VACLOVIR®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking VACLOVIR?

VACLOVIR contains the active ingredient valaciclovir hydrochloride. VACLOVIR tablets belong to a group of medicines called antivirals. They are used for the treatment of genital herpes, shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis).

For more information, see Section 1. Why am I taking VACLOVIR? in the full CMI.

2. What should I know before I take VACLOVIR?

Do not take if you have ever had an allergic reaction to valaciclovir or aciclovir or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before I take VACLOVIR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VACLOVIR and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take VACLOVIR?

Your doctor or pharmacist will tell you

- how many tablets to take at each dose
- how many doses to take each day
- when to take your doses each day.

More instructions can be found in Section 4. How do I take VACLOVIR? in the full CMI.

5. What should I know while taking VACLOVIR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking VACLOVIR. • Drink plenty of fluid while you are taking VACLOVIR.
Things you should not do	• Do not stop taking VACLOVIR suddenly or alter the dose, without first checking with your doctor. • Do not use VACLOVIR to treat any other complaints unless your doctor says to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how VACLOVIR affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep VACLOVIR tablets in a cool, dry place where it stays below 25°C. • Keep your tablets in their pack until it is time to take them. If you take the tablets out of their pack, they may not keep well.

For more information, see Section 5. What should I know while taking VACLOVIR? in the full CMI.

6. Are there any side effects?

Less serious side effects: headache, gastrointestinal discomfort, dry mouth, fever, difficulty sleeping, chills or back pain. **Serious side effects**: sensitivity to UV light, dizziness, confusion, hallucinations, difficulty in thinking, drowsiness or decreased consciousness or high blood pressure. **Very serious side effects**: unusual bruising or bleeding, agitation or tremor, uncoordinated eye and muscle movements and speech or difficulty speaking, psychotic episodes, convulsions or seizures or coma or brain injury. **Please note this is not a complete list of all side effects**.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

VACLOVIR®

Active ingredient: *valaciclovir hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking VACLOVIR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking VACLOVIR.**

Where to find information in this leaflet:

1. Why am I taking VACLOVIR?
2. What should I know before I take VACLOVIR?
3. What if I am taking other medicines?
4. How do I take VACLOVIR?
5. What should I know while taking VACLOVIR?
6. Are there any side effects?
7. Product details

1. Why am I taking VACLOVIR?

VACLOVIR contains the active ingredient valaciclovir hydrochloride. VACLOVIR belongs to a group of medicines called antivirals.

VACLOVIR is used for the treatment of genital herpes, shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region) and cold sores (herpes labialis). It also used to prevent cytomegalovirus (CMV) infection and disease following solid organ transplantation. CMV is another type of herpes virus that can cause symptoms similar to glandular fever (high temperature, sore throat and swollen glands).

VACLOVIR works by stopping the multiplication of the virus which causes herpes, shingles and cold sores. It can reduce the length and severity of an outbreak and duration of pain, and shorten the healing time of crusts, associated with herpes, shingles and cold sores. VACLOVIR does not eliminate the herpes virus (Herpes Simplex Virus or HSV) from the body.

For treatment of shingles

It is important the treatment for shingles is started within the first three days of the shingles attack.

For treatment of cold sores

For the treatment of cold sores, the tablets should be taken at the earliest symptom of a cold sore (e.g. tingling, itching, or burning).

For treatment of herpes simplex (genital herpes)

For the treatment of herpes simplex, start taking the tablets as soon as you feel an outbreak starting, as you may prevent the blisters from developing, or help the blisters to heal more quickly.

VACLOVIR can also be taken long term to help prevent or reduce recurrent outbreaks of HSV and reduce the risk of transmitting the virus that causes genital herpes but does not cure or completely eliminate the risk of transmission. Therefore, in addition to therapy with VACLOVIR, it is recommended that patients avoid contact when symptoms are present and always use condoms.

VACLOVIR (or any other antiviral) is not a cure for genital herpes. Because genital herpes is a sexually transmitted disease, you should minimise having intercourse when you have an outbreak of herpes or show any symptoms. This will avoid the risk of spreading herpes to your partner.

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

Ask your doctor if you have any questions about why VACLOVIR tablets have been prescribed for you. Your doctor may have prescribed it for another reason.

VACLOVIR is not addictive.

2. What should I know before I take VACLOVIR?

Warnings

Do not take VACLOVIR if:

- you are allergic to valaciclovir or aciclovir, or any of the ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin.

  Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have any other medical conditions
- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition
- are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should
- have or have had any of the following medical conditions:
  - kidney or liver conditions
  - are anaemic (reduced red blood cells or iron stores)
    Care should be taken to ensure adequate fluid intake in patients who are at risk of dehydration, such as the elderly.
  - previous skin reactions with VACLOVIR which may include a rash, fever, facial swelling or blistering/peeling skin.

If you have not told your doctor about any of the above, please do so before you take VACLOVIR.

Immunocompromised patients with ophthalmic zoster or those with a high risk for disease dissemination and visceral organ involvement should be treated with intravenous antiviral therapy.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take VACLOVIR if you are pregnant or are trying to become pregnant.

It may affect your developing baby if you take it during pregnancy. Check with your doctor if you are pregnant or intend to become pregnant.

Do not breast-feed if you are taking this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of taking VACLOVIR when pregnant or whilst breastfeeding.

Use in children

Do not give VACLOVIR to children.

There is not enough information to recommend the use of VACLOVIR in children.

3. What if I am taking other medicines?

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

Tell your doctor if you are taking any of the following medicines:

- mycophenolate mofetil, ciclosporin, tacrolimus
- aminoglycosides
- organoplatinum compounds
- iodinated contrast media
- methotrexate
- pentamidine
- foscarnet
- tenofovir
- cimetidine
- probenecid.

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

Mycophenolate mofetil, ciclosporin and tacrolimus are medicines commonly taken by transplant patients and require close attention.

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

Do not take VACLOVIR after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well. who are at risk of dehydration, such as the elderly.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VACLOVIR.

4. How do I take VACLOVIR?

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 or pharmacist will tell you:

- how many tablets to take at each dose
- how many doses to take each day
- when to take your doses each day.

If you do not understand the directions, ask your doctor or pharmacist for help.

For prevention of CMV infection and disease

- The usual dose for adults and children over 12 years of age is four 500 mg tablets four times a day for 90 days.
- If you have a kidney disease your doctor may reduce your dose.

For treatment of shingles

- 500 mg tablets: The normal dose to take is two tablets with water three times a day.

For treatment of cold sores

- 500 mg tablets: The normal dose to take for the one-day regimen is four tablets with water twice a day, with the second dose taken about 12 hours (and no fewer than 6 hours) after the first dose.

For treatment of acute (short term) genital herpes:

- If you have had a herpes infection before, you should start to take VACLOVIR tablets as early as possible if you think you are about to have another recurrence (attack). Dosing should ideally start just before, or straight after the first signs of HSV infection appear.
- 500 mg tablets: For the treatment of HSV infection, the usual dose to take is one tablet with water twice daily.

For suppressive (long term) treatment of genital herpes:

- 500mg tablets: To prevent the herpes infection appearing again, the usual dose to take is 500 mg

once daily. Your doctor may recommend that you take this as a divided dose (i.e. 250 mg twice daily).
- If you previously have had more than 10 recurrences (attacks) in one year, your doctor may recommend that you take 1000 mg of VACLOVIR once daily to prevent recurrences.

If you think you have been advised to take a different dose, talk to your doctor or pharmacist.

When to take VACLOVIR

It does not matter if you take this medicine before or after food.

For the prevention of CMV infection and disease

- The tablets should be taken four times a day (i.e. morning, noon, afternoon and evening).

For the treatment of shingles

- The usual times to take the tablets are in the morning, afternoon and evening.

For the treatment of cold sores

- The tablets should be taken at the earliest symptom of a cold sore (e.g. tingling, itching, or burning).
- Treatment for cold sores should not exceed 1 day (2 doses) and the doses should be taken 12 hours apart.
- The shingles and cold sore packs are designed to help you to remember to take the tablets at the correct times.

For the treatment of herpes simplex infections (genital herpes)

- The usual times to take the tablets are in the morning and evening.

How to take VACLOVIR

- Swallow the tablets with a glass of water.

  You should drink plenty of fluids while taking VACLOVIR tablets, especially if you are elderly.

How long to take VACLOVIR

For the prevention of CMV infection and disease

- The usual course of treatment is 90 days.

For the treatment of shingles

- The usual course of treatment is 7 days
- Do not stop taking VACLOVIR tablets before the course of treatment is finished just because you feel better. The shingles may not be completely over.

For the treatment of cold sores

- The course of treatment should not exceed 1 day (2 doses), and the doses should be taken 12 hours apart.

For the treatment of herpes simplex (genital herpes)

- For the treatment of herpes infections, the usual course of treatment is 5 days. However, in some instances your doctor may want you to take your tablets for 10 days.

For the prevention of herpes infections

- You should continue to take this medicine every day as prescribed by your doctor.
- Do not stop taking VACLOVIR tablets just because you feel better. The herpes outbreak may not be completely over.

If you forget to take VACLOVIR

VACLOVIR should be taken regularly at the same time each day.

For prevention of CMV infection and disease, the treatment of shingles or the treatment of herpes simplex (genital herpes)

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

For the treatment of cold sores

- Take the second dose as soon as possible once 12 hours have passed.
- Do not take a double dose to make up for the dose you missed.
- If you miss more than one dose, or you are not sure what to do ask your doctor or pharmacist.

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

If you take too much VACLOVIR

If you think that you or anyone else has taken too much VACLOVIR, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking VACLOVIR?

Things you should do

- Drink plenty of fluids while you are taking VACLOVIR.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VACLOVIR.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

- Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking VACLOVIR.
- 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.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
- Keep all your doctor's appointments so that your progress can be checked.

  Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- It is recommended that patients using VACLOVIR continuously to prevent or reduce recurrent outbreaks, or to reduce the risk of transmitting the virus that causes genital herpes, also avoid contact when symptoms are present and always use condoms.

  VACLOVIR does not cure genital herpes or completely eliminate the risk of transmission. Because genital herpes is a sexually transmitted disease, you should minimise having intercourse when you have an outbreak of herpes or show any symptoms. This will avoid the risk of spreading herpes to your partner.

Things you should not do

- Do not stop taking VACLOVIR suddenly or alter the dose, without first checking with your doctor.
- Do not give VACLOVIR to anyone else, even if their symptoms seem similar to yours.
- Do not use VACLOVIR to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VACLOVIR affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 25°C.
- Keep your tablets in their pack until it is time to take them. If you take the tablets out of their pack, they may not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Check with your doctor as soon as possible if you have any problems while taking this medicine, even if you do not think the problems relate to the medicine or are not listed in this leaflet.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache • gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion) • dry mouth • fever • difficulty sleeping • chills • back pain • nervousness • skin rash which may be itchy • weakness	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Some of these side effects are more common in patients with kidney disease or in those taking high doses of VACLOVIR: • sensitivity to UV light, which may include development of a rash-like sunburn even after short period of exposure to UV or sunlight • dizziness, confusion, imagining sights or sounds (hallucinations), difficulty in thinking	**Call your doctor straight away if you notice any of these serious side effects.**

Serious side effects	What to do
• drowsiness or decreased consciousness • tiredness, dizziness, or being short of breath when exercising (signs of anaemia) • high blood pressure • thrombotic thrombocytopenic purpura • haemolytic uraemic syndrome • neurological disorders	

Very serious side effects

Very serious side effects	What to do
• damage to the kidney, which gets better when VACLOVIR 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 • skin reactions which may include a rash, fever, facial swelling or blistering or peeling skin • renal pain, acute renal failure and tubulointerstitial nephritis (elderly population) • damage to the liver, which gets better when VACLOVIR treatment is stopped. • agitation or tremor • uncoordinated eye and muscle movements and speech or difficulty speaking • psychotic episodes • convulsions or seizures or coma • brain injury • symptoms of an allergic reaction including 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 • Severe skin reactions, including drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP), toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS) and erythema multiforme (EM). Symptoms may include widespread rash, blistering or peeling skin, mouth sores, fever, swollen glands or swelling of the face. • Some other side effects may occur in some people, for example changes in kidney or liver function, can only be found when your doctor does tests from time to time to check your progress.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some other side effects may occur in some people, for example changes in kidney or liver function, can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What VACLOVIR contains

Active ingredient (main ingredient)	valaciclovir
Other ingredients (inactive ingredients)	• microcrystalline cellulose • magnesium stearate • Opadry complete film coating system White OY-58900 (ID: 3446)

Do not take this medicine if you are allergic to any of these ingredients.

What VACLOVIR looks like

VACLOVIR tablets are white coloured, oval shaped, biconvex film coated tablet with break line on one side and plain on the other side.

Available in:

- Blister packs of 10, 30 and 42 tablets (AUST R 153822).
- Bottles of 30 tablets (AUST R 153823).

Who distributes VACLOVIR

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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VACLOVIR® is a Viatris company trade mark

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