

VIDEX(R) EC

didanosine

Consumer Product Information

What is in this leaflet

Read this leaflet carefully before taking VIDEX EC capsules. This leaflet answers some common questions about VIDEX EC.

It does not contain all the available information. Some of the information contained in this leaflet may not apply to you.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking VIDEX EC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Always follow the instructions that your doctor or pharmacist give you about VIDEX EC capsules.

Keep this leaflet with the medicine. You may need to read it again.

What VIDEX EC is used for

VIDEX is a trade name (manufacturer's name) for the medicine, didanosine. VIDEX belongs to a group of medicines called nucleoside (NUKE-lee-O-side) analogues. You may also know didanosine as "ddI".

VIDEX is used to treat adults and children infected with the Human Immunodeficiency Virus (HIV).

VIDEX EC capsules are a different presentation of VIDEX. EC stands for 'enteric coated'. The didanosine in the capsules has a special coating which prevents acid in the stomach from destroying it. The enteric coat protects the beads of didanosine in the stomach, and then release the didanosine in the small intestine where there is no acid, and the didanosine can be absorbed.

What is HIV

HIV is a virus that kills important cells in the immune system over time (eg. CD4 cells). When enough of the immune cells have been killed by HIV, the body can become prone to certain types of infections. Some infections are the cause of "AIDS-defining" illnesses. This is when someone is said to have developed the Acquired Immunodeficiency Syndrome or AIDS. AIDS is a serious condition and can lead to death.

How VIDEX EC works

When HIV infects cells in the immune system it takes over part of the cell's internal workings and uses building blocks from the cell to produce new viruses.

The didanosine in VIDEX EC is a "pretend" building block called a nucleoside analogue. When HIV infects a healthy cell it can pick up didanosine instead of the cell's real

building blocks stopping HIV from producing more viruses. Interfering with the production of new viruses helps to reduce the total amount of HIV in the body and slows down the damage to the immune system.

VIDEX EC is not a cure for HIV infection. Taking it will not necessarily prevent the illnesses that commonly occur in people with HIV infection or AIDS. You can still infect other people with HIV while you are taking this medicine.

It is not known how safe VIDEX EC is when it is used for long periods.

VIDEX EC is not addictive.

Your doctor may have prescribed VIDEX EC for another reason. Ask your doctor if you have any questions about why VIDEX EC has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take VIDEX EC capsules

It is important that you check the Information below before taking VIDEX EC.

When you must not take VIDEX EC

Do not take VIDEX EC capsules if you have an allergy to it or to any ingredients in the formulation listed at the end of this leaflet.

Do not take VIDEX EC capsules after the expiry date (EXP) printed on the pack. If you take this

medicine after the expiry date has passed, it may not work as well.

Do not use VIDEX EC capsules if the packaging is torn or shows signs of tampering.

Before you start to take VIDEX EC

Tell your doctor if:

1. you have allergies to:
 - * other medicines from the nucleoside analogue group such as zidovudine (AZT)
 - * any other medicines you have been given or purchased
 - * substances such as foods, preservatives or dyes.

Symptoms of an allergic reaction may include:

- * swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, or
- * severe and sudden onset of pinkish, itchy swellings on the skin, also called hives.

2. you are pregnant or intend to become pregnant. Experience is limited with the use of VIDEX EC in pregnant women. Therefore, it should not be used during pregnancy unless it is clearly needed. If there is an urgent need to consider VIDEX EC during pregnancy, your doctor will discuss with you the benefits and risks of taking it.

3. you are breast-feeding or planning to breast-feed. It is not known whether VIDEX EC passes into breast milk. Therefore to avoid possible side effects in the nursing infant, mothers should stop breast-feeding if they are taking VIDEX EC (breast-feeding can also transfer HIV to babies).

4. you currently experience or have experienced any medical conditions, especially:
 - * pancreatitis, inflammation of the pancreas which may cause severe upper stomach pain,

often with nausea and vomiting

- * peripheral neuropathy, a condition which causes tingling, burning pain, or numbness of the hands or feet
- * a history of taking neurotoxic medicines ie. medicines that have harmful effects on the nervous system
- * liver problems including hepatitis, yellowing of the skin or eyes (jaundice) or prior use of medicines toxic to the liver. Liver problems may cause higher levels of VIDEX EC in the blood, increasing the chance of side effects
- * history of alcohol consumption and/or alcoholism
- * kidney disorders
- * infections due to low white cell counts
- * anaemia, a condition in which there is a decreased number of red blood cells
- * eye problems such as retinitis

If you have not told your doctor about any of the above, tell them before you take VIDEX EC.

When VIDEX EC is taken with other medicines

Tell your doctor if you are taking other medicines, including vitamin supplements, herbal preparations or any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

It is very important that you do not take other medicines which might cause or worsen peripheral nerve disease (peripheral neuropathy), or pancreatitis while taking VIDEX EC. For example pentamidine may increase the risk of developing pancreatitis.

Other medicines may be affected by VIDEX EC, or may affect how well it works. You may need to use different amounts of your medicine, take your medicines at different times or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking VIDEX EC capsules.

How to take VIDEX EC Capsules

VIDEX EC should only be taken once daily. VIDEX EC has been prescribed for you because your doctor believes that a once daily dosing schedule of didanosine (the active ingredient in VIDEX EC) is right for you. The preferred dosing schedule of didanosine is twice daily with VIDEX tablets or VIDEX Powder for Oral Solution.

VIDEX EC should be taken only when prescribed by your doctor. Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

Your doctor will have prescribed the dose of VIDEX EC for you. The dose is related to your body weight (and surface area for children).

The recommended starting doses for VIDEX are:

Adults greater than or equal to 60 kg in body weight: 400 mg of VIDEX EC, once a day.

Adults less than 60 kg in body weight: 250 mg of VIDEX EC, once a day.

For People with Peripheral Neuropathy:

If you develop peripheral neuropathy while taking VIDEX EC (eg. tingling, burning pain or numbness in

the hands or feet), your doctor may advise you to stop taking VIDEX EC until the symptoms improve and may then place you back onto VIDEX EC at a reduced dose. It is important to tell your doctor if you do develop peripheral neuropathy and follow your doctor's instructions.

For People with Kidney or Liver Problems:

Your doctor may tell you to adjust your daily dosage of VIDEX EC if you have a kidney or liver disorder.

How to take VIDEX EC

Videx EC capsules should be swallowed whole with a drink of water.

Take your dose of VIDEX EC on an empty stomach. Food interferes with the absorption of VIDEX EC and should not be taken at the same time as VIDEX EC.

When to take VIDEX EC

Take VIDEX EC on an empty stomach.

You should take VIDEX EC at approximately the same time each day. It is taken as a single dose once a day. Taking your capsules at the same time each day will have the best effect. Creating a routine around the time you take VIDEX EC will help you to not miss any doses.

For people with kidney failure being treated with haemodialysis, take VIDEX EC after the haemodialysis session has finished. On days when you do not receive dialysis, VIDEX EC should be taken at the same time of day as it is on days when you receive dialysis.

How long to take VIDEX EC

VIDEX EC helps control your condition, but does not cure it. Therefore you must take VIDEX EC every day as directed by your doctor. Continue taking capsules for as long as your doctor tells you to. Do not

stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take VIDEX EC

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take the HIV medicines, ask your pharmacist for some hints and inform your doctor if you have missed a dose. It is very important not to miss your doses of VIDEX EC. If you miss doses the virus may become resistant to your HIV medicines.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131126 in Australia or 03 474 7000 in New Zealand), or go to the Accident and Emergency Centre at your nearest hospital, if you or anyone else takes too much VIDEX EC. Do this even if there are no signs of discomfort or poisoning.

While you are using VIDEX EC

Things you must do

If you become pregnant while taking VIDEX EC tell your doctor immediately. Pregnant women have experienced serious side-effects when taking didanosine (the active ingredient in VIDEX EC) in

combination with ZERIT(R) (stavudine).

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking VIDEX EC. VIDEX EC may interfere with the new medicine you are about to start.

If you are about to have any medical tests, tell your doctor that you are taking VIDEX EC, VIDEX EC may interfere with the results of these tests.

If you plan to have surgery, tell your doctor or dentist that you are taking VIDEX EC. You may wish to discuss disclosure issues with your doctor about who you think should know you are taking VIDEX EC.

Make sure that you visit your doctor frequently for regular check-ups and medical tests throughout your entire course of treatment with VIDEX EC. You should have your kidney and liver functions and blood tested when your doctor advises on a regular basis to ensure that the body chemistry is functioning normally and that VIDEX EC is working.

Things you must not do

Do not give VIDEX EC to anyone else, even if they have the same condition as you.

Do not use VIDEX EC to treat any other complaints unless your doctor tells you to.

Do not stop taking VIDEX EC or lower the dosage without checking with your doctor. Your doctor may gradually want to reduce the amount of VIDEX EC you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how VIDEX EC affects you. Some patients taking VIDEX EC have experienced dizziness. It is not known if this was caused by VIDEX EC. Make sure you know how you react to VIDEX EC before you drive

a car, operate machinery or do anything else that could be dangerous if you are dizzy.

If you are taking other medicines that cause pancreatitis, you should avoid drinking alcohol while taking VIDEX EC.

Things that may help

Things that may help general health are suggested below:

- * exercise
- * healthy eating
- * stress reduction
- * counselling
- * regular visits to your doctor to monitor your health
- * good oral hygiene. HIV and/or drug therapy may cause dryness of the mouth which can lead to gum disease. It is recommended that you see your dentist regularly to ensure good oral health.
- * support groups

Talk with your doctor about all of the above suggestions. You can also access further information about HIV and services for people with HIV by contacting your local AIDS Council, Positive Living Centre or People Living with HIV/AIDS (PLWH/A) organisation.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VIDEX EC capsules. VIDEX EC helps most people with HIV infection, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, stop taking VIDEX EC capsules and tell your doctor immediately, or go to the Accident and Emergency Centre at your nearest hospital:

- * swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- * hives
- * fainting
- * yellowing of the skin or eyes, also called jaundice.

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

Tell your doctor immediately, or go to the Accident and Emergency Centre at your nearest hospital if you notice any of the following:

- * inflammation of the pancreas (pancreatitis) which may cause severe upper stomach pain, often with nausea or vomiting. Pancreatitis is the major serious side effect of VIDEX EC, which can be fatal in some people and must be treated immediately.
- * peripheral neuropathy which causes tingling, burning pain or numbness in the hands and/or feet
- * gout, which causes painful swelling in the joints
- * changes in vision
- * limbs turning a bluish colour due to reduced blood circulation, associated with dizziness and confusion (lactic acidosis)
- * enlarged liver which is tender to the touch (hepatomegaly).

These are serious side effects of VIDEX EC. You may need urgent medical attention.

Tell your doctor if you notice any of the following and they worry you:

- * headache
- * weight loss
- * flatulence
- * indigestion
- * chills, fever

- * depression
- * dry mouth and/or dry eyes

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using VIDEX EC

Storage

Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the bottle they may not keep as well.

Keep VIDEX EC capsules in a cool dry place where the temperature stays well below 30 degrees C.

Do not store VIDEX EC or any other medicines in the bathroom or near a sink. Do not leave VIDEX EC in the car. Heat and dampness can destroy some medicines.

Keep VIDEX EC where children cannot reach it. A locked cupboard at least 1 1/2 metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the capsules, or if they have passed their expiry date, ask your pharmacist what to do with any that are left over.

Keep any unused medicine out of reach of children.

Product Description

What VIDEX EC looks like

VIDEX EC capsules are hard, opaque, and white with printing on both sides.

VIDEX EC 125mg '6671' on one side and 'BMS/125 mg' on the other.

VIDEX EC 200mg '6672' on one side and 'BMS/200 mg' on the other.

VIDEX EC 250mg '6673' on one side and 'BMS/250 mg' on the other.

VIDEX EC 400mg '6674' on one side and 'BMS/400 mg' on the other.

VIDEX EC capsules are supplied as single bottles, each bottle contains 30 capsules.

Ingredients list

VIDEX EC capsules contain:

Active ingredients:

didanosine

Inactive ingredients:

carboxymethylcellulose sodium

diethyl phthalate

methacrylic acid copolymer

sodium starch glycolate

sodium hydroxide

talc

Capsule shell

gelatin

sodium lauryl sulphate

titanium dioxide

edible ink

Manufacturer/Supplier

VIDEX EC capsules are manufactured by Bristol-Myers Squibb Co., USA.

Distributed in Australia by:

Bristol-Myers Squibb
Pharmaceuticals,

A Division of Bristol-Myers Squibb
Australia Pty. Ltd.

556 Princes Highway

NOBLE PARK VIC. 3174

Distributed in New Zealand by:

Bristol-Myers Squibb (NZ) Ltd

Stanway Business Park/Tower 2 -
Level 1

646 Great South Road

Ellerslie, AUCKLAND

Registration Numbers:

VIDEX EC 125mg AUST R 78351

VIDEX EC 200mg AUST R 78353

VIDEX EC 250mg AUST R 78355

VIDEX EC 400mg AUST R 78357

*VIDEX is a registered trademark of a Bristol-Myers Squibb Company.

This leaflet was produced based on information known to Bristol-Myers Squibb Australia Pty Ltd in April 2001. You need to consult your doctor regularly as your doctor has access to information on any changes which may affect you. This information in no way replaces the advice of your doctor or pharmacist.

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