PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORM:

Aciclovir Sandoz® 200 (tablets)

Aciclovir Sandoz® 400 (tablets)

Please read this leaflet carefully before taking ACICLOVIR SANDOZ

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

The active ingredient is aciclovir.

ACICLOVIR SANDOZ 200:

Each ACICLOVIR SANDOZ 200 tablet contains aciclovir 200 mg.

The other ingredients are:

Cellulose microcrystalline, copolyvidone, lactose monohydrate, magnesium stearate, silica (colloidal anhydrous) and sodium starch glycollate (Type A).

Contains sugar (lactose monohydrate 213,6 mg per tablet).

ACICLOVIR SANDOZ 400:

Each ACICLOVIR SANDOZ 400 tablet contains aciclovir 400 mg.

The other ingredients are:

Cellulose microcrystalline, copolyvidone, magnesium stearate, silica colloidal anhydrous and sodium starch glycollate (Type A).

Sugar free.

2. WHAT ACICLOVIR SANDOZ IS USED FOR:

ACICLOVIR SANDOZ is an antiviral medicine, which is used to treat a variety of infections:

- Treatment of initial and recurrent (returning after intermission) Herpes simplex infections of the skin and mucous membranes (inner lining of the mouth, nasal passages, vagina and urethra, any membrane or lining which contains mucous secreting glands), including initial and recurrent (returning after intermission) genital Herpes simplex virus infections. (Herpes simplex is either of two viral diseases caused by Herpes viruses that are marked especially by watery blisters on the skin or mucous membranes of the lips, mouth, face, or genital region).
- Prophylaxis (protective or preventive treatment) of Herpes simplex infections in patients with impaired or weakened immune systems.
- Herpes zoster (shingles) infections if the lesions are not older than 72 hours. Herpes zoster is a reactivation of the same Herpes virus that is responsible for chicken pox. This results in a painful blistery red rash that is confined to one side of the body.
- Varicella zoster (chickenpox), within 24 hours of the appearance of the typical chickenpox rash.

3. BEFORE YOU TAKE ACICLOVIR SANDOZ:

Do not take ACICLOVIR SANDOZ:

- If you are hypersensitive (allergic) to aciclovir or any of the other ingredients of ACICLOVIR SANDOZ. (see “WHAT ACICLOVIR SANDOZ CONTAINS”).

Take special care with ACICLOVIR SANDOZ:

- If you have kidney problems, your doctor will adjust the dose.
- If you are over 65 years of age.

Taking ACICLOVIR SANDOZ with food or drink:

ACICLOVIR SANDOZ can be taken with or without food.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ACICLOVIR SANDOZ.

Important information about some of the ingredients of ACICLOVIR SANDOZ:

ACICLOVIR SANDOZ contains lactose monohydrate (which is a type of sugar). Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ACICLOVIR SANDOZ.

ACICLOVIR SANDOZ contains lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with ACICLOVIR SANDOZ:

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

ACICLOVIR SANDOZ should not be used in patients who are taking, or have recently taken the following medicines:

- Probenecid and cimetidine–aciclovir will stay for a longer period than normal in the blood and therefore the dosing times of ACICLOVIR SANDOZ should be further apart.

- Nephrotoxic medicines – the risk of kidney impairment is increased by the concomitant use of other nephrotoxic medicines (a group of medication known to be toxic or destructive to kidney cells for example aminoglycosides, cisplatin, ciclosporine, foscarnet, pentamidine, vancomycin, neomycin, isoflurane, kanamycin and cyclophosphamide).

4. HOW TO TAKE ACICLOVIR SANDOZ:

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

Always take ACICLOVIR SANDOZ 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 ACICLOVIR SANDOZ is too strong or too weak, talk to your doctor or pharmacist.
- It is important that you complete the course of treatment as directed by your doctor.
- Do not stop taking your medicine before you have consulted with your doctor.

Adults:

Treatment of recurrent Herpes simplex infection of skin and mucous membranes (see "WHAT ACICLOVIR SANDOZ IS USED FOR"):

200 mg five times per day, every four hours omitting the night time dose.

Treatment should be continued for 5 days. In case of severe initial infection, your doctor may have to extend this period.

If you that are severely immunocompromised (patients with impaired or weakened immune systems) or you have decreased gut absorption the dose may be doubled to 400 mg or alternatively, your doctor may consider intravenous ACICLOVIR SANDOZ (administration of the medicine through the veins).

Dosing should be started as early as possible following the start of an infection and for recurrent episodes, this should be in the prodromal stages (the time from the moment of exposure to the virus to the development of the visible signs of the infection) or when lesions first appear.

Suppression of recurrent (returning after intermission) genital Herpes simplex infections in adults with impaired or weakened immune systems (see "WHAT ACICLOVIR SANDOZ IS USED FOR" for an explanation of "genital Herpes simplex infection"):

200 mg four times per day at six hourly intervals, or 400 mg twice daily at 12 hourly intervals. Your doctor may lower the dose to 200 mg aciclovir eight to twelve hourly. Your doctor will interrupt therapy, every 6 to 12 months, to observe possible changes in the natural history of the disease.

Prophylaxis (protective or preventive treatment) of Herpes simplex infections in adults with impaired or weakened immune systems:

200 mg four times daily at 6 hourly intervals.

If you have severely impaired or weakened immune systems or in patients with decreased gut absorption the dose may be doubled to 400 mg or alternatively your doctor may consider intravenous ACICLOVIR SANDOZ (administration of the medicine through the vein).

The doctor will determine the duration of preventive treatment by the duration of the period at risk.

Treatment of varicella zoster (chickenpox) and Herpes zoster infections (shingles) in adults:

800 mg five times daily at four hourly intervals, omitting the night time dose for a minimum period of 7 days. Dosing should be started as early as possible after the start of an infection.

The dosage for management in patients with severe impaired or weakened immune systems is 800 mg four times daily (every 6 hours).

Treatment of Herpes zoster infections (shingles) in adolescents (12 to 18 years):

800 mg four times daily for 5 days.

Children:

Treatment and prophylaxis (preventative treatment) of Herpes simplex infections in children with impaired or weakened immune systems:

Two years and older:

Adult dosage.

Below 2 years:

Half the adult dosage. The use of ACICLOVIR SANDOZ tablets in patients less than 2 years of age has not been fully studied.

Dosing for Varicella (chickenpox):

20 mg aciclovir per kg body mass (not exceeding 800 mg) four times daily.

Treatment should be started within 24 hours after appearance of typical chickenpox rash, and will be continued for 5 days.

Limited data suggest that for severely immunocompromised children (children with impaired or weakened immune systems) over 2 years, the adult dosage can be given.

Elderly:

Elderly patients should take plenty of fluids while they are being treated with ACICLOVIR SANDOZ tablets.

A lower dosage is recommended in elderly patients with kidney impairment.

Your doctor may change your dose according to your kidney function.

If you take more ACICLOVIR SANDOZ than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take any remaining tablets and the container with you and show the pack to the doctor.

The symptoms of overdosage are nausea, vomiting, headache and confusion.

Treatment will be supportive and symptomatic.

If you forget to take ACICLOVIR SANDOZ:

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

5. POSSIBLE SIDE EFFECTS:

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

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

- Sudden life-threatening allergic reaction causing swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash, itching, hives on skin.
- Liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, dark coloured urine, yellowing of the skin and eyes also called jaundice.
- Stevens Johnson Syndrome, a rare skin condition with severe blisters and bleeding on the lips, eyes, mouth, nose and genitals.
- Erythema multiforme: severe condition of the skin that may affect the mouth and other parts of the body with red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea.
- Toxic epidermal necrolysis: severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.
- Encephalopathy a disease of the brain, fits, coma.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty breathing.
- Anaemia, a condition in which there is a decreased number of red blood cells, tiredness, headaches, being short of breath when exercising, dizziness and looking pale, leukopaenia signs associated with lack of white blood cells, thrombocytopaenia condition causing frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Kidney problems such as kidney pain and kidney failure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Abnormal blood test result.
- High levels of blood in urine and high creatinine level.
- Confusion, unsteadiness when walking, difficulty in speaking, seeing, feeling or hearing things that are not there, drowsiness.
- Headache, dizziness, agitation, shaking.
- Itching, skin rash, sensitivity to light, hives, accelerated diffuse hair loss.
- Fatigue, fever.
- Nausea, diarrhoea, vomiting, stomach pain,

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ACICLOVIR SANDOZ:

Store at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in a dry place.

Do not remove blisters/tablets from outer container until required for use.

Store in the original package or container as dispensed by your pharmacist.

Keep the carton tightly closed.

Protect from light.

Do not use after the expiry date stated on the label carton or bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

7. PRESENTATION OF ACICLOVIR SANDOZ:

ACICLOVIR SANDOZ 200: Transparent or white opaque PVC/Aluminium blister packs containing 25 tablets.

ACICLOVIR SANDOZ 400: Transparent or white opaque PVC/Aluminium blister packs containing 70 tablets.

8. IDENTIFICATION OF ACICLOVIR SANDOZ:

ACICLOVIR SANDOZ 200: White, round convex tablets with a break notch on one side.

ACICLOVIR SANDOZ 400: White, round biconvex tablets with a break notch on one side.

9. REGISTRATION NUMBERS:

ACICLOVIR SANDOZ 200: 32/20.2.8/0378

ACICLOVIR SANDOZ 400: 32/20.2.8/0379

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

11. DATE OF PUBLICATION:

Date of Registration:

ACICLOVIR SANDOZ 200: 10 October 2000

ACICLOVIR SANDOZ 400: 28 March 2001

Date of most recent approval of patient information leaflet: 22 August 2019