

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

VIDEX EC 250 and 400 mg capsules.

### Read all of this leaflet carefully before you start using VIDEX EC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VIDEX EC 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 VIDEX EC CONTAINS

The active substance is **didanosine** (also known as ddl).

VIDEX EC capsules contain 250 or 400 mg didanosine per capsule respectively.

The other ingredients are:

carboxymethylcellulose sodium 12, colloidal silicon dioxide, diethyl phthalate, gelatine, methacrylic acid copolymer, sodium hydroxide, sodium lauryl sulphate, sodium starch glycolate, talc and titanium dioxide.

## **WHAT VIDEX EC IS USED FOR**

VIDEX EC is used in combination with other medicines to treat adults who are infected with HIV (the human immunodeficiency virus, the virus that causes AIDS). VIDEX EC belongs to a class of medicines called nucleoside analogues.

VIDEX EC will not cure your HIV infection.

VIDEX EC does not prevent a patient infected with HIV from passing the virus to other people. To protect others, you must continue to practice safe sex and take precautions to prevent others from coming in contact with your blood and other body fluids.

## **BEFORE YOU TAKE VIDEX EC**

### **Do not take VIDEX EC:**

- if you are hypersensitive (allergic) to any of its ingredients, including its active ingredient, didanosine and the inactive ingredients. Tell your doctor if you think you have had an allergic reaction to any of these ingredients.
- If you have impaired liver function.

### **Take special care with VIDEX EC:**

Tell your doctor or healthcare professional:

- If you have kidney disease: VIDEX EC is not suitable for you if your kidneys do not function properly. If your kidneys are not working properly, your doctor will need to do regular tests to check how they are working while you take VIDEX EC. Your doctor may also lower your dosage of VIDEX EC.

- if you have ever had pancreatitis (pain and inflammation of the pancreas)
- if you have ever had peripheral neuropathy (numbness, tingling or pain in your hands or feet)
- if you have received treatment with stavudine (a medicine used to treat HIV infection) or hydroxyurea (a medicine used to treat cancer).

**Pregnancy and Breastfeeding:**

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

You should not take VIDEX EC if you are pregnant or breastfeeding your infant.

Pregnant women have experienced serious side effects when taking VIDEX EC in combination with stavudine also known as d4T and other HIV medicines.

Inform your doctor if you are breastfeeding. It is recommended that HIV-infected women should not breastfeed under any circumstances in order to avoid transmission of HIV to the baby.

**Taking other medicines with VIDEX EC:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines). The use of VIDEX EC with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Alcohol: Do not drink alcohol while taking VIDEX EC since alcohol may increase your risk of pancreatitis (pain and inflammation of the pancreas) or liver damage.

Other medicines: Other medicines, including those you can buy without a prescription (and including complementary or traditional medicines), may interfere with the actions of VIDEX EC or may increase the possibility or severity of side effects. Do not take any medicine, vitamin supplement, or other health preparation without first checking with your doctor.

## **HOW TO TAKE VIDEX EC**

### **DO NOT SHARE VIDEX EC PRESCRIBED FOR YOU WITH ANY OTHER PERSON**

Your doctor will determine your dose based on your body weight, kidney and liver function, other medicines you are taking, and any side effects that you may have had with VIDEX EC or other medicines. Take VIDEX EC on an empty stomach - that means at least 1 hour before or 2 hours after eating. Do not take VIDEX EC with food. Try not to miss a dose, but if you do, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.

If you have taken an overdose of VIDEX EC, get medical help right away. Contact your doctor or a poison control centre.

## **POSSIBLE SIDE EFFECTS**

If the following happens, stop taking VIDEX EC and tell your doctor immediately or go to the casualty department at your nearest hospital:

**Pancreatitis:** Pancreatitis is a dangerous inflammation of the pancreas that may cause death. Signs of pancreatitis include:

- stomach pain
- nausea
- vomiting.

This condition is more likely to happen in people who have had it before. It is also more likely in people with advanced HIV disease. However, it can occur at any stage of HIV disease. It may be frequent in patients with kidney problems, those who drink alcohol, and those who are also treated with stavudine or hydroxyurea.

**Lactic acidosis** (excess of lactic acid in the blood), severe liver enlargement, high blood pressure in the large vein of the liver (portal hypertension) and liver failure, including death have been reported among patients taking VIDEX EC (including pregnant women).

Symptoms that may indicate a liver problem are:

- feeling very weak, tired or uncomfortable,
- unusual or unexpected stomach discomfort,
- feeling cold, dizzy or lightheaded
- suddenly developing a slow or irregular heartbeat.

Women, overweight patients, and those who have been treated for a long time with other medicines used to treat HIV infection are more likely to develop lactic acidosis.

Your doctor should check your liver function periodically while you are taking VIDEX EC. You should be especially careful if you have a history of heavy alcohol use or a liver problem.

Pancreatitis and Lactic acidosis are serious side effects for VIDEX EC. You may need urgent medical attention or hospitalisation.

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

**Vision changes:** VIDEX EC may affect the nerves in your eyes. Because of this, you should have regular eye examinations. You should also report any changes in vision to your doctor right away. This includes for example, seeing colours abnormally or blurred vision.

**Peripheral neuropathy** (numbness, tingling or pain in the hands or feet).

This condition is more likely to happen in people who have had it before. It is also more likely in patients taking medicines that affect the nerves and in people with advanced HIV disease. However, it can occur at any stage of HIV disease. If you get peripheral neuropathy, your doctor will tell you to stop taking VIDEX EC. After stopping VIDEX EC, the symptoms may get worse for a short time and then get better. Once symptoms of peripheral neuropathy go away completely, you and your doctor should decide if starting VIDEX EC is right for you. If so, you might be started at a lower dose.

**Other frequent side effects in combination with other HIV medicines include:**

- diarrhoea
- rash
- headache

- nausea and vomiting.

Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

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

### **STORING AND DISPOSING OF VIDEX EC**

VIDEX EC should be stored at room temperature not exceeding 25 °C.

Store all medicines out of reach and sight of children.

Return unused medicine to the pharmacy.

Do not dispose of unused medicine in drains or sewerage systems.

### **PRESENTATION OF VIDEX EC**

VIDEX EC capsules:

Colourless Aclar and aluminium foil blister packs with 30 capsules.

### **IDENTIFICATION OF VIDEX EC**

VIDEX EC capsule 250 mg: White, opaque, Size#1, two-piece hard gelatine capsule printed in blue with BMS, 250 mg and 6673. Contents of capsules: white to off-white, film coated beadlets.

VIDEX EC capsule 400 mg: White, opaque, Size#0, two-piece hard gelatine capsule printed in red with BMS, 400 mg and 6674. Contents of capsules: white to off-white, film coated beadlets.

#### **REGISTRATION NUMBER/REFERENCE NUMBER**

VIDEX EC capsules 250 mg: 36/20.2.8/0065

VIDEX EC capsules 400 mg: 36/20.2.8/0066

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

\*Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene 0157

Pretoria

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