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**Product Name:** AUROTEM

**Dosage form and strength:** Each film coated tablet contains 200 mg of Emtricitabine and 25 mg of Tenofovir Alafenamide (equivalent to 28 mg of Tenofovir Alafenamide Fumarate)

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### 1.3.2 Approved Patient Information Leaflet

#### PATIENT INFORMATION LEAFLET

S4

#### AUROTEM

emtricitabine/tenofovir alafenamide

Sugar free

**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 AUROTEM. IT IS IMPORTANT NOT TO STOP TAKING AUROTEM WITHOUT TALKING TO YOUR DOCTOR. YOU MUST REMAIN UNDER THE CARE OF YOUR DOCTOR WHILE TAKING AUROTEM.

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**Read all of this leaflet carefully before you are given AUROTEM.**

Read all of this leaflet carefully before you start taking **AUROTEM**.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **AUROTEM** 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 **AUROTEM** is and what it is used for
2. What you need to know before you use **AUROTEM**
3. How to use **AUROTEM**
4. Possible side effects
5. How to store **AUROTEM**
6. Contents of the pack and other information

## **1. What AUROTEM is and what it is used for**

**AUROTEM** 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)

**AUROTEM** blocks the action of the reverse transcriptase enzyme, which is essential for the virus to multiply. **AUROTEM** therefore reduces the amount of HIV in your body.

**AUROTEM** in combination with other medicines is for the **treatment of human immunodeficiency**

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**virus 1 (HIV-1) infection** in adults and adolescents 12 years of age and older, who weigh at least 35 kg.

## 2. What you need to know before your take AUROTEM

### Do not take AUROTEM:

- If you are allergic (hypersensitive) to emtricitabine, tenofovir alafenamide or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

### 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 **AUROTEM**. It is important not to stop taking **AUROTEM** without talking to your doctor.

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

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

During HIV therapy such as with **AUROTEM** there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

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Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as **AUROTEM**. 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 **AUROTEM**:

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 **AUROTEM**. Do not stop taking **AUROTEM** without talking to your doctor: see section 3, Do not stop taking **AUROTEM**.
- Your doctor may not prescribe **AUROTEM** to you if the virus has a K65R mutation.

While you are taking **AUROTEM**

Once you start taking **AUROTEM**, 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 **AUROTEM**, is started. It is thought that these symptoms are

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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 **AUROTEM** 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 **AUROTEM**, there is a possibility that you may experience kidney problems when taking **AUROTEM** 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 35 kg.

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

### **Other medicines and AUROTEM:**

Always tell your healthcare professional if you are taking any other medicine.

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(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. **AUROTEM** may interact with other medicines. As a result, the amounts of **AUROTEM** 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 used in treating hepatitis B infection:

You should not take **AUROTEM** with medicines containing:

- Tenofovir alafenamide
- Tenofovir disoproxil
- Lamivudine
- Adefovir dipivoxil

Tell your doctor if you are taking any of these medicines.

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

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**herbal remedies** used to treat depression and anxiety containing:

- St. John's wort (*Hypericum perforatum*)

### **Interactions between the individual active substances of AUROTEM**

#### **(emtricitabine and tenofovir alafenamide) and other medicines**

Talk to your doctor if you are taking:

**antifungal medicine**, used to treat fungal infections

- Ketoconazole, itraconazole, fluconazole, isavuconazole

**anti-hepatitis C virus medicines**, used for treatment of a viral infection that affects the liver:

- Ledipasvir, sofosbuvir, velpatasvir, sofosbuvir, voxilaprevir

**HIV protease inhibitors**, medicine that prevent the HIV virus from making more copies of themselves:

- Atazanavir, cobicistat, ritonavir, darunavir, lopinavir, tipranavir

**other HIV antiretrovirals**, used to treat people infected with the HIV virus:

- Dolutegavir, rilpivirine, efavirenz, maraviroc, nevirapine, raltegravir

**anti-depressants**, used to treat depression

- Sertraline

**immunosuppressants**, medicine that prevent your immune system from



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attacking healthy cells and tissues by mistake.

- Ciclosporin

**oral contraceptives**, used for the prevention of pregnancy

- Norgestimate, ethinylestradiol

**sedatives/hypnotics**, used to reduce tension and anxiety and induce calm

(sedative effect) or to induce sleep (hypnotic effect).

- Midazolam

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

**Taking AUROTEM with food and drink**

**AUROTEM** 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 **AUROTEM**.

**Use effective contraception while taking AUROTEM**

Ask your doctor or pharmacist for advice before taking any medicine when pregnant.

If you have taken **AUROTEM** during your pregnancy, your doctor may request regular blood

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tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

**Do not breastfeed your baby during treatment with AUROTEM.**

One of the active substances in **AUROTEM** (emtricitabine) passes 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**

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

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

**3. How to take AUROTEM**

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

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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 **AUROTEM**. following completion of dialysis.

### **If you take more AUROTEM. than you should**

If you take more than the recommended dose of **AUROTEM**. 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 AUROTEM**

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

If you notice this miss dose within 18 hours of the time you usually take **AUROTEM**., 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 **AUROTEM**., 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 **AUROTEM**., you should take another tablet.

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**Do not stop taking AUROTEM**

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

When your supply of **AUROTEM**. 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 **AUROTEM**. 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 **AUROTEM**. 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 **AUROTEM**., ask your doctor or pharmacist.

**4. Possible side effects**

**AUROTEM** can have side effects.

Not all side effects reported for **AUROTEM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AUROTEM**, please consult your healthcare provider for advice.

**AUROTEM** can cause some serious side effects.

Possible serious side effects: tell a doctor immediately

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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 **AUROTEM** 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 **AUROTEM**. 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.

*Frequent side effects*

- Feeling sick (nausea)
- Abnormal dreams
- Headache
- Dizziness
- Diarrhoea
- Vomiting

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- Stomach pain
- Wind (flatulence)
- Rash
- Tiredness (fatigue)

*Less frequent side effects*

- Swelling of the face, lips or throat with difficult breathing (angioedema)

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

- Itching (pruritus)
- Hives (urticaria)
- Low red blood cell count (anaemia)
- Problems with digestion resulting in discomfort after meals (dyspepsia)
- Joint pain (arthralgia)

If any of the side effects get serious tell your doctor.

Other effects that may be seen during HIV treatment

*The frequency of the following side effects is not known* (frequency cannot be estimated from the available data).

Bone problems. Some patients taking combination antiretroviral medicines

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such as **AUROTEM** 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.

During HIV therapy such as with **AUROTEM** there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

### Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **AUROTEM**.

## 5. How to store AUROTEM

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- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store all medicines 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 °C.
- 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 AUROTEM contains

The active substance is emtricitabine and tenofovir alafenamide. Each tablet contains 200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are:

Microcrystalline Cellulose

Croscarmellose Sodium USNF

Magnesium Stearate USNF (Ligamed MF-2-V)

Constituents of coating material:

Purified water (USP)

Opadry II white contains:

Polyvinyl Alcohol – Part Hydrolyzed

Titanium Dioxide E171



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Macrogol/PEG 3350

Talc E553b

### **What AUROTEM looks like and contents of the pack**

#### **AUROTEM:**

White to off-white coloured, capsule-shaped, biconvex, film-coated tablets

debossed with "ET" on one side and plain on the 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 of 1 g of silica gel sachet. These HDPE bottles shall be packed in pre-printed carton with a packaging leaflet.

**Pack size:** 30s

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 of 2 g of silica gel sachet. These HDPE bottles shall be packed in pre-printed carton with a packaging leaflet.

**Pack size:** 90s

### **HOLDER OF THE CERTIFICATE OF REGISTRATION**

AUROBINDO PHARMA (PTY) LTD

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

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Johannesburg

South Africa

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