

# HERPEVEX 400 TABLETS

# HERPEVEX 800 TABLETS

## Acyclovir

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### 1. What is HERPEVEX and what is its use

HERPEVEX belongs to a group of medicines called antivirals and it is used to treat herpes simplex infections.

HERPEVEX is indicated for:

- The treatment of herpes simplex virus infections of the skin and mucous membranes including initial and recurrent genital herpes.
- The suppression (prevention of recurrences) of recurrent herpes simplex infections in immunocompetent patients.
- The prophylaxis of herpes simplex infections in immunocompromised patients.
- The treatment of varicella (chickenpox) and herpes zoster (shingles) infections. Early treatment of shingles with HERPEVEX has a beneficial effect on pain and can reduce the

incidence of post-herpetic neuralgia (zoster-associated pain).

Ask your doctor why you have to take this medicine.

### 2. How HERPEVEX works

HERPEVEX works by killing or stopping the growth of viruses.

### 3. What you need to know before you take HERPEVEX

#### Do not take HERPEVEX

- In case of hypersensitivity to Acyclovir or valAcyclovir or to any of the other ingredients
- If you are pregnant or breast feeding mother

#### Be cautious with HERPEVEX

The dose of HERPEVEX must be adjusted in patients with kidney problems and elderly as acyclovir is eliminated by kidney. Both elderly patients and patients with kidney problems are at increased risk and should be closely monitored. In the reported cases, these reactions were generally reversible on discontinuation of treatment. Patients receiving higher oral doses of acyclovir should drink more water.

#### Pregnancy

Ask your doctor's or pharmacist's advice before you take any medicine.

#### Lactation

Ask your doctor's or pharmacist's advice before you take any medicine.

#### Driving or operating machinery

There is currently no evidence that taking Herpevex tablets can affect your ability to drive or operate machine ; however care should be taken when performing these tasks.

#### Administration of other medication

Let your doctor or pharmacist know if you are taking or have recently taken any other medicines, even the ones you buy without medical prescription, especially:

- Probenecid
- Cimetidine
- Mycophenolate mofetil

#### 4. How to take HERPEVEX

Ensure that patients on high doses of acyclovir drink more water.

Always take Herpevex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

#### If you take more Herpevex than you should

Herpevex is not usually harmful, unless you take too much over several days. Talk to your doctor or pharmacist if you take too much Herpevex. Take the medicine pack with you.

## Consumer Medication Information Leaflet (RiMUP)

### If you forget to take Herpevex

- If you forget to take Herpevex, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

### 5. Possible side effects

The frequency categories associated with the adverse events below are estimates. For most events, suitable data for estimating incidence were not available. In addition, adverse events may vary in their incidence depending on the indication.

The following convention has been used for the classification of undesirable effects in terms of frequency:-  
Very common 1/10, common 1/100 and <1/10, uncommon 1/1000 and <1/100, rare 1/10,000 and <1/1000, very rare <1/10,000.

#### Blood and lymphatic system disorders:

Very rare: Anaemia, leukopenia, thrombocytopenia.

#### Immune system disorders:

Rare: Anaphylaxis.

#### Psychiatric and nervous system disorders:

Common: Headache, dizziness.

Very rare: Agitation, confusion, tremor, ataxia, dysarthria hallucinations, psychotic symptoms, convulsions, somnolence, encephalopathy, coma.

The above events are generally reversible and usually reported in patients with renal impairment or with other predisposing factors (see 4.4 Special Warnings and Precautions for Use).

#### Respiratory, thoracic and mediastinal disorders:

Rare: Dyspnoea.

#### Gastrointestinal disorders:

Common: Nausea, vomiting, diarrhoea, abdominal pains.

#### Hepato-biliary disorders:

Rare: Reversible rises in bilirubin and liver related enzymes.

Very rare: Hepatitis, jaundice.

#### Skin and subcutaneous tissue disorders:

Common: Pruritus, rashes (including photosensitivity).

Uncommon: Urticaria.

Accelerated diffuse hair loss.

Accelerated diffuse hair loss has been associated with a wide variety of disease processes and medicines, the relationship of the event to Acyclovir therapy is uncertain.

Rare: Angioedema

#### Renal and urinary disorders:

Rare: Increases in blood urea and creatinine.

Very rare: Acute renal failure, renal pain.

Renal pain may be associated with renal failure and crystalluria.

#### General disorders and administration site conditions:

Common: Fatigue, fever.

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](http://portal.bpfk.gov.my) (Consumers → Reporting)

### 6. Storage and Disposal of HERPEVEX

#### Storage

- Keep them out of the reach of the children.
- Do not store in temperature over 25°C. Keep it at its original pack. Protect it from light and humidity. Do not use

it after its expiring date, recorded on the packaging.

#### Disposal

- 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.

### 7. Product Description

#### What HERPEVEX looks like

HERPEVEX 400 are white, flat, round tablets, scored on one side.

HERPEVEX 800 are white, concave, oblong tablets, scored on one side.

#### What HERPEVEX contains

The active ingredient is acyclovir.

The other ingredients are microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate.

#### Registration No:

HERPEVEX 400:  
MAL08082722AC

HERPEVEX 800:  
MAL08111837AC

### 8. Manufacturer:

Aegis Ltd,  
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**9. Marketing authorisation holder**

Apex Pharmacy Marketing  
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47500 Subang Jaya,  
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Malaysia.

**10. Date of Revision**

17 June 2013