**PATIENT INFORMATION LEAFLET FOR**

**ACITAB 200 / 400 / 800 DT**

**SCHEDULING STATUS: S4**

**ACITAB-200 DT (200 mg, dispersible tablets)**

**ACITAB-400 DT (400 mg, dispersible tablets)**

**ACITAB-800 DT (800 mg, dispersible tablets)**

**Acyclovir**

**Contains sweetener as follows:**

**ACITAB-200 DT - Aspartame 5 mg/tablet**

**ACITAB-400 DT - Aspartame 10 mg/tablet**

**ACITAB-800 DT - Aspartame 20 mg/tablet**

**Sugar-free**

**Read all of this leaflet carefully before you start taking ACITAB**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor pharmacist, nurse or other health care provider.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See **section 4**)
- ACITAB 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 ACITAB is and what it is used for

2. What you need to know before you take ACITAB

3. How to take ACITAB

4. Possible side effects

5. How to store ACITAB

6. Contents of the pack and other information.

## 1. What ACITAB is what it is used for

ACITAB contains the active ingredient Acyclovir which belongs to a group of medicines called antivirals. Acyclovir works by stopping the multiplication of the virus in the body. This reduces the length and severity of an infection.

ACITAB is indicated for the treatment of

- to treat chicken-pox and shingles
- to treat cold sores, genital herpes and other herpes simplex infections
- to stop cold sores, genital herpes and other herpes virus infections from coming back after you have had them.
- to prevent herpes virus infections in people whose immune systems work less well, which means their bodies are less able to fight infections
- ss treatment to prevent viral infection following bone marrow transplantation.

## 2. What you need to know before you take ACITAB

**Do not take ACITAB:**

- If you hypersensitive (allergic) to acyclovir, valacyclovir, or any of the other ingredients of ACITAB (listed in **Section 6**).

**Warnings and precautions**

Take special care with ACITAB:

- If you are pregnant or intend to become pregnant
- you are breastfeeding or planning to breastfeed

- you have a kidney condition (ensure that you drink adequate fluids whilst you are taking ACITAB if this is the case or if you are taking a high dose.)
- you have a liver condition
- you are elderly
- you develop a skin reaction that includes a fever, facial swelling and a rash or small blisters containing pus/liquid.

If any of the above applies to you, or if you are unsure if they apply to you, and if you have not already discussed with your doctor, tell your doctor or pharmacist before you start taking ACITAB.

**Other medicines and ACITAB**

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

Take special care with ACITAB if you are taking any of the following medicines: theophylline, probenecid, cimetidine or mycophenolate mofetil (immunosuppressant agent used in kidney transplants).

**Pregnancy, breastfeeding and fertility**

You should not breastfeed your infant if you are on treatment with ACITAB.

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

**Driving and using machines**

Some side effects such as feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

It is not always possible to predict to what extent ACITAB may interfere with your daily activities Ensure that you do not engage in the above activities until you are aware of the measure to which ACITAB affects you.

**ACITAB contains aspartame**

Aspartame is a source of phenylalanine. It may be harmful if you have the rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly (phelylketonuria / PKU)

**3. How to take ACITAB**

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

Always take ACITAB exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on how long treatment with ACITAB will last.

If you have the impression that the effect of ACITAB is too strong or too weak, tell your doctor of pharmacist.

**If you take more ACITAB that you should**

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

**If you forget to take ACITAB**

Take one dose as soon as you remember and then take the next dose at the correct time.

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

**4. Possible Side Effects**

ACITAB can have side effects.

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

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

- severe allergic reaction symptoms which include, sudden wheeziness, fluttering or tightness in the chest, collapse, swelling of eyelids, face, lips or elsewhere, skin rash or weals.

These are all very serious side effects. If you have them, you or your child may have had a serious allergic reaction to ACITAB. You may need urgent medical attention or hospitalisation. Do NOT take any more of this medicine unless your doctor has advised you to do so.

Tell your doctor if you experience any of the following side effects:

Frequent side effects include:

- headache, dizziness
- feeling or being sick (nausea, vomiting), diarrhoea and stomach cramps
- itching, skin rashes (including a skin reaction after exposure to sunlight)
- fever and feeling tired
- minor skin reactions e.g., hives/nettle rash
- hair loss.

Less frequent side effects include:

- difficulty breathing
- effects on some blood and urine tests. Let the doctor know that you are taking ACITAB if you are having a blood or urine test
- liver problems, or yellowing of the skin and the whites of the eyes

- impaired kidney function or kidney failure
- weakness, tiredness, feeling faint or shortness of breath. These symptoms may mean you have reduced number of red blood cells (anaemia)
- although you may not notice any symptoms, this medicine may cause a decrease in your white blood cells
- bruising or nose bleeds. These symptoms mean you have a low number of platelets, a type of white blood cell
- agitation, confusion, shakiness, irregular body movements, difficulties with speech, hallucinations, fits, drowsiness, sleepiness during the day, loss of contact with reality
- pain in the flank/kidney area of your back.

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

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ACITAB.

## 5. HOW TO STORE ACITAB

Store at or below 25 °C and in dry place.

Protect from light.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

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

Do not use if the expiry date on the packaging has passed.

## 6. Contents of the pack and other information

### What ACITAB contains

The active substance acyclovir.

Other ingredients are aspartame , colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, povidone, purified talc, sodium starch glycolate, trusil banana special (flavour).

### What ACITAB looks like and contents of the pack

ACITAB-200 DT:

White to off-white, circular, flat, bevelled, uncoated tablets with “AC 200” debossed on one face and a central break-line on the other.

ACITAB-400 DT:

White to off-white, circular, flat, bevelled, uncoated tablets with “AC 400” debossed on one face and a central break-line on the other.

ACITAB-800 DT:

White to off-white, capsule-shaped tablet with central break-line on one face and AC embossed on the other face.

ACITAB-200 DT: Packed in a PVC/Aluminium foil blister pack of 25 tablets packed in a carton.

ACITAB-400 DT: Packed in a PVC/Aluminium foil blister packs of 25, 56, 60 or 70 tablets packed in a carton.

ACITAB-800 DT: Packed in a PVC/Aluminium foil blister packs of 35 tablets packed in a carton.

### Holder of certificate of registration

**CIPLA MEDPRO (PTY) LTD**.

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**Registration numbers(s)**

ACITAB-200 DT: 38/20.2.8/0129

ACITAB-400 DT: 38/20.2.8/0128

ACITAB-800 DT: 38/20.2.8/0130

Namibia: ACITAB-200 DT NS2 11 / 20.2.8 / 0118

ACITAB-400 DT NS2 11 / 20.2.8 / 0124

Botswana: ACITAB-200 DT S2 BOT1101945

ACITAB-400 DT S2 BOT1101946

**Access to the corresponding Professional Information**

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:
The QR Code to be generated and included after approval.