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APPROVED
keshmika , 2025/07/01, 14:05:20

SHILOVA P1539815

SHILOVA P1539815

PROFESSIONAL INFORMATION

SCHEDULING STATUS:
SOUTH AFRICA: S4
NAMIBIA: NS2

AUROGEN

1 NAME OF THE MEDICINE

SHILOVA 500 mg TABLETS (tablets)
SHILOVA 1 g TABLETS (tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

For full list of excipients, see section 6.1.

Sugar free.

3 PHARMACEUTICAL FORM

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.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

SHILOVA TABLETS is indicated for the treatment of herpes zoster (shingles). **SHILOVA TABLETS** reduces the duration of zoster-associated pain, which includes acute and postherpetic neuralgia, thus accelerating resolution of pain. **SHILOVA TABLETS** also reduces the proportion of patients with zoster-associated pain.

SHILOVA TABLETS is indicated for the episodic treatment of recurrent genital herpes in immunocompetent adult patients.

SHILOVA TABLETS is indicated for the prevention (suppression) of recurrent herpes simplex infection of the skin and mucous membrane of the ano-genital area.

SHILOVA TABLETS is indicated for the prophylaxis of cytomegalovirus (CMV) infection, CMV disease and other herpes virus infections following organ transplantation, where special risk exists.

4.2 Posology and method of administration

Posology
Dosage in adults:
For the treatment of Herpes Zoster:
1000 mg of **SHILOVA TABLETS** to be taken three times per day for seven days.

Recurrent genital herpes:
The recommended dosage for the treatment of recurrent genital herpes is 500 mg twice daily for 5 days. Dosing should begin as early as possible. For recurrent episodes of herpes simplex, this should ideally be during the prodromal period or immediately the first signs or symptoms appear. There are no data on the effectiveness of **SHILOVA TABLETS** when initiated more than 24 hours after the onset of signs and symptoms.

For the prevention (suppression) of recurrences of herpes simplex infection:
Immunocompetent patients: 500 mg to be taken once daily. Some patients with very frequent recurrences (e.g. 10 or more per year) may gain additional benefit from the daily dose of 500 mg being taken as a divided dose (250 mg twice daily).

Immunocompromised patients:
500 mg twice daily.

Prophylaxis of cytomegalovirus infection (CMV) and disease:
Adults and adolescents (from 12 years of age): 2000 mg to be taken four times a day. Dosing should be initiated as early as possible post-transplant. This dose should be reduced according to creatinine clearance (See **Dosage in Renal Impairment**). The duration of treatment will usually be 90 days but may need to be extended in high-risk patients.

Paediatric population
No data is available.

Special populations
Dosage in the elderly:
Dosage modification is not required unless renal function is impaired (see **Dosage in Renal Impairment**). Adequate hydration should be maintained.

Dosage in Renal Impairment:
The dose of **SHILOVA TABLETS** should be modified as follows in patients with significantly impaired renal function:

HERPES ZOSTER

Creatinine Clearance	Dose
15 - 30 mL/min	1000 mg twice a day
< 15 mL/min	1000 mg once a day

RECURRENT GENITAL HERPES

Creatinine Clearance	Dose
> 15 mL/min	500 mg twice daily
0 - 15 mL/min	500 mg once daily

PREVENTION OF RECURRENCE

Creatinine Clearance	Dose	
	Immunocompetent	Immunocompromised
15 - 30 mL/min	No dosage adjustment required	No dosage adjustment required
< 15 mL/min	250 mg once daily	500 mg once daily

In patients on haemodialysis, the **SHILOVA TABLETS** dose recommended for patients with a creatinine clearance of less than 15 mL/min should be used, but the dose should be administered after the haemodialysis has been performed.

CMV PROPHYLAXIS: The dosage of **SHILOVA TABLETS** should be adjusted in patients with impaired renal function as shown in the table below:

Creatinine Clearance	Dose
≥ 75 mL/min	2000 mg four times daily
50 to < 75 mL/min	1500 mg four times daily
25 to < 50 mL/min	1500 mg three times daily
10 to < 25 mL/min	1500 mg twice daily
< 10 mL/min or dialysis**	1500 mg once daily

** In patients on haemodialysis, the **SHILOVA TABLETS** dosage should be administered after the haemodialysis has been performed.
The creatinine clearance should be monitored frequently, especially during periods when renal function is changing rapidly e.g. immediately after transplantation or engraftment. The **SHILOVA TABLETS** dosage should be adjusted accordingly.

Dosage in hepatic impairment:
Dose modification is not required in patients with mild or moderate cirrhosis (hepatic synthetic function maintained). Pharmacokinetic data in patients with advanced cirrhosis (impaired hepatic synthetic function and evidence of portal-systemic shutting) do not indicate the need for dosage adjustment; however, clinical experience is limited. For higher doses recommended for CMV prophylaxis, see section 4.8.

Method of administration
To be taken orally.

4.3 Contraindications

SHILOVA TABLETS is contraindicated in patients known to be hypersensitive to valaciclovir, aciclovir or any component of their formulations.
Safety in pregnancy and lactation has not been established. (See section 4.6).

4.4 Special warnings and precautions for use

Thrombotic, Thrombocytopenic Purpura/Haemolytic Uraemic Syndrome (TTP/HUS):
TTP/HUS in some cases resulted in death, has been reported in patients with advanced Human Immunodeficiency Viruses (HIV) disease and also in bone marrow transplant and renal transplant recipients.

Cases of acute renal failure have been reported in:

- Elderly patients with or without reduced renal function. Caution should be exercised when administering **SHILOVA TABLETS** to elderly patients and dosage reduction is recommended for those with impaired renal function.
- Patients with underlying renal disease who received higher than recommended doses of **SHILOVA TABLETS** for their level of renal function. Dosage reduction is recommended when administering **SHILOVA TABLETS** to patients with renal impairment.
- Patients receiving other nephrotoxic medicines. Caution should be exercised when administering **SHILOVA TABLETS** to patients receiving potentially nephrotoxic medicines.
- Patients without adequate hydration. Precipitation of aciclovir in renal tubules may occur when solubility (2,5 mg/mL) is exceeded in the intratubular fluid. Adequate hydration should be maintained for all patients.

In the event of acute renal failure and anuria, the patient may benefit from haemodialysis until renal function is restored.

Central Nervous System (CNS)
CNS adverse reactions, including agitation, hallucinations, confusion, delirium, seizures, and encephalopathy, have been reported in both adult and paediatric patients with or without reduced renal function and in patients with underlying renal disease who received higher than recommended doses of **SHILOVA TABLETS** for their level of renal function. Elderly patients are more likely to have CNS adverse reactions. **SHILOVA TABLETS** should be discontinued if CNS adverse reactions occur.

Skin and appendage
Severe Cutaneous Adverse Reactions (SCARs) including Toxic Epidermal Necrolysis (TEN), Stevens Johnson Syndrome (SJS) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), which could be life-threatening or fatal, have been reported with **SHILOVA TABLETS** (see section 4.8). At the time of prescription, patients should be advised of the signs and symptoms of severe skin reactions and closely monitored. If signs and symptoms suggestive of these reactions appear, **SHILOVA TABLETS** should be discontinued immediately, and an alternative treatment should be considered. If the patient has developed a serious reaction such as SJS, TEN or DRESS with use of **SHILOVA TABLETS**, treatment with **SHILOVA TABLETS** must not be restarted in this patient at any time.

Use in genital herpes
Patients should be advised to avoid intercourse when symptoms are present even if treatment with an antiviral has been initiated. Continuous therapy with **SHILOVA TABLETS** in patients with recurrent genital herpes reduces the risk of transmitting genital herpes. It does not cure genital herpes or completely eliminate the risk of transmission. In addition to therapy with valaciclovir, it is recommended that patients use safer sex practices. As genital herpes is a sexually transmitted infection, patients should, in order to further reduce the risk of infecting partners, avoid contact with lesions, damaged skin/mucosa, and avoid intercourse when lesions and/or symptoms are present. Genital herpes is frequently transmitted in the absence of symptoms through asymptomatic viral shedding; therefore, patients should be counselled to use safer sex practices. The effect of **SHILOVA TABLETS** on transmission of sexually transmitted infections other than herpes (including HIV, gonorrhoea, syphilis and chlamydia) is unknown.

The efficacy of **SHILOVA TABLETS** for reducing transmission of genital herpes has not been established in individuals with multiple partners, non-heterosexual couples and couples not counselled to use safer sex practices.

4.5 Interaction with other medicines and other forms of interaction

No clinically significant interactions have been identified.

Cimetidine and probenecid increase the area under the plasma concentration time curve of aciclovir by reducing its renal clearance: however, no dosage adjustment is necessary because of the wide therapeutic index of aciclovir. Other medicines which affect renal physiology could affect plasma levels of aciclovir.

In patients receiving high-dose **SHILOVA TABLETS** (8 g/day) for CMV prophylaxis, caution is required during concurrent administration with medicines which compete with aciclovir for elimination, because of the potential for increased plasma levels of one or both medicines or their metabolites.

Increases in plasma AUCs of aciclovir and of the inactive metabolite of mycophenolate mofetil, an immunosuppressant agent used in transplant patients, have been shown when the medicines are co-administered.

Care is also required (with monitoring for changes in renal function) if administering high-dose **SHILOVA TABLETS** with medicines which affect other aspects of renal physiology (e.g. cyclosporin, tacrolimus).

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (see section 4.3).

Teratogenicity:
Foetal abnormalities were observed in rats.

4.7 Effects on ability to drive and use machines

When driving vehicles or using machines it should be taken into account that dizziness or weariness or visual disturbances may occur.

DETACH BEFORE DISPENSING

4. Moontlike newe-effekte

SHILOVA TABLETS kan newe-effekte hê.
Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid sou verswak of indien jy enige ongunstige effekte ondervind terwyl jy **SHILOVA TABLETS** neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige raadpleeg.

Indien enige van die volgende voorkom, hou op om **SHILOVA TABLETS** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk en asemhaling kan veroorsaak,
- uitslag of gejeuk,
- floute.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op **SHILOVA TABLETS** gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Nierversaking en senuweestelselprobleme kom nie dikwels voor nie, maar by party pasiënte wat SHILOVA TABLETS neem kan dit ernstig wees.
Senuweestelselprobleme sluit in aggressiewe gedrag, wankelrige bewegings, rukkerige bewegings, verwardheid, spraakprobleme, hallusinasies (sien of hoor goed wat nie regtig daar is nie), toevalle en koma. **Sê altyd voordat jy SHILOVA TABLETS neem vir jou gesondheidsorgverskaffer indien jy nierprobleme het. Kontak dadelik jou dokter indien jy 'n senuweestelselprobleem ontwikkel terwyl jy SHILOVA TABLETS neem.**

Newe-effekte van **SHILOVA TABLETS** wat dikwels by volwassenes voorkom, sluit hoofpyn, naarheid, maagpyn, braking en duiseligheid in.

Ander newe-effekte wat minder dikwels by volwassenes voorkom, sluit in pynlike menstruasie by vrouens, gewrigspyn, depressie, lae bloedseltellings, en veranderings in toetse wat bepaal hoe goed die lewer en niere werk.

Die algemeenste newe-effek wat by kinders onder 18 jaar gesien is, was hoofpyn.

Frekwensie onbekend
'n Ernstige velreaksie bekend as medisynereaksie met eosinofilie en sistemiese simptome (DRESS) kan voorkom, wat 'n ernstige velreaksie kan veroorsaak wat een of meer organe kan affekteer. Jy kan die volgende ervaar: koors, erge uitslag, vel skiffer af, swelling van die gesig, geswelde limfkliere, voel grieperig, geel vel of oë, kortasemheid, droë hoes, pyn of ongemak in die borskas, voel dors, urineer minder dikwels, minder urine.

Bespreek dit met jou gesondheidsorgverskaffer indien jy enige newe-effekte ontwikkel wat jou bekommer.

Rapportering van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety-toepassing (Medsafety X SAHPRA) en eRapportering-platform (who-umc.org), wat op SAHPRA se webwerf beskikbaar is. Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van **SHILOVA TABLETS** te verskaf.

5. Hoe om SHILOVA TABLETS te bewaar

Bêre by of onder 25 °C.
Hou die HDPE-houers dig toe.
Hou die stulpstroke in die karton tot nodig vir gebruik.
BEWAAR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne wegdoen nie.

6. Inhoud van die verpakking en ander inligting

Wat SHILOVA TABLETS bevat:
Die aktiewe bestanddeel is valasiklovirhidrochloried.
SHILOVA 500 mg TABLETS: Elke filmbedekte tablet bevat 500 mg valasiklovir.
SHILOVA 1 g TABLETS: Elke filmbedekte tablet bevat 1 g valasiklovir.
Die ander bestanddele van **SHILOVA TABLETS** is mikrokristalline sellulose, kruispovidoon, magnesiumstearaat en povidoon.
SHILOVA TABLETS: Die bestanddele van die Opadry Blue 13B50578 filmlagie is:: FD&C Blue #2/ indigokarmyn-aluminiumlak (K.I. nr.: 73015), hipromellose, makrogol, polisorbaat 80 en titaandioksied (K.I. nr.: 77891).

Hoe SHILOVA TABLETS lyk en inhoud van die verpakking
SHILOVA 500 mg TABLETS:
Stulpstroke:
Tablette word in 250 mm PVC film bedek met 90 g/m² PVdc en gedrukte 25 mm aluminiumfoelie met 7 g/m² hitteseëllak.
Verpakkingsgrootte:
10s - Elke stolpstrokie bevat 5 tablette. Elke karton bevat 2 stolpstrokies van 5 tablette elk.
30s - Elke stolpstrokie bevat 5 tablette. Elke karton bevat 6 stolpstrokies van 5 tablette elk.
42s - Elke stolpstrokie bevat 7 tablette. Elke karton bevat 6 stolpstrokies van 7 tablette elk.

SHILOVA 1 g TABLETS:
Stulpstroke:
Tablette word verpak in deurskynende 250 mikron PVC-film, bedek met 90 g/m² PVdC en bedrukte 25 mikron aluminiumfoelie, met 7 g/m² hitteseëlak.
Verpakkingsgrootte: 21s – Elke karton bevat 3 stulpstroke met 7 tablette elk.

Hoe SHILOVA TABLETS lyk
SHILOVA 500 mg TABLETS:
Blou, filmbedekte, kapsulevormige tablette met 'n gedeeltelike keep aan beide kante met "F" aan die een kant en "9" en "3" aan die ander kant.
SHILOVA 1 g TABLETS:
Blou, filmbedekte, kapsulevormige tablette met 'n gedeeltelike keep aan beide kante met "F" aan die een kant en "8" en "3" aan die ander kant.

Registrasienommers
SUID-AFRIKA:
SHILOVA 500 mg TABLETS: 45/20.2.8/0590
SHILOVA 1 g TABLETS: 45/20.2.8/0591
NAMIBIË:
SHILOVA 500 mg TABLETS: 18/20.2.8/0045

Houer van Registrasiesertifikaat
Aurogen South Africa (Edms.) Bpk.
Woodhill Office Park, Gebou 1, Eerste vloer,
Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12,
Johannesburg,
Suid-Afrika,
1448.

Hierdie inligtingsblad is laas hersien
13 Februarie 2025

PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS
SUID-AFRIKA: S4
NAMIBIË: NS2

SHILOVA 500 mg TABLETS (tablette)
SHILOVA 1 g TABLETS (tablette)
Valasiklovirhidrochloried
Suikervry.

Lees hierdie inligtingsblad noukeurig deur voordat jy begin om SHILOVA TABLETS te neem.
- Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter of jou apteker.
- **SHILOVA TABLETS** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit kan skadelik wees vir hulle, al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingsblad

1. Wat is **SHILOVA TABLETS** en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy **SHILOVA TABLETS** neem
3. Hoe om **SHILOVA TABLETS** te neem
4. Moontlike newe-effekte
5. Hoe om **SHILOVA TABLETS** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat is SHILOVA TABLETS en waarvoor word dit gebruik

SHILOVA TABLETS word gebruik:
- Vir die behandeling van herpes zoster (gordelroos).
- Om die duur van pyn wat met gordelroos gepaard gaan, te verkort.
- Vir die episodiese behandeling van herhalende genitale herpes by pasiënte met normale immuunstelsels.
- Om te keer dat infeksie met herpes simplex van die vel en slymvlies van die area by die anus en geslagsdele weer voorkom.

2. Wat jy moet weet voordat jy SHILOVA TABLETS neem

Moenie SHILOVA TABLETS neem nie:
- Indien jy allergies vir valasiklovir, asiklovir, of vir enige van die ander bestanddele van **SHILOVA TABLETS** is (gelys by afdeling 6).
- Indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet met SHILOVA TABLETS geneem word:
- Indien jou nierfunksie belemmer is.
- Indien jy gevorderde MIV-siekte het.
- Indien jy 'n beenmurg- of nierooorplanting gehad het.
- **SHILOVA TABLETS** moet met omsigtigheid aan bejaarde pasiënte toegedien word. Verlaging van die dosis word vir bejaarde pasiënte met nierprobleme aanbeveel.
- Indien jy ander medikasie neem wat 'n uitwerking op die niere het.

Gebruik by genitale herpes:
Dit word aanbeveel dat pasiënte **SHILOVA TABLETS** aaneenlopend gebruik om herhalende episodes te voorkom of te verminder, of om die risiko te verlaag dat die virus oorgedra word wat genitale herpes veroorsaak, vermy ook kontak wanneer daar simptome is en gebruik altyd kondome.
SHILOVA TABLETS genees nie genitale herpes of elimineer die risiko van oordrag heeltemal nie. Omdat genitale herpes 'n seksueel oordraagbare siekte is, moet jy so min as moontlik seksuele omgang hê wanneer jy 'n uitbraak van herpes of enige simptome daarvan het. Dit sal voorkom dat jy herpes na jou maat oordra.

Kinders en adolessente
Daar is geen data vir die gebruik van **SHILOVA TABLETS** by kinders nie.

SHILOVA TABLETS met kos, drinkgoed en alkohol
SHILOVA TABLETS kan met of sonder kos geneem word.

Swangerskap, borsvoeding en vrugbaarheid
Dit is nie bepaal of **SHILOVA TABLETS** veilig is om deur vrouens wat swanger is of borsvoed gebruik te word nie.

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy **SHILOVA TABLETS** neem.

Bestuur en gebruik van masjinerie:
SHILOVA TABLETS kan duiseligheid en probleme met jou sig veroorsaak. Indien jy enige ander medisyne neem, word, moenie bestuur of masjinerie gebruik nie.

Dit is nie altyd moontlik om te voorspel tot watter mate **SHILOVA TABLETS** met jou daaglikse aktiwiteite mag inmeng nie. Verseker asseblief dat jy nie bogenoemde aktiwiteite uitvoer nie, totdat jy weet tot watter mate **SHILOVA TABLETS** jou affekteer.

Ander medisynes en SHILOVA TABLETS:
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisynes in.)
- Simetidien en probenesied kan die uitwerking van **SHILOVA TABLETS** verleng deurdat dit die uitskeiding via urine verminder.
- Sorg is nodig (met monitering vir veranderings in nierfunksie) indien hoë dosisse **SHILOVA TABLETS** toegedien word saam met medisynes wat ander aspekte van nierfunksie affekteer, byvoorbeeld die medisynes siklosporien en takrolimus.

3. Hoe om SHILOVA TABLETS te neem

Moenie medisynes wat vir jou voorgeskryf is, met enigiemand anders deel nie. Neem **SHILOVA TABLETS** altyd presies soos wat jou dokter vir jou aangedui het. Jou dokter sal jou inlig hoe lank jou behandeling met **SHILOVA TABLETS** gaan duur. Vra gerus jou dokter of apteker indien jy onseker is. Indien jy die indruk kry dat die uitwerking van **SHILOVA TABLETS** te sterk of te swak is, bespreek dit met jou dokter of apteker.

SHILOVA TABLETS kan met of sonder kos geneem word.
Dosering by volwassenes wissel afhangende van die behandeling wat jy nodig het, soos wat deur jou dokter aangedui word.
Dosering moet gewysig word afhangende van jou nierfunksie.
Dit is nie nodig om die dosis aan te pas by pasiënte met geringe tot matige lewerabnormaliteite nie.
Geen data is beskikbaar vir dosering by kinders nie.

Indien jy meer SHILOVA TABLETS neem as wat jy behoort te neem:
In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om SHILOVA TABLETS te neem:
Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

4.8 Undesirable effects

MedDRA system organ class	Frequency	Adverse reactions
Blood and the lymphatic system disorders	Less frequent	Aplastic anaemia Thrombocytopenia Haemolytic anaemia, micro-angiopathic, neutropenia Leukocytoclastic vasculitis
Immune system disorders	Less frequent	Acute hypersensitivity reactions and anaphylaxis and angioedema
Nervous system disorders	Frequent	Headache
	Less frequent	Decreased consciousness in patients with renal insufficiency Dizziness, somnolence, convulsions Fatigue Aggressive behaviour Agitation Ataxia, coma, confusion, dysarthria, encephalopathy, seizures and tremors
Psychiatric disorders	Less frequent	Mania and psychosis, including auditory and visual hallucinations
Eye disorders	Less frequent	Visual abnormalities
Cardiac disorders	Less frequent	Tachycardia
Vascular disorder	Less frequent	Hypertension
Gastrointestinal disorders	Frequent	Nausea
	Less frequent	Gastrointestinal disturbances such as constipation, diarrhoea, loss of appetite, stomach pain, vomiting
Hepato-biliary disorders	Less frequent	Hepatitis with liver function test abnormalities, jaundice
Skin and subcutaneous tissue disorders	Less frequent	Facial oedema Skin reactions such as erythema multiforme, photosensitivity, or rash (redness of the skin) Alopecia, SJS, TEN, urticaria, pruritus
	Unknown frequency	Acute generalised exanthematous pustulosis (AGEP), DRESS
Musculoskeletal, connective tissue and bone disorders	Less frequent	Arthralgia
Renal and urinary disorders	Less frequent	Renal insufficiency manifested by increased serum creatinine, acute renal failure
Reproductive system and breast disorders	Less frequent	Dysmenorrhoea

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose
Symptoms and signs:
There are at present no data available on overdose with **SHILOVA TABLETS**.

In animal studies, large doses caused obstructive uropathy and crystalluria.

Management:
In the event of asymptomatic **SHILOVA TABLETS** overdose occurring, aciclovir is removable by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacological classification: A 20.2.8 Antiviral agents

Pharmacotherapeutic group: Antivirals for systemic use. Nucleosides and nucleotides excluding reverse transcriptase inhibitors.
ATC Code: J05AB11

Valaciclovir, an antiviral, is the L-valine ester of aciclovir. Aciclovir is a purine (guanine) nucleoside analogue.

Valaciclovir is a nucleoside analogue DNA polymerase inhibitor.

Valaciclovir is rapidly and almost completely converted in man to aciclovir and L-valine probably by the enzyme valaciclovir hydrolase.

Aciclovir is a specific inhibitor of the herpes viruses with *in vitro* activity against herpes simplex viruses (HSV) type 1 and type 2, Varicella Zoster Virus (VZV), Epstein-Barr Virus (EBV), CMV and human herpes virus 6 (HHV-6). Aciclovir inhibits herpes virus DNA synthesis once it has been phosphorylated to the active triphosphate form. The first stage of phosphorylation requires the activity of a virus-specific enzyme. In the case of HSV, VZV and EBV this enzyme is the viral Thymidine Kinase (TK), which is only present in virus infected cells.

Selectivity is maintained in CMV with phosphorylation, at least in part, being mediated through the phosphotransferase gene product of the UL97 gene of CMV. This gene encodes for the viral kinase which facilitates the intracellular anabolism of aciclovir.

The requirement for activation of aciclovir by a virus-specific enzyme largely explains its unique selectivity. The phosphorylation process is completed (conversion from mono- to triphosphate) by cellular kinases.

Aciclovir triphosphate competitively inhibits the virus DNA polymerase and incorporation of this nucleoside analogue result in obligate chain termination, halting virus DNA synthesis and thus blocking virus replication.

Extensive monitoring of clinical isolates from patients receiving aciclovir therapy or prophylaxis has revealed that herpes simplex virus and varicella zoster virus with reduced sensitivity to aciclovir is rare in the immunocompetent and is only found infrequently in severely immunocompromised individuals e.g. solid organ or bone marrow transplant recipients, patients receiving chemotherapy for malignant disease and people infected with the HIV.

Resistance is normally due to a thymidine kinase deficient phenotype which results in a virus which is profoundly disadvantaged in the natural host. Infrequently, reduced sensitivity to aciclovir has been described as a result of subtle alterations in either the virus thymidine kinase or DNA polymerase. The virulence of these variants resembles that of the wild-type virus.

5.2 Pharmacokinetic properties
Absorption:
After oral administration valaciclovir is well absorbed from the gastrointestinal tract and almost completely converted to aciclovir and L-valine by first-pass intestinal and/or hepatic metabolism.

Metabolism:
Aciclovir is converted to a small extent to inactive metabolites by aldehyde oxidase and by alcohol and aldehyde dehydrogenase. Neither valaciclovir nor aciclovir is metabolised by cytochrome P450 enzymes. Peak plasma concentrations of unconverted valaciclovir are low and transient, generally becoming non-quantifiable 3 hours after administration.

Peak plasma concentration of valaciclovir occurs at median time of 45 – 60 minutes post dose. Peak plasma valaciclovir concentrations are generally less than 0,5 µg/ mL at all doses. After single-dose administration of 1 gram of valaciclovir, average plasma valaciclovir concentrations observed were 0,5; 0,4 and 0,8 µg/mL in patients with hepatic dysfunction, renal insufficiency, and in healthy volunteers who received concomitant cimetidine and probenecid, respectively.

Distribution:
The binding of valaciclovir to human plasma proteins ranges from 13,5 % to 17,9 %. The binding of aciclovir to human plasma proteins ranges from 9 % to 33 %.

Elimination:
The elimination plasma half-life of aciclovir after both single and multiple dosing with valaciclovir averaged 2,5 to 3,3 hours in volunteers with normal renal function. Less than 1 % of the administered dose of valaciclovir is recovered in the urine. Valaciclovir is eliminated principally as aciclovir and the known aciclovir metabolite, 9-carboxymethoxymethyl-guanine (CMMG), in the urine.

Renal impairment: Following administration of valaciclovir to patients with renal impairment, the average half-life of aciclovir is approximately 14 hours. During haemodialysis, the aciclovir half-life is approximately 4 hours. Approximately one third of aciclovir in the body is removed by dialysis during a 4-hour haemodialysis session. Apparent plasma clearance of aciclovir in dialysis patients is 86,3 +/. 21,3 mL/min/1,73 m^2 compared with 679,16 +/. 162,76 mL/min/ 1,73 m^2 in healthy volunteers.

Characteristics in patients:
Herpes zoster and herpes simplex does not significantly alter the pharmacokinetics of valaciclovir and aciclovir after oral administration of **SHILOVA TABLETS**. In transplant recipients receiving valaciclovir 2000 mg 4 times daily, aciclovir peak concentrations are similar to or greater than those in healthy volunteers receiving the same dose. The estimated daily area under the plasma concentration curves (AUCs) is appreciably greater.

5.3 Preclinical safety data
Not applicable.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
- Cellulose microcrystalline,
- Crospovidone, magnesium stearate and
- Povidone.

Opadry blue 13b50578 film coating ingredients:
- Fd&c blue #2/ indigo carmine aluminium lake (c.i. no.: 73015),
- Hypromellose,
- Macrogol,
- Polysorbate 80 and
- Titanium dioxide (c.i. no.: 77891).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at or below 25 °C.
Keep HDPE containers tightly closed.
Keep the blisters in the carton until required for use.

6.5 Nature and contents of container
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.

SHILOVA 1 g 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 7 g/m^2 heat seal lacquer.
Pack size: 21s – Each carton contains 3 blisters of 7 tablets each.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue,
Meyersdal, Ext. 12,
Johannesburg,
South Africa.
+27 11 867 9100
www.auro-space.com

8 REGISTRATION NUMBER(S)

SOUTH AFRICA:
SHILOVA 500 mg TABLETS: 45/20.2.8/0590
SHILOVA 1 g TABLETS: 45/20.2.8/0591

NAMIBIA:
SHILOVA 500 mg TABLETS: 18/20.2.8/0045

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
15 August 2013

10 DATE OF REVISION OF THE TEXT
13 February 2025

P1539815

DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS
SOUTH AFRICA: S4
NAMIBIA: NS2

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
2. What you need to know before you take **SHILOVA TABLETS**
3. How to take **SHILOVA TABLETS**
4. Possible side effects
5. How to store **SHILOVA TABLETS**
6. Contents of the pack and other information

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

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

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
SOUTH AFRICA:
SHILOVA 500 mg TABLETS: 45/20.2.8/0590
SHILOVA 1 g TABLETS: 45/20.2.8/0591
NAMIBIA:
SHILOVA 500 mg TABLETS: 18/20.2.8/0045

Holder of Certificate of Registration
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This leaflet was last revised in
13 February 2025

P1539815

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Team Leader: Kiran Kumar Initiator: Bhogeswara Rao	Dimensions: 280 x 480 mm	Font Type: Helvetica	Font Size: 6 pt	
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Sign / Date

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