

HIVID

pronounced "Hiv-id"
zalcitabine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about HIVID tablets. It does not contain all the available information.

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 HIVID tablets against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What HIVID is used for

HIVID belongs to a group of medicines called anti-HIV drugs. Within this group, HIVID belongs to a class of drugs called nucleoside analogues. HIVID is used for the treatment of HIV (Human Immunodeficiency Virus). It works by interfering with the viral reproductive cycle.

HIVID may be used alone or in combination with other medicines to treat the HIV virus such as Retrovir(R) (zidovudine, AZT) and Invirase(R) (saquinavir).

Please note that you should always report any changes in your condition to your doctor to ensure that any infections which occur due to your

low immunity (called opportunistic infections) are treated promptly.

Your doctor, however, may have prescribed HIVID for another purpose.

Ask your doctor if you have any questions why HIVID has been prescribed for you.

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

Before you take HIVID

Do not take HIVID if:

- * **you have had an allergic reaction to HIVID or any ingredients listed at the end of this leaflet**
- * **the package is torn or shows signs of tampering**
- * **the expiry date (EXP) printed on the pack has passed..**

If you take this medicine after the expiry date has passed it may not work.

If you are not sure if you should be taking HIVID, talk to your doctor.

Do not give HIVID to children less than 12 years of age.

Safety and effectiveness in younger children have not been established.

Before you start to take it

Your doctor must know about all the following before you start to take HIVID.

1. if you are pregnant or plan to become pregnant

It is not known whether HIVID is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take HIVID when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

2. if you are breastfeeding or plan to breastfeed

It is not known whether HIVID passes into breast milk. Your doctor will decide whether or not you should breastfeed.

3. if you have any other health problems including:

- * any illness affecting the nerves, even if you have since recovered
- * kidney disease
- * liver disease
- * pancreas disease
- * diabetes (increased blood sugar levels)

4. if you are allergic to any other medicines, foods, dyes or preservatives

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or healthfood shop.

Some medicines may interfere with HIVID or increase the risk of side effects. These medicines include:

- * didanosine (ddI, Videx(R))
- * phenytoin (Dilantin(R))

- * amphotericin (Fungilin(R))
- * foscarnet
- * pentamidine
- * probenecid
- * cimetidine
- * metronidazole (Flagyl(R))
- * antacids containing magnesium and aluminium.

Antacids can be taken if at least 2 hours apart from your dose of HIVID.

- * lamivudine or medicines that contain lamivudine (Combivir(R), 3TC(R), Trizivir(R), Zeffix(R)).

These medicines may be affected by HIVID or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking HIVID.

If you have not told your doctor about any of the above, tell them before you start taking HIVID.

How to take HIVID

How much to take

Take HIVID exactly as your doctor has prescribed. Your doctor will tell you how many HIVID tablets to take each day.

The recommended dose of HIVID is one 0.75 mg tablet three times daily.

If you are older, have poor kidney function or have experienced side effects, your doctor may recommend a lower dose.

How to take it

Tablets should be swallowed whole with a glass of water.

When to take it

Take your HIVID at regular eight-hour intervals at about the same time each day.

Taking your tablets at the same time each day will have the best effect on the HIV infection. It will also help you remember to take the tablets.

How long to take HIVID

HIVID helps control your HIV infection but does not cure it. Therefore HIVID must be taken every day. Continue taking HIVID for as long as your doctor prescribes.

If you forget to take HIVID

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember together with some food and then go back to taking it as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not double a dose to make up for one you have missed.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much HIVID, even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking HIVID

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking HIVID.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Continue to use safe sexual practices while taking HIVID. HIVID has not been shown to decrease the chance of giving HIV to your partner.

If you become pregnant while taking HIVID, tell your doctor.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

If you have liver disease, your doctor may want to take regular blood samples while you are taking HIVID.

Things you must not do

Do not stop taking HIVID or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Do not give HIVID to anyone else even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how HIVID affects you.

HIVID generally does not cause problems with your ability to drive a car or operate machinery. However, as with many medicines, HIVID may cause dizziness in some people. Make sure you know how you react to HIVID before you drive a car or operate machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking HIVID.

HIVID helps most people with HIV infection but it may have unwanted side effects in some 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.

Frequently it is difficult to tell whether side effects are the result of taking HIVID, effects of the HIV disease or side effects of other medicines you may be taking. For this reason it is very important to inform your doctor of any change in your condition. Your doctor may want to change your dose or advise you to stop taking HIVID.

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

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

- * numbness or burning pains in the hands or feet
- * stomach discomfort or pain
- * feeling sick
- * ulcers in the mouth or oesophagus
- * headache
- * tiredness, weakness
- * skin problems such as itching and rash.

There are some side effects that may occur with nucleoside analogues. As mentioned earlier, HIVID belongs to this class of drugs, and may cause the following side effects:

- * body fat distribution changes including loss of fat from the limbs and increased fat around the stomach; in women breast enlargement could also occur.

HIVID may be prescribed with other HIV medicines such as Retrovir(R) (AZT, zidovudine) and Invirase(R) (saquinavir). Using HIVID together with other HIV medicines may increase the risk of side effects above that of when only one medicine is taken.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking HIVID

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep HIVID in a cool dry place where the temperature stays below 30 degrees C. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep HIVID where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking HIVID, or the tablet has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What HIVID looks like

HIVID 0.375 mg tablets are beige oval-shaped tablets imprinted with 'HIVID 0.375' on one side and 'ROCHE' on the other.

HIVID 0.750 mg tablets are grey oval-shaped tablets imprinted with 'HIVID 0.750' on one side and 'ROCHE' on the other.

HIVID is packed in amber glass bottles.

Ingredients

Active ingredient - zalcitabine

- * HIVID 0.375 each tablet contains 0.375 mg of zalcitabine;
- * HIVID 0.750 each tablet contains 0.750 mg of zalcitabine.

Inactive ingredients -

- * HIVID 0.375 and HIVID 0.750 tablets contain lactose, microcrystalline cellulose (460), croscarmellose sodium, magnesium stearate (470), shellac, ammonium hydroxide, polysorbate 20, lecithin, simethicone, hypromellose, polyethylene glycol and polysorbate 80.
- * HIVID 0.375 also contains the colours iron oxides brown, black (172), red (172) and yellow (172) and titanium dioxide (171).

- * HIVID 0.750 also contains the colours black iron oxide (172) and titanium dioxide (171).

HIVID tablets are gluten free.

HIVID 0.375 and HIVID 0.750 come in packs of 100 tablets.

Manufacturer

HIVID is distributed by:

Roche Products Pty Limited

ACN 000 132 865 ABN 70 000 132
865

4 - 10 Inman Road

Dee Why NSW 2099

Customer enquiries: 1 800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers:

- * HIVID 0.375 tablets

AUST R 39300

- * HIVID 0.750 tablets

AUST R 39299

This leaflet was prepared on:

1 February 2005.