APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME (and dosage form):

VOLRITE 500 mg TABLETS (tablets)

VOLRITE 1 g TABLETS (tablets)

Valaciclovir hydrochloride

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **VOLRITE 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.

1. WHAT VOLRITE TABLETS CONTAINS

The active ingredient is valaciclovir hydrochloride.

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

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

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

VOLRITE 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).

2. WHAT VOLRITE TABLETS IS USED FOR:

VOLRITE 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.

3. BEFORE YOU TAKE VOLRITE TABLETS:

Do not take VOLRITE TABLETS:

- If you are allergic to valaciclovir, aciclovir, or any of the other ingredients of **VOLRITE TABLETS.**
- If you are pregnant or breastfeeding.

Take special care with VOLRITE 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 **VOLRITE 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.

Taking VOLRITE TABLETS with food and drink

VOLRITE TABLETS can be taken with or without food.

Pregnancy and Breast-feeding:

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

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

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

Taking other medicines with VOLRITE TABLETS:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of VOLRITE TABLETS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

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

4. HOW TO TAKE VOLRITE TABLETS:

Always take VOLRITE TABLETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of VOLRITE TABLETS is too strong or too weak, talk to your doctor or pharmacist.

VOLRITE 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.

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 VOLRITE TABLETS:

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

5. POSSIBLE SIDE EFFECTS:

VOLRITE TABLETS can have side effects.

Kidney failure and nervous system problems are infrequent, but can be serious in some patients taking VOLRITE 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 VOLRITE TABLETS. Call your doctor right away if you get a nervous system problem while you are taking VOLRITE TABLETS.

Frequent side effects of **VOLRITE 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.

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

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

6. STORING AND DISPOSING OF VOLRITE TABLETS:

Store at or below 30 °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

7. PRESENTATION OF VOLRITE TABLETS:

VOLRITE 500 mg 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: 42's – Each carton contains 6 blisters of 7 tablets each.

Text Information on Printed foil repeated as often as possible:

Proprietary name, Lot No, Expiry date, Name of the holder of the certificate of registration.

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: 42's - One HDPE container contains 42 tablets.

Text Information on container Label / Carton:

Proprietary name, Lot No, Expiry date, Name of the holder of the certificate of registration.

VOLRITE 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: 21's – Each carton contains 3 blisters of 7 tablets each.

Text Information on Printed foil repeated as often as possible:

Proprietary name, Lot No, Expiry date, Name of the holder of the certificate of registration.

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: 21's - One HDPE container contains 21 tablets.

Text Information on container Label / Carton:

Proprietary name, Lot No, Expiry date, Name of the holder of the certificate of registration.

8. IDENTIFICATION OF VOLRITE TABLETS:

VOLRITE 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.

VOLRITE 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.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

VOLRITE 500 mg TABLETS: 45/20.2.8/0586

VOLRITE 1 g TABLETS: 45/20.2.8/0587

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12

Johannesburg

South Africa

1448

11. DATE OF PUBLICATION

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15 August 2013

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