

## SHILOVA 500 & 1000 Tablets

for herpes simplex, herpes zoster and herpes labialis  
*valaciclovir*

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about SHILOVA tablets. 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 risks and benefits. Your doctor has weighed the risks of you taking SHILOVA tablets against the benefits this medicine is expected to 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 SHILOVA tablets are used for

##### *How SHILOVA tablets work*

SHILOVA tablets belong to a group of medicines called antivirals. SHILOVA tablets are used for the treatment of genital herpes infection, shingles (infection zoster), ophthalmic zoster (shingles affecting the eye region), cold sores (herpes labialis) and for the prevention of Cytomegalovirus (CMV) infection in people following an organ transplant.

SHILOVA tablets work by stopping the multiplication of the virus which causes herpes, shingles and cold sores. They can reduce the length and severity of an outbreak of herpes, shingles and cold sores and the duration of pain and shorten the time to healing of crusts associated with herpes.

##### **Genital herpes**

SHILOVA tablets do not eliminate the herpes virus from the body. The herpes virus is also known as the Herpes Simplex Virus, or HSV.

SHILOVA tablets help 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.

SHILOVA tablets can also be taken long term to help prevent the HSV infection coming back.

SHILOVA tablets can also reduce the risk of transmitting the virus that causes genital herpes in patients who are taking it continuously to prevent or reduce recurrent outbreaks. It does not cure genital herpes or completely eliminate the risk of transmission. Therefore, in addition to therapy with SHILOVA, it is recommended that patients avoid contact when symptoms are present and always use condoms.

SHILOVA (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.

##### **Shingles**

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

##### **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).

##### **Cytomegalovirus (CMV)**

SHILOVA is used to prevent the cytomegalovirus (CMV) infection in people following an organ transplant.

CMV is a common viral infection caused by human herpes virus. It can be spread by contact with infectious blood or body secretions (e.g. saliva, urine, cervical mucus, or semen). CMV may cause symptoms similar to glandular fever (fatigue, fever, sore throat and swollen glands).

SHILOVA tablets are more effective in patients 50 years of age and older.

Ask your doctor if you have any questions about why SHILOVA tablets have been prescribed for you.

SHILOVA tablets are not addictive.

#### Before you take SHILOVA tablets

##### *When you must not take them*

- **Do not take SHILOVA tablets if you have ever had an allergic reaction to valaciclovir, aciclovir or any of the ingredients listed at the end of this leaflet.**  
**Refer to "Side Effects" section for some common symptoms of an allergic reaction.**
- **Do not take SHILOVA tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**  
Your doctor will discuss the risks and benefits of using SHILOVA tablets when pregnant and during breastfeeding.
- **Do not take SHILOVA tablets 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.
- **Do not take SHILOVA tablets if the packaging is torn or shows signs of tampering.**  
**If you are not sure whether you should be taking SHILOVA, talk to your doctor.**

##### *Before you start to take them*

**You must tell your doctor if:**

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you have a kidney or liver condition.**

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

##### *Taking other medicines*

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

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking SHILOVA tablets with other medicines.

##### *Use in children*

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

#### How to take SHILOVA tablets

Take SHILOVA tablets exactly as your doctor has prescribed. 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.

The label on the pack will give the same information. If there is something you do not understand, ask your doctor or pharmacist.

##### *How much to take for the treatment of genital herpes*

Your doctor will decide what dose you should take, how often you should take it and what strength SHILOVA tablets you should use. The dosage may vary depending on your medical history.

##### **Acute (short term) treatment of genital herpes:**

If you have had a herpes infection before, you should start to take SHILOVA 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.

If you have been prescribed SHILOVA 500 mg tablets for, the treatment of HSV infection, the usual dose to take is one tablet with water twice daily.

##### **Suppressive (long term) treatment of genital herpes:**

If you have been prescribed SHILOVA 500 mg 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. 250mg twice daily).

If you previously have had more than 10 recurrences (attacks) in one year, your doctor may recommend that you take 1000mg of SHILOVA once daily to prevent recurrences.

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

##### *How much to take for the treatment of shingles*

If you have been prescribed SHILOVA 500 mg tablets, the normal dose to take is two tablets with water three times a day.

If you have been prescribed SHILOVA 1000 mg tablets, the normal dose to take is one tablet with water three times a day.

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

##### *How much to take for the treatment of cold sores*

If you have been prescribed SHILOVA 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 after the first dose.

If you have been prescribed SHILOVA 1000 mg tablets, the normal dose to take for one day regimen is two tablets with water twice a day, with the second dose taken about 12 hours after the first dose.

## How much to take for the treatment of CMV

The usual dose for adults and children over 12 years of age is 2000 mg (two 1000 mg tablets or four 500 mg tablets) taken four times a day.

If you have a kidney disease your doctor may reduce your dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

### How to take them

Swallow the tablets with a glass of water.

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

### When to take them

#### Genital herpes

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

#### Shingles

The shingles packs are designed to help you to remember to take the tablets at the correct times.

**For the treatment of shingles the usual times to take the tablets are in the morning, afternoon and evening.**

#### Cold sores

The cold sore packs are designed to help you to remember to take the tablets at the correct times.

**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.**

#### CMV

**Unless your doctor tells you otherwise, take SHILOVA four times a day (i.e. morning, noon, afternoon and evening).**

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### How long to take them

#### Genital herpes

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

**Do not stop taking SHILOVA tablets just because you feel better. The herpes outbreak may not be completely over.**

#### Shingles

For shingles the usual course of treatment is seven days

**Do not stop taking SHILOVA tablets before the course of treatment is finished just because you feel better. The shingles may not be completely over.**

#### Cold sores

For cold sores the course of treatment should not exceed 1 day (2 doses) and the doses should be taken 12 hours apart.

#### CMV

Continue taking this medicine four times daily for the full course of the treatment.

The usual course of treatment is 90 days.

**Do not stop taking your medicine before the course of treatment is finished unless advised by your doctor.**

### If you forget to take them

For treatment of genital herpes, shingles and CMV, 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.

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 that you missed.**

### If you take too much (overdose)

**Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much SHILOVA tablets, 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 SHILOVA tablets

---

### Things you must do

**Tell your doctor or pharmacist that you are taking SHILOVA tablets if you are about to be started on any new medicines.**

**Tell your doctor if you become pregnant or are trying to become pregnant or intend to breastfeed while you are taking SHILOVA tablets.**

**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.

**Be careful driving or operating machinery until you know how SHILOVA tablets affect you.**

### Things you must not do

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

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not use SHILOVA tablets to treat any other complaints unless your doctor says to.**

---

## Side Effects

---

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

Like all medicines, SHILOVA tablets can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side effects are:

- headache

- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion)
- sensitivity to UV light, such as the development of a rash or sunburn, even after short exposure

For patients taking SHILOVA for the prevention of CMV infection and disease, you should report the above side effects to the doctor or pharmacist if they are severe or become troublesome.

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

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

- dry mouth
- fever
- difficulty sleeping
- chills
- back pain
- nervousness
- skin rash which may be itchy
- weakness

**Some people are allergic to medicines.**

**Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.**

**If you think you are having an allergic reaction to SHILOVA tablets, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital.**

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.

**Some rare side effects of SHILOVA tablets include:**

- 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 SHILOVA 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 SHILOVA 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 SHILOVA:

- Dizziness
- Confusion or imagining sights or sounds (hallucinations)
- Drowsiness.

**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 SHILOVA tablets

---

### *Storage*

**Keep this medicine 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.

**Keep SHILOVA tablets in a cool, dry place where it stays below 25°C. Do not store them, or any other medicine, in a bathroom or near a sink.**

**Do not leave them in the car or on window sills.**

Heat and dampness can destroy some medicines

**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.

### *Disposal*

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

---

## Product Description

---

### *What SHILOVA tablets look like*

SHILOVA 500 is presented in pack size of 10,30 &90 tablets in blister and 30, 100 & 500 in bottle.

SHILOVA 1000 is presented in pack size of 10 & 30 tablets in blister and 30, 100 & 500 in bottle.

#### **SHILOVA 500**

Blue, film-coated, capsule shaped tablets with a partial scorebar on both sides containing 'F' on one side and '9' and '3' on the other side.

#### **SHILOVA 1000**

Blue, film-coated, capsule shaped tablets with a partial scorebar on both sides containing 'F' on one side and '8' and '3' on the other side..

### *Ingredients*

#### **Active Ingredient:**

Valaciclovir (as hydrochloride)

Each tablet contains either 500 mg or 1000 mg of valaciclovir as hydrochloride.

#### **Other Ingredients:**

- microcrystalline cellulose
- crospovidone
- povidone
- magnesium stearate
- opadry blue 13B50578 (PI-ARTG No. 106487).

Please read this leaflet carefully before you start taking SHILOVA. You may wish to keep it to read again.

#### **Name and Address of the Sponsor**

Aurobindo Pharma Australia Pty Ltd  
Unit 3 North Rydelink  
277-283 Lane Cove Road  
Macquarie Park NSW 2113  
Australia

#### **Date of Approval**

18 October 2011