PATIENT INFORMATION LEAFLET FOR ANVIRO 500 TABLETS

Please read this leaflet carefully before using ANVIRO 500 TABLETS

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

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ANVIRO 500 TABLETS

1. WHAT ANVIRO 500 TABLETS CONTAINS

Active ingredient:

Each film coated tablet contains valaciclovir hydrochloride monohydrate equivalent to 500 mg valaciclovir.

Inactive ingredients:

Microcrystalline cellulose, crospovidone, povidone K-90, purified water, magnesium stearate, Opadry II 85F18422 White.

Sugar free.

2. WHAT ANVIRO 500 TABLETS IS USED FOR

ANVIRO 500 TABLETS is used to treat the following virus infections:

- Herpes zoster ((shingles) an acute, painful inflammation of a group nerves with a skin rash often forming a girdle around the middle of the body).
- Genital herpes in patients whose immune systems are comprised.

ANVIRO 500 TABLETS is used in the prevention of the following virus infections:

- Herpes virus infections (of the skin, anus or genital area).
- Cytomegalovirus infection (can cause no symptoms, or can be the source of serious illness in people with weak immune systems).
- Disease after organ transplantation in patients with a special risk.

3. BEFORE YOU USE ANVIRO 500 TABLETS

Do not take ANVIRO 500 TABLETS:

- If you are allergic (hypersensitive) to valaciclovir, aciclovir or any of the ingredients in the formulation (see **WHAT ANVIRO 500 TABLETS CONTAINS**).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with ANVIRO 500 TABLETS:

- If you have advanced HIV disease
- If you had a bone marrow transplant
- If you had a kidney transplant
- If you have kidney impairment

A syndrome called thrombocytopenic purpura or haemolytic uraemia has been reported, with some cases being fatal. This syndrome has not been observed in patients with normal immune system function.

Taking ANVIRO 500 TABLETS with food or drink:

The tablets can be taken with or without food.

You should take adequate amounts of liquids (water or juice) when receiving high doses of **ANVIRO 500 TABLETS**.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ANVIRO 500 TABLETS**.

DO NOT use **ANVIRO 500 TABLETS** if you are pregnant or suspect that you are pregnant. Contact

you doctor or healthcare professional immediately.

DO NOT use **ANVIRO 500 TABLETS** during breastfeeding.

Driving and using machinery:

It is unlikely for **ANVIRO 500 TABLETS** to make you drowsy. However, please make sure how **ANVIRO 500 TABLETS** affects you before driving or using machinery.

Using other medicines with ANVIRO 500 TABLETS:

- Always tell your healthcare professional if you taking any other medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ANVIRO 500 TABLETS** with these medicines may cause undesirable interactions.
- Although no clinically significant interactions between **ANVIRO 500 TABLETS** and other medicines have been reported, any medicine which is excreted through the kidneys may interact with **ANVIRO 500 TABLETS**. Caution should be taken with such medicines.
- Cimetidine and probenecid have been shown to decrease the excretion of aciclovir.
- Co-administration of aciclovir and mycophenolate mofetil (a medicine used during organ transplant) has been shown to increase blood levels of both medicines.

4. PROPER USE OF THIS MEDICATION

Do not share medicines prescribed for you with any other person.

You and your doctor should talk about the benefits and risks of treatment with **ANVIRO 500 TABLETS**.

The dose of **ANVIRO 500 TABLETS** will be different for different patients and may depend on what the medicine is being used for, your age and if other medicines are also being given or taken at the same time.

For the treatment of Herpes zoster (shingles), take two tablets (1000 mg) three times a day for seven days.

For the treatment of recurrent genital herpes, take one tablet (500 mg) twice a day for five days. It should be taken as soon as signs or symptoms (such as burning or tingling) appear.

For the prevention of recurrent herpes simplex infections in patients with a normal immune system, take one tablet (500 mg) once a day. In patients with a compromised immune system, take one tablet (500 mg) twice a day.
For prophylaxis a viral infection called cytomegalovirus (CMV), take four tablets (2000 mg) four times a day. It should be taken as soon as possible after the organ transplant has been performed.

If you have a kidney disease or kidney impairment, the dosages will be adjusted by your doctor according to the seriousness of your disease or impairment.

If you have any questions about the proper dose of **ANVIRO 500 TABLETS**, ask your doctor.

If you take more ANVIRO 500 TABLETS than you should:
In the event of overdosage, consult your doctor or pharmacist, if neither is available, contact the nearest hospital or poison control centre. Take this leaflet and the remaining tablets with you so the doctor will know what you have taken.

5. POSSIBLE SIDE EFFECTS

ANVIRO 500 TABLETS may have side effects. Not all side effects reported for **ANVIRO 500 TABLETS** are included in this leaflet.

Some side effects may occur that usually do not need medical attention.
Should your general health worsen while or if you experience any untoward effects taking **ANVIRO 500 TABLETS**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop taking **ANVIRO 500 TABLETS** and contact your doctor or healthcare professional immediately:

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

- acute anxiety, hallucinations, sleeplessness or over excitement

These are all very serious side effects. If you have them, you may have had a serious allergic reaction or a contradicting effect to **ANVIRO 500 TABLETS**. You may need urgent medical attention. All of these side effects are very serious.

Side effects that may occur frequently include:

- Headache, nausea.

Less frequent side effects that may occur include the following:

- Skin rashes, gastrointestinal disturbances, confusion and dizziness.

6. STORAGE AND DISPOSAL OF ANVIRO 500 TABLETS

- Store at or below 25 °C.
- Keep container tightly closed.
- Protect from light and moisture.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF ANVIRO 500 TABLETS

ANVIRO 500 TABLETS are packed into plain Aluminium/transparent PVC/PVDC foil blisters.

ANVIRO 500 TABLETS are available in blister strips of 1 x 10 tablets or 3 x 10 tablets.

8. IDENTIFICATION OF ANVIRO 500 TABLETS

ANVIRO 500 TABLETS: White to off white, capsule shaped, biconvex, film coated tablets, debossed with “500” on one side and median line on the other side. Tablet should be free of all physical defects.

9. REGISTRATION NUMBER

42/20.2.8/0820

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

Zydus Healthcare SA (Pty) Ltd.

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion

0157

Tel. no.: 012 748 6400

11. DATE OF PUBLICATION

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