

APO-ACYCLOVIR TABLET

Consumer Medication Information Leaflet (RiMUP)

Acyclovir (200mg, 400mg, 800mg)

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What Apo-Acyclovir is used for

Apo-Acyclovir is indicated for the treatment of herpes genitalis (a common sexually transmitted infection marked by genital pain and sore) and herpes zoster (shingles)

How Apo-Acyclovir works

Apo-Acyclovir is a prescription medication containing the active ingredient, acyclovir. Apo-Acyclovir is an antiviral medicine. It slows the growth and spread of the herpes virus so that the body can fight off the infection.

Before you use Apo-Acyclovir

- When you must not use it

Do not use this product if you are allergic to acyclovir, or any ingredients in this medication (refer to **Product Description**)

Pregnancy and lactation

Do not take Apo-Acyclovir if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Acyclovir if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before you start to use Apo-Acyclovir, your doctor needs to know any medical condition that you may have, including kidney and liver disease.

Inform your doctor if you are pregnant or plan to pregnant before taking Apo-

Acyclovir. Your doctor will discuss the risk and benefit of taking it with you.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Example of medicines that might interact with Apo-Acyclovir when taken together is probenacid, a medicine used to treat high uric acid.

Consult your doctor or pharmacist if you are not sure, as they will have a more complete and detail list of medicines that might interact with Apo-Acyclovir.

How to use Apo-Acyclovir

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Herpes Genitalis:

In general, the normal dose is 200mg 5 times a day (to be taken every 4 hours) for 10 days. However, your doctor may adjust the dose according to disease condition such as initial infection or recurrent infection.

Herpes Zoster:

800mg every 4 hours, 5 times daily for 7 to 10 days. Treatment should be initiated within 72 hours of the onset of lesions. In clinical trials, the greatest benefit occurred when treatment was begun within 48 hours of the onset of lesions.

If you have kidney problem, doctor will adjust the dose according to the severity of your kidney disease.

Children:

For treatment of herpes simplex

infections (cold sores) and the prevention of cold sores in the immune-compromised children, adult dose will be given to children of 2 years old and over. Children < 2 years will be given half the adult dose.

Treatment of Varicella infection (chicken pox):

doctor will calculate the dose base on 20mg/kg body weight 4 times daily for 5 days.

Take your dose according to what your doctor has prescribed. It may be different from the dose written in this leaflet.

- When to use it

Use as directed by your doctor or pharmacist. Swallow the tablet(s) with water and without chewing.

Your doctor will initiate the therapy for you as early as possible following the occurrence of signs and symptoms.

- How long to use it

Never increase or decrease the amount of Apo-Acyclovir given to you unless your doctor tells you to and do not stop taking this medication without consulting your doctor.

- 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

<p>poisoning. You may need urgent medical attention.</p>	<p>This is not a complete list of side effects for Apo-Acyclovir. If you are not sure, consult your doctor or pharmacist as they will have a more detail and complete list.</p>	<p>- Inactive ingredients Inactive ingredients (200mg): Lactose Monohydrate NF, Microcrystalline Cellulose, Magnesium Stearate, Croscarmellose Dosium, Indigotine Al Lake, Colloidal Silicon Dioxide.</p>
<p>While you are using it - <u>Things you must do</u></p>	<p>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).</p>	<p>Inactive ingredients (400mg): Purified Water, Magnesium Stearate, Croscarmellose Sodium, Red Ferric Oxide, Colloidal Silicon Dioxide, Microcrystalline Cellulose.</p>
<p>Take your medicine exactly as your doctor has told you.</p>	<p>Storage and Disposal of Apo-Acyclovir - <u>Storage</u></p>	<p>Inactive ingredients (800mg): Purified Water, Magnesium Stearate, Croscarmellose Sodium, Indigotine AL Lake, Brilliant Blue, Colloidal Silicon Dioxide, Microcrystalline Cellulose.</p>
<p>Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Acyclovir.</p>	<p>Remember to keep Apo-Acyclovir and all medications safely away from children.</p>	<p>- <u>MAL numbers:</u></p>
<p>Tell your doctor immediately if you become pregnant while taking this medication.</p>	<p>Do not use this medicine after the month and year written after EXP on the container.</p>	<p>Apo-Acyclovir 200mg tablet MAL19984321AZ</p>
<p>- <u>Things you must not do</u></p>	<p>Store Apo-Acyclovir at 20-25°C in a dry place and protected from light.</p>	<p>Apo-Acyclovir 400mg tablet MAL19984322AZ</p>
<p>Do not stop taking the medicine unless advised by your doctor.</p>	<p>- <u>Disposal</u></p>	<p>Apo-Acyclovir 800mg tablet MAL19984323AZ</p>
<p>Do not take any new medicines without consulting your doctor.</p>	<p>Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.</p>	<p>Manufacturer Apotex Incorporated, 150 Signet Drive, Weston, Ontario, Canada M9L 1T9</p>
<p>Do not give Apo-Acyclovir to anyone else, even if they have the same symptoms or condition as you.</p>	<p>Product Description - <u>What it looks like</u></p>	<p>Product Registration Holder Pharmaforte (M) Sdn Bhd 2, Jalan PJU 3/49 Sunway Damansara 47810 Petaling Jaya</p>
<p>- <u>Things to be careful of</u></p>	<p>The 200mg tablets are round, blue, flat-faced, beveled-edged tablets, engrave "APO" over "200" on one side, other side plain.</p>	<p>Date of revision 06/01/2016</p>
<p>If you feel any other forms of discomfort when you take the medication, let your doctor know as soon as possible.</p>	<p>The 400mg tablets are pink, round, flat-faced, beveled-edged tablets, engrave "APO" over "400" on one side, other side plain.</p>	<p>Serial Number BPFK(R4/1)041115/00396</p>
<p><u>Driving and using machines</u></p>	<p>The 800mg tablets are oval, blue, biconvex tablets, engrave "APO" over "800" on one side, other side plain.</p>	
<p>This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.</p>	<p>- <u>Ingredients</u></p>	
<p>Side effects Like all medicines, Apo-Acyclovir can cause side effects, although not everybody gets them.</p>	<p>- Active ingredient Acyclovir</p>	
<p>Adverse events observed in association with the use of Acyclovir include: Nausea, vomiting, headache, and less frequent side effects include diarrhoea, dizziness, and anorexia (eating disorder).</p>		
<p>Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.</p>		