

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**CITENVIR** (tablet)

Efavirenz, emtricitabine and tenofovir disoproxil fumarate

### Read all of this leaflet carefully before you start taking CITENVIR.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

CITENVIR 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 CITENVIR CONTAINS

The active ingredients are efavirenz, emtricitabine and tenofovir disoproxil fumarate.

#### **CITENVIR 600/200/300:**

Each film coated tablet contains efavirenz 600 mg, emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg. Contains titanium dioxide. CITENVIR is sugar free.

The other ingredients of CITENVIR are croscarmellose sodium, hydroxyl propyl cellulose, magnesium stearate, microcrystalline cellulose, Opadry II white and sodium lauryl sulphate.

Opadry II white contains macrogol, poly vinyl alcohol, talc and titanium dioxide (C.I. No: 77891).

### WHAT CITENVIR IS USED FOR

CITENVIR contain 3 medicines, efavirenz, emtricitabine and tenofovir disoproxil fumarate (also called tenofovir DF). Each of these medicines is also known as antiretroviral medicines.

CITENVIR can be used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection in adults.

## **BEFORE YOU TAKE CITENVIR**

### **Do not take CITENVIR:**

If you are allergic to efavirenz, emtricitabine and tenofovir disoproxil fumarate or any of the ingredients of CITENVIR.

If you are suffering from moderate to severe kidney problems (renal impairment).

Astemizole (used to treat hay fever or other allergies).

Bepidil (used to treat heart disease).

Cisapride (used to treat heartburn).

Ergot alkaloids (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine) (used to treat migraines and cluster headaches).

Midazolam or triazolam (used to help you sleep).

Pimozide (used to treat certain mental conditions).

Voriconazole (used to treat fungal infections).

St. John's wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety).

### **Take special care with CITENVIR :**

If you have serious liver problems (hepatotoxicity) or liver enlargement (hepatomegaly).

If you have a history of mental illness including depression.

If you have a history of convulsions (fits or seizures).

If you are pregnant.

If you are suffering from kidney problems.

If you have any signs of skin rash.

CITENVIR may cause lactic acidosis, together with an enlarged liver, which can be fatal.

Deep, rapid breathing, drowsiness, and non-specific symptoms such as nausea, vomiting and stomach pain, might indicate the development of lactic acidosis.

If you became pregnant while taking CITENVIR your baby may develop blood and nervous system disorders. Your doctor will monitor your baby's condition.

Pancreatitis is a dangerous inflammation of the pancreas that may cause death. Tell your doctor right away if you develop stomach pain, nausea or vomiting. These can be signs of pancreatitis.

Tell your doctor if you have liver disease (including hepatitis B). CITENVIR should not be used to treat chronic hepatitis B virus infection (HBV; an ongoing liver infection). Tell your doctor if you have or think you may have HBV.

CITENVIR may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face and/or gain fat around the abdomen (tummy) and internal organs; get larger breasts or fatty lumps on the back of the neck (buffalo hump). If you are taking CITENVIR for the first time you may develop a condition known as Immune Reconstitution Inflammatory Syndrome (IRIS), within the first few months of treatment. This condition can cause opportunistic infections that are being treated to become worse or opportunistic diseases that were asymptomatic to be unmasked. Tell your doctor or healthcare professional if your general health worsens or if you think you may have an infection. You should not stop taking CITENVIR. Your doctor will treat the infections appropriately.

You may develop a condition known as osteonecrosis while taking CITENVIR. Seek medical advice if you experience joint aches and pain, joint stiffness or difficulty in movement.

**Taking CITENVIR with food and drink:**

CITENVIR can be taken as one tablet once daily, taken orally on an empty stomach.

Do not take with grapefruit.

**Pregnancy and Breastfeeding:**

Do not take CITENVIR if:

You are pregnant.

You are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CITENVIR.

**Driving and using machinery:**

CITENVIR may affect the performance of skilled tasks including driving.

You may get side effects after taking CITENVIR, dizziness, impaired concentration, and/or drowsiness. If this happens, do not drive or use machines that require you to be alert.

**Important information about some of the ingredients of CITENVIR:**

CITENVIR is sugar free.

**Taking other medicines with CITENVIR:**

You should not take CITENVIR with some medicines. E.g. antihistamines (astemizole), calcium channel blockers (bepridil), ergot derivatives (dihydroergotamine, ergometrine, ergotamine and methylergometrine), gastrointestinal medicines (cisapride), antipsychotics (pimozide), and sedatives and hypnotics (midazolam and triazolam).

Antibacterials - Rifampicin, increased dose of efavirenz may be necessary.

Antifungals - Voriconazole, due to increased plasma concentrations of efavirenz, decreased dose of efavirenz and increased dose of voriconazole is advised.

Grapefruit - the metabolism of efavirenz may be inhibited by concomitant ingestion of grapefruit juice.

Antidiabetics - Metformin - Fatal lactic acidosis has been reported when given concomitantly with didanosine, stavudine and tenofovir.

St. John's wort (*Hypericum perforatum*) (may decrease the plasma concentration of efavirenz).

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

**HOW TO TAKE CITENVIR**

Do not share medicines prescribed for you with any other person.

CITENVIR should be swallowed whole with a half a glass of water.

**For adults:** The dose of CITENVIR is one tablet once daily, taken orally on an empty stomach. Dosing at bedtime may improve the tolerability of nervous system symptoms.

Because CITENVIR is a fixed-dose combination, should not be prescribed for patients requiring dosage adjustment such as those with moderate or severe renal impairment (creatinine clearance less than 50 ml/min).

Not recommended for use in patients less than 18 years of age.

Always take CITENVIR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of CITENVIR is too strong or too weak, talk to your doctor or pharmacist.

**If you take more CITENVIR than you should:**

If you accidentally taken too many CITENVIR tablets, contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

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

**If you forget to take CITENVIR:**

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

**POSSIBLE SIDE EFFECTS**

CITENVIR can have side effects.

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

Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.

Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.

Severe itching of the skin (with raised lumps).

Also, stop taking CITENVIR and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect.

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

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

Severe depression

Dizziness

Insomnia (inability to sleep)

Somnolence (sleepiness)

Impaired concentration

Nausea (feeling sick)

Vomiting

Diarrhoea

Rashes (including red spots or blotches sometimes with blistering and swelling of the skin)

Pruritus (itching)

Fatigue

Loss of strength and energy

Sinusitis (inflammation of a sinus)

**Tell your doctor if you notice any of the following:**

Abnormal thinking/behaviour or dreaming

Loss of the appetite for food

Abdominal pain/discomfort

Headache

Allergic skin reactions

An itchy skin eruption/rash

Pain in joints and muscles

Restlessness

Confusion

Hallucinations

Loss of memory

An exaggerated feeling of physical and mental well-being

Convulsions

Anxiety

ringing or booming sensation in one or both ears

Rapid and irregular heart beat

Inflammation in the lungs

Inflammation of mucous membrane of the nose

**The following side effects are with unknown frequencies:**

Aggressive behaviour

Nervousness

Constipation

Skin discoloration

Passing large amounts of urine

Weight gain

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

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

**STORING AND DISPOSING OF CITENVIR**

Store at or below 30 °C.

Keep HDPE containers tightly closed.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7. PRESENTATION OF CITENVIR**

### **HDPE Container Pack:**

Tablets are packed in white opaque HDPE containers and white opaque closures with induction sealing wad with one no. of 1 g silica gel sachet and polyester fibre coil. Each container contains 30 tablets.

**Pack size: 30's** - One HDPE container contains 30 tablets.

### **IDENTIFICATION OF CITENVIR**

White to off white, oval shaped, biconvex, film-coated tablets debossed with 'I48' on one side and plain on the other side.

### **REGISTRATION NUMBER**

47/20.2.8/0504

### **NAME AND ADDRESS OF REGISTRATION HOLDER**

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#### **FOR NAMIBIA ONLY:**

Schedule: NS2

**Registration Number:**

Citenvir: 13/20.2.8/0240