nausea and vomiting
- Cold or blue hands and feet
- Feeling dizzy or lightheaded
- Fast or abnormal heartbeat

Too much lactic acid is a serious medical emergency that can lead to death.

Frequent side effects

- feeling sick (nausea)
- abnormal dreams
- headache

- dizziness
- diarrhoea
- vomiting
- stomach pain
- wind (flatulence)
- rash
- tiredness (fatigue)
- neutropenia (low levels of white blood cells). Symptoms are infections of the skin and other areas of the body, swollen gums, and sore mouth.
- Kidney problems

Less frequent side effects

- swelling of the face, lips or throat with difficult breathing (angioedema)
- liver problems

The following side effects are reported but the frequency is not known:

- itching (pruritus)
- hives (urticaria)
- low red blood cell count (anaemia)
- problems with digestion resulting in discomfort after meals (dyspepsia)
- joint pain (arthralgia)
- inflammation on pancreas

If you notice any of these symptoms tell your doctor.

- During HIV therapy such as with **TAFORTRIP** 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 side effects, talk to your doctor, pharmacist or nurse. You can also report side Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **TAFORTRIP**.

5 How to store TAFORTRIP

KEEP OUT OF REACH OF CHILDREN.

- Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Store at or below 30 ºC.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What TAFORTRIP contains:

The active substances are dolutegravir, emtricitabine and tenofovir alafenamide. Each tablet contains 50 mg of dolutegravir, 200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are:

Microcrystalline Cellulose USNF (PH-102)

Croscarmellose Sodium USNF (Ac-Di-Sol-SD-711)

Magnesium Stearate USNF (Ligamed MF-2-V)

Mannitol USP (Pearlitol® 25 C) ##

Microcrystalline Cellulose USNF (Microcel-101 SD)

Povidone USP (Plasdone K – 29/32)

Ferric Oxide USNF (Sicovit Red 30)

Purified Water USP/Ph.Eur

Sodium Starch Glycolate (Type A) USNF (Primojel)

Sodium Stearyl Fumarate USNF

Opadry II white 85F18422

What TAFORTRIP looks like and contents of the pack

TAFORTRIP : White to off-white coloured, modified capsule shaped, film-coated tablets debossed with 'DET' on one side and plain on other side..

HDPE Container Pack:

White opaque colour HDPE container closed with white opaque 33 mm - 400 polypropylene child resistant closure with wad having induction sealing liner. The HDPE container also contains 4 No's. of 1 g of silica gel sachet.

Pack size: 30's

White opaque colour HDPE container closed with white opaque 38 mm - 400 polypropylene child resistant closure with wad having induction sealing liner. The HDPE container also contains 3 No's. of 2 g of silica gel sachet.

Pack size: 90's

Holder of Certificate of Registration

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