ACIC TABLET®

Acyclovir (200mg, 400mg and 800mg)

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What Acic is used for

Acic is used in the treatment of herpes simplex infections (cold sores) of the skin and mucous membrane. It also prevents herpes simplex infections in patients whose immune system is not working properly and treats chickenpox and shingles infection.

How Acic works

Acic contains an active ingredient, Acyclovir. It is an antiviral medicine, which acts on infected cells by preventing the growth of virus.

Before you use Acic

- When you must not use it

Do not used Acic if you are hypersensitive to acyclovir and valaciclovir or any other ingredients in Acic.

- Before you start to use it

Tell your doctor if you:

- Have kidney problem
- Have nervous system abnormalities
- Are an elderly
- Are pregnant or breastfeeding

- Pregnancy and lactation

Few human data has shown that acyclovir can pass into breast milk. Therefore, acyclovir should only be prescribed to pregnant and lactating mothers unless the potential benefits outweigh the possibility of unknown risks.

If you are not sure whether you should start taking this medicine, consult your doctor.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other

medicines, including medicines obtained without a prescription. Especially probenecid and cimetidine as these reduce acyclovir excretion via the kidneys, which may increase acyclovir persistence in the body.

How to use Acic

Always take Acic exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure. The dosage given to you by your doctor may not be the same as suggested below.

- How much to use

Herpes simplex infections

- 200mg acyclovir 5 times daily at 4 hours interval, daily for 5 days. Treatment may be extended to 10 days in severe initial infection.
- May be double to 400mg in patients whose immune system is not working properly or with impaired absorption.

Prevention of recurrent genital herpes simplex infection

Immunologically healthy patients

- 200mg to 400mg acyclovir, 4 times daily (every 6 hours).
- Alternatively, 400mg acyclovir can be taken twice a day (every 12 hours).
- Effective preventive treatment can also be achieved with 200mg 3 times daily (every 8 hours) or 200mg twice a day (every 12 hours).

<u>Immunosuppressed patients</u>

• 200mg to 400mg acyclovir, 4 times daily (every 6 hours) can be used in patients whose immune system is not working properly or with impaired absorption.

Varicella and Herpes zoster infections (Chickenpox and shingles)

• 800mg acyclovir 5 times daily at 4 hours intervals, omitting the night time dose. Treatment should continue for 5-7 days.

Dosage in Children

For treatment of Herpes simplex infections, and prevention of Herpes simplex infection in the immune-compromised,

• children aged 2 years and above should be given adult dosages

• children below the age of 2 years should be given half the adult doses

Dosage in Elderly

- The possibility of kidney failure in the elderly must be considered and your doctor will adjust the dose accordingly.
- Adequate hydration of elderly patients taking high oral doses of acyclovir should be maintained.

Dosage in Renal Failure

Inform your doctor if you have any kidney problem. Your doctor will adjust the dose based on the type of infection and the severity of kidney problem you have.

- When to use it

The tablet should be taken unchewed after meals with sufficient amount of liquid (a glass of water). Maintain adequate hydration by taking sufficient water, especially if you are an elderly, taking high oral doses or with kidney problem.

- How long to use it

Continue to take your medicine as long as your doctor tells you. If you are not sure, check with your doctor of pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, headache and confusion.

While you are using it

- Things you must do
- Always take Acic exactly according to the instructions given by your doctor or pharmacists. Check with your doctor or pharmacist if you are unsure.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Acic tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Acic.
- Things you must not do
- Do not stop taking your medicines without consulting your doctor.
- Do not use Acic after the expiry date which is stated on the carton and bottle.
- Do not give this medication to anyone else, even if they have the same condition as you.
- Things to be careful of
- Driving and using machines:

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

Side effects

Like many medicines, Acic tablets can cause side effects, although not everybody gets them.

Tell your doctor if you have any of these symptoms:

• Common:

Headache, dizziness, nausea, vomiting, diarrhea, abdominal pains, rashes including sensitive to sun light (photosensitivity), itching, fatigue and fever.

• Uncommon:

Pale or red irregular raised patches with severe itching (hives), and accelerated diffuse hair loss.

• Rare:

Anaphylaxis (allergic reaction), breathing difficulty, reversible rises in bilirubin and

liver related enzymes, angioedema (swelling under the skin), increases in blood urea and creatinine (metabolic waste).

• Very rare:

Changes in numbers and types of your blood cells (anaemia, leucopenia,

thrombocytopenia), excitement, confusion, tremor, uncoordinated movement, difficulty speaking, hallucinations, delusions, convulsions (fit), drowsiness, encephalopathy (brain disease), coma, inflammation of the liver (hepatitis), yellowing of the skin or whites of the eyes (jaundice), kidney pain, and kidney failure.

Tell your doctor or pharmacist if you notice any other side effects and it worries you,

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting)

Storage and Disposal of Acic

Storage

Store in a cool, dry place below 25°C. Protect from light.

Keep out of the reach of children.

- Disposal

If your doctors tell you to stop taking Acic or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining medicines.

Product Description

- <u>What it looks like</u>

ACIC 200 Tablet

The tablet shall be white, round, biconvex with a score notch and a smooth surface.

ACIC 400 Tablet

The tablet shall be white, round, biconvex with a score notch and a smooth surface.

ACIC 800 Tablet

The tablet shall be white, oblong tablets with score notches on both sides and a smooth surface.

- Ingredients
- Active ingredient

ACIC 200 Tablet

• 200mg of Acyclovir

ACIC 400 Tablet

• 400mg of Acyclovir

ACIC 800 Tablet

- 800mg of Acyclovir
- Inactive ingredients

ACIC 200 Tablet

• Lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, copolyvidone, and magnesium stearate.

ACIC 400 Tablet

• Silica colloidal anhydrous, sodium starch glycollate, microcrystalline cellulose, copolyvidone, and magnesium stearate.

ACIC 800 Tablet

• Silica colloidal anhydrous, sodium starch glycollate, microcrystalline cellulose, copolyvidone, and magnesium stearate.

- Packing

ACIC 200 Tablet: Blister pack of 25 tablets and 100 tablets

ACIC 400 Tablet: Blister pack of 35 tablets and 70 tablets

ACIC 800 Tablet: Blister pack of 35 tablets

- MAL Number

ACIC 200 Tablet: MAL20000724ACZ

ACIC 400 Tablet: MAL19986960ACZ

ACIC 800 Tablet MAL19986961ACZ

Manufacturer

SALUTAS PHARMA GMBH Otto-Von-Guericke-Allee 1, D-39179, Barleben, Germany.

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

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