

VALNIR

for the treatment of cytomegalovirus
valaciclovir (as valaciclovir hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VALNIR.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

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

What VALNIR is used for

VALNIR is used to prevent cytomegalovirus (CMV) infection and disease following solid organ transplantation.

VALNIR contains valaciclovir (as valaciclovir hydrochloride) and belongs to a group of medicines called antivirals.

It works by stopping the production of CMV, preventing infection. VALNIR also prevents herpes simplex infections.

CMV is another type of herpes virus. It can cause symptoms similar to glandular fever.

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

Your doctor may have prescribed it for another reason.

VALNIR is not recommended for use in children as there have been no studies of its effects in children.

VALNIR tablets are available only with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take VALNIR if you are allergic to medicines containing valaciclovir, aciclovir or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath or fainting.

Do not take VALNIR if the expiry date (Exp.) printed on the pack has passed.

Do not take VALNIR if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking VALNIR during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking VALNIR when breastfeeding.

Tell your doctor if you have, or have had any medical conditions especially the following:

- anaemia
- kidney or liver condition.

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

Taking other medicines

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

Some medicines may be affected by VALNIR or may affect how well it works. These include:

- mycophenolate mofetil
- cyclosporin
- tacrolimus.

These medicines are commonly taken by transplant patients and require close attention.

Your doctor can tell you what to do if you are taking any of these medicines.

Check with your doctor or pharmacist if you are not sure whether you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking VALNIR.

How to take it

How much to take

Follow all directions given to you by your doctor.

The usual initial dose is four 500 mg tablets (2 grams) four times a day for ninety days.

Patients with kidney disease or the elderly may need a reduced dose.

How to take it

Swallow the tablets with a glass of water.

For the prevention of CMV infection, VALNIR must be taken four times a day (morning, noon, afternoon and evening).

If you forget to take it

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

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

How long to take it

Keep taking VALNIR for as long as your doctor recommends.

Usually, VALNIR is initially taken for 90 days before the dose is reduced.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much VALNIR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking VALNIR.

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

Tell your doctor if you become pregnant, are trying to become pregnant or intend to breastfeed while you are taking VALNIR.

Visit your doctor regularly so they can check on your progress.

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.

Drink plenty of fluids while you are taking VALNIR.

Things you must not do

Do not stop taking VALNIR tablets or alter the dose, without first checking with your doctor.

Do not use VALNIR to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

VALNIR does not normally affect alertness; however make sure you know how it affects you before driving, operating machinery or anything else that could be dangerous whilst taking this medicine.

Side effects

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

Like all other medicines, VALNIR may have unwanted side effects in some people. 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.

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

- headache
- gastrointestinal discomfort
- vomiting, nausea, diarrhoea, constipation, abdominal pain and indigestion
- tiredness, drowsiness or short of breath
- high blood pressure

- hallucinations
- dizziness and confusion
- muscle weakness.

If you think you are having an allergic reaction to VALNIR tablets stop taking the tablets and tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash (hives)
- fainting.

Some rare side effects of VALNIR are as follows:

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light. **Talk to your doctor or pharmacist if you experience this.**
- unusual bruising or bleeding. **Tell your doctor immediately if you notice any bruising or bleeding, as this may indicate that your blood is not clotting properly.**
- kidney problems, which get better when VALNIR treatment is stopped
- liver problems, which get better when VALNIR treatment is stopped.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ingredients

Active ingredient:

Each VALNIR tablet contains 500 mg of valaciclovir (as valaciclovir hydrochloride).

Inactive ingredients:

- microcrystalline cellulose
- crospovidone
- povidone
- purified talc
- magnesium stearate
- Opadry II 85F18738 White (ARTG 12135).

VALNIR tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharma Pty Ltd

34-36 Chandos Street
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Australia

Australian registration number:
AUST R 147607

This leaflet was revised in November 2011.

After taking it

Storage

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Keep VALNIR where children cannot reach it.

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

Keep your tablets in their pack until it is time to take them.

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

Do not store VALNIR or any other medicine in the bathroom or near a sink. Do not leave VALNIR in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

VALNIR is a capsule shaped white tablet marked with 'VA 500' on one side and plain on the other side.

Each pack contains 10, 30 or 42 tablets.