

# APO-Valaciclovir

*for genital herpes simplex*

*Contains the active ingredient valaciclovir hydrochloride monohydrate*

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## Consumer Medicine Information

**For a copy of a large print leaflet, Ph: 1800 195 055**

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### What is in this leaflet

#### **Read this leaflet carefully before taking your medicine.**

This leaflet answers some common questions about valaciclovir. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### **Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet
- if you are worried about taking your medicine
- to obtain the most up-to-date information

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

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### What this medicine is used for

The name of your medicine is APO-Valaciclovir. It contains the active ingredient valaciclovir hydrochloride monohydrate.

It is used to treat genital herpes simplex infection.

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

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

#### **How it works**

Valaciclovir belongs to a group of medicines called antivirals.

Valaciclovir works by stopping the multiplication of the virus which causes herpes. It can reduce the length and severity of an outbreak of herpes, the duration of pain and shorten the time to healing of crusts associated with herpes. They do not eliminate the herpes virus from the body. The herpes virus is also known as the Herpes Simplex Virus, or HSV.

Valaciclovir helps the blisters to heal more quickly. If you start taking them as soon as you feel an outbreak starting, you may actually prevent the blisters from developing.

In immunocompromised patients, valaciclovir can also be taken long

term to help prevent the HSV infection coming back.

Valaciclovir (or any other antiviral) is not a cure for genital herpes.

Because genital herpes is a sexually transmitted disease, you should minimise having intercourse and always use condoms when you have an outbreak of herpes or show any symptoms. This will avoid the risk of spreading herpes to your partner.

Valaciclovir is more effective in patients 50 years of age and older.

There is no evidence that this medicine is addictive.

#### **Use in children**

**There is not enough information to recommend the use of this medicine in children.**

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### Before you take this medicine

#### **When you must not take it**

- **Do not take this medicine if you have had an allergic reaction to aciclovir, valaciclovir or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint

pain or rash, itching or hives on the skin.

- **Do not take this medicine 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 take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.**

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

### ***Before you start to take it***

**Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines.
  - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
  - a kidney or liver condition
  - you are anaemic (reduced red blood cells or iron stores)
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are taking or are planning to take any other medicines; this includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with valaciclovir. These include:

- Mycophenolate mofetil, cyclosporin and tacrolimus - medicines commonly taken by transplant patients and require close attention.
- Aminoglycoside antibiotics
- Pentamidine, used to treat or prevent certain infections
- Foscarnet, used against viruses
- Methotrexate, used for conditions including rheumatoid arthritis and cancer
- Organoplatinum compounds, used in cancer
- Iodine based contrast media for scans.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with valaciclovir.

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## **How to take this medicine**

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**Follow carefully all directions given to you by your doctor or pharmacist.**

Their instructions may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

### ***How much to take***

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

- Acute (short term) treatment of genital herpes:  
Dosing should ideally start just before, or straight after the first signs of HSV infection appear. The usual dose is one 500 mg tablet with water, two times a day.

- Suppressive (long term) treatment of genital herpes in immunocompromised patients:  
The usual dose is one 500 mg tablet with water, two times a day.

### ***How to take it***

Swallow the tablets with a glass of water. You should drink plenty of fluids whilst taking valaciclovir, especially if you are elderly.

### ***When to take it***

For genital herpes infection, the usual times to take the tablets are in the morning and evening.

### ***How long to take it for***

For the treatment of genital herpes infections, the usual course of treatment is five days. However, in some instances your doctor may want you to take your tablets for ten days.

For the prevention of genital herpes infections in immunocompromised patients, you should continue to take this medicine every day as prescribed by your doctor.

Continue taking your medicine for as long as your doctor tells you.

Do not stop taking it unless your doctor tells you to - even if you feel better.

Make sure you have enough to last over weekends and holidays.

### ***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 it as soon as you remember, then go back to taking it as you would normally.

If you miss more than one dose, or you are not sure what to do, ask your doctor or pharmacist.

**Do not take a double dose to make up for missed doses.**

This may increase the chance of side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

### ***If you take too much (overdose)***

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

Signs of an overdose with valaciclovir may include:

- acute renal failure, which may present as: decreased urine; fluid retention causing swollen legs, ankles or feet; nausea; drowsiness; fatigue; difficulties breathing.
- confusion, hallucinations, agitation, decreased consciousness and coma.
- nausea and vomiting

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## **While you are taking this medicine**

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### ***Things you must do***

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking valaciclovir.
- Tell your doctor immediately if you become pregnant or are trying to become pregnant, or intend to breastfeed while you are taking valaciclovir.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
- Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

- 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.

### ***Things you must not do***

**Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

### ***Things to be careful of***

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

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## **Possible side effects**

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Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

- headache
- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion)
- dizziness
- infections or flu like symptoms
- back or joint pain
- skin rash, which may be itchy
- weakness

Below is a list of other possible side effects. These may be serious side effects and you may need medical attention.

- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light
- damage to the kidney, which gets better when valaciclovir treatment is stopped.
- unusual bruising or bleeding. Tell your doctor immediately if you notice any bruising or bleeding, as it may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood are reduced.
- damage to the liver, which gets better when valaciclovir treatment is stopped.

You should contact your doctor if you experience any of the following side effects, which are more common in patients with kidney disease or in those taking high doses of valaciclovir:

- dizziness
- confusion or imagining sights or sounds (hallucinations)
- drowsiness
- decreased consciousness.

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

### ***Allergic reactions***

**If you think you are having an allergic reaction to valaciclovir, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting

- hay fever-like symptoms.

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## Storage and disposal

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### Storage

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 25°C.**

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep this medicine 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.

### Disposal

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### **What APO-Valaciclovir looks like**

#### **500 mg tablets**

The 500 mg tablets are dark blue, capsule-shaped, biconvex film-coated tablets, engraved "APO" on one side, "VAL 500" on the other side.

Blisters of 2, 4, 6, 8, 10, 20, 30, 42, 60, 80, 90, 100 tablets and bottles of 100 tablets.

#### **1000mg tablets**

White, oval shaped, biconvex film-coated tablet, partially scored and

engraved "APO" on one side, "VAL 1000" on the other side.

Blisters of 3, 4, 21 tablets and bottles of 4 and 100

Not all strengths, pack types and/or pack sizes may be available.

### **Ingredients**

Each tablet contains valaciclovir as the active ingredient.

It also contains the following inactive ingredients:

- Stearic Acid
- Colloidal Anhydrous Silica
- Hypromellose
- Macrogol 8000
- Titanium Dioxide
- Indigo Carmine Aluminium Lake

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

### **Australian Registration Numbers**

APO-Valaciclovir 500 mg tablets (blister pack): AUST R 158911

APO-Valaciclovir 500 mg tablets (bottle): AUST R 158910

APO-Valaciclovir 1000 mg tablets (blister pack): AUST R 158906

APO-Valaciclovir 1000 mg tablets (bottle): AUST R 158907

### **Sponsor**

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

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This leaflet was prepared in September 2014.