PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

SHILOVA 500 mg TABLETS (tablets)

SHILOVA 1 g TABLETS (tablets)

Valaciclovir hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking SHILOVA TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SHILOVA TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SHILOVA TABLETS is and what it is used for

SHILOVA TABLETS is used:

- For the treatment of herpes zoster (shingles).
- To reduce the duration of pain associated with shingles.
- For the episodic treatment of recurrent genital herpes in patients with normal immune systems.
- For the prevention of recurrent herpes simplex infection of the skin and mucous membrane of the ano-genital area.

2. What you need to know before you take SHILOVA TABLETS

Do not take SHILOVA TABLETS:

- If you are allergic to valaciclovir, aciclovir, or any of the other ingredients of **SHILOVA TABLETS** (listed in section 6).
- If you are pregnant or breastfeeding.

Warnings and precautions

Special care should be taken with SHILOVA TABLETS:

- If you have impaired kidney function.
- If you have advanced HIV disease.
- If you had a bone marrow or kidney transplant.
- Caution should be exercised when administering **SHILOVA TABLETS** to elderly patients. Dose reduction is recommended for elderly patients with kidney problems.
- If you are taking other medication that has an effect on the kidneys.

Use in genital herpes:

It is recommended that patients using **SHILOVA TABLETS** 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.

SHILOVA TABLETS do 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.

Children and adolescents

There is no data for use of **SHILOVA TABLETS** in children.

SHILOVA TABLETS with food, drink and alcohol

SHILOVA TABLETS can be taken with or without food.

Pregnancy, breastfeeding and fertility

Safety of **SHILOVA TABLETS** in pregnant and lactating women has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **SHILOVA TABLETS**.

Driving and using machinery:

SHILOVA TABLETS may cause dizziness and problems with your vision. If affected, do not drive or operate machinery.

It is not always possible to predict to what extent **SHILOVA TABLETS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **SHILOVA TABLETS** affects them.

Other medicines and SHILOVA TABLETS:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Cimetidine and probenecid may prolong the effects of **SHILOVA TABLETS** by reducing its elimination through urine.
- Care is required (with monitoring for changes in kidney function) if administering high doses of **SHILOVA TABLETS** with medicines which affect other aspects of kidney function, for example the medicine ciclosporin and tacrolimus.

3. How to take SHILOVA TABLETS

Do not share medicines prescribed for you with any other person. Always take **SHILOVA TABLETS** exactly as your doctor has instructed you. Your doctor will tell you how long your treatment with **SHILOVA TABLETS** will last. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **SHILOVA TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

SHILOVA TABLETS may be given with or without food.

Dosage in adults varies depending on the treatment you require as instructed by your doctor.

Dosage must be altered depending on the kidney function.

Dose modification is not required in patients with mild to moderate liver abnormalities.

No data is available for dosage in children.

If you take more SHILOVA TABLETS than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SHILOVA TABLETS:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SHILOVA TABLETS can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SHILOVA TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **SHILOVA TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in,
- swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SHILOVA TABLETS**. You may need urgent medical attention or hospitalisation.

Kidney failure and nervous system problems are infrequent but can be serious in some patients taking SHILOVA TABLETS.

Nervous system problems include aggressive behaviour, unsteady movement, shaky movements, confusion, speech problems, hallucinations (seeing or hearing things that are really not there), seizures, and coma.

Always tell your healthcare provider if you have kidney problems before taking SHILOVA TABLETS. Call your doctor right away if you get a nervous system problem while you are taking SHILOVA TABLETS.

Frequent side effects of **SHILOVA TABLETS** in adults include headache, nausea, stomach pain, vomiting, and dizziness.

Other less frequent side effects in adults include painful periods in women, joint pain, depression, low blood cell counts, and changes in tests that measure how well the liver and kidneys work.

The most common side effect seen in children < 18 years of age was headache.

Frequency Unknown

A serious skin reaction may occur known as (DRESS) Drug reaction with eosinophilia and systemic symptoms which may cause a serious skin reaction that may affect one or more organs).You may experience the following fever, severe rash, peeling skin, swelling of the face, swollen lymph glands, flu-like feeling, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feel thirsty, urinating less often, less urine.

Talk to your healthcare provider if you develop any side effects that concern you.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **SHILOVA TABLETS.**

5. How to store SHILOVA TABLETS

Store at or below 25 °C.

Keep HDPE containers tightly closed.

Keep the blisters in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine.

6. Contents of the pack and other information

What SHILOVA TABLETS contains:

The active ingredient is valaciclovir hydrochloride.

SHILOVA 500 mg TABLETS: Each film-coated tablet contains 500 mg valaciclovir.

SHILOVA 1 g TABLETS: Each film-coated tablet contains 1 g valaciclovir.

The other ingredients of **SHILOVA TABLETS** are cellulose microcrystalline, crospovidone, magnesium stearate and povidone.

SHILOVA TABLETS: The ingredients of opadry blue 13B50578 film coating agent are: FD&C Blue #2/ indigo carmine aluminium lake (C.I. No.: 73015), hypromellose, macrogol, polysorbate 80 and titanium dioxide (C.I. No.: 77891).

What SHILOVA TABLETS looks like and contents of the pack

SHILOVA 500 mg TABLETS:

Blister Pack:

Tablets are packed in clear 250 µm PVC film coated with 90 g/m^2 PVdc and printed 25 µm aluminium foil with 7g/m^2 heat seal lacquer.

Pack sizes:

10s - Each blister contains 5 tablets. Each carton contains 2 blisters of 5 tablets each.

30s - Each blister contains 5 tablets. Each carton contains 6 blisters of 5 tablets each.

42s – Each blister contains 7 tablets. Each carton contains 6 blisters of 7 tablets each.

HDPE Container Pack:

Tablets are packed in 60 ml white opaque colour HDPE container of 38 mm neck finish with 38 mm – 400 RS closure with induction sealing wad.

Each container contains 42 tablets.

Pack size: 42s - One HDPE container contains 42 tablets.

SHILOVA 1 g TABLETS:

Blister Pack:

Tablets are packed in clear 250 micron PVC film coated with 90 g/m^2 PVdC and printed 25 micron aluminium foil with 7 g/m^2 heat seal lacquer. Each blister contains 7 tablets.

Pack size: 21s – Each carton contains 3 blisters of 7 tablets each.

HDPE Container Pack:

Tablets are packed in 60 ml white opaque colour HDPE container of 38 mm neck finish with 38 mm – 400 RS closure with induction sealing wad. Each container contains 21 tablets.

Pack size: 21s - One HDPE container contains 21 tablets.

What SHILOVA TABLETS looks like

SHILOVA 500 mg TABLETS:

Blue, film coated, capsule shaped tablets with a partial score bar on both sides containing “F” on one side and “9” and “3” on the other side.

SHILOVA 1 g TABLETS:

Blue, film coated, capsule shaped tablets with a partial score bar on both sides containing “F” on one side and “8” and “3” on the other side.

Registration Number

SHILOVA 500 mg TABLETS: 45/20.2.8/0590

SHILOVA 1 g TABLETS: 45/20.2.8/0591

Holder of Certificate of Registration

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