

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Fenilabial 500mg film-coated tablet  
famciclovir

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Fenilabial has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **In this leaflet:**

1. What Fenilabial is and what it is used for
2. Before you take Fenilabial
3. How to take Fenilabial
4. Possible side effects
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### **1. What Fenilabial is and what it is used for**

Fenilabial is an antiviral medicine. It stops the infecting virus from reproducing. Since the virus reproduces very early in the infection, you will benefit most from treatment if you take Fenilabial as soon as the first symptoms appear.

#### **How Fenilabial works**

Fenilabial is used to treat cold sores (herpes labialis) of the lips in adults. Cold sores are an infection caused by a virus called herpes simplex type 1. Cold sores usually begin on or around the lips, as small red bumps that turn into fluid-filled blisters. Cold sores can be tender or painful. Many people who get cold sores know when one is coming by a tingling, burning, itchy or painful sensation or redness in the area.

### **2. What you need to know before you take Fenilabial**

#### **Do not take Fenilabial**

- If you are allergic (hypersensitive) to famciclovir, to any of the other ingredients of Fenilabial listed in section 6, or to penciclovir (the active metabolite of famciclovir and an ingredient of some other medicines).

**Ask your doctor for advice**, if you think you may be allergic.

#### **Warnings and precautions**

##### **Talk to your doctor or pharmacist before taking Fenilabial:**

- If you have kidney problems (or have had them before), please refer to your doctor who may recommend you another treatment.
- If you have problems with your body's immune system.
- If you have liver problems.

If any of these applies to you, tell your doctor before you take Fenilabial.

Children and adolescents (below the age of 18 years)

Fenilabial is not recommended for use in children and adolescents.

### **Other Medicines and Fenilabial**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Before taking Fenilabial, it is especially important that you tell your doctor or pharmacist if you are taking any of the following medicines:

- Raloxifen (used to prevent and treat osteoporosis).
- Probenecid (used to treat high blood levels of uric acid associated with gout and to increase blood levels of penicillin-type antibiotics), or any other medicine that can affect your kidneys.

### **Taking Fenilabial with food and drink**

You can take Fenilabial with or without food.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or think you may be, tell your doctor. Fenilabial is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risks of taking Fenilabial during pregnancy.

If you are breast-feeding, tell your doctor. Fenilabial is not to be used during breast-feeding unless clearly necessary. Your doctor will discuss with you the possible risks of taking Fenilabial during breast-feeding.

### **Driving and using machines**

Fenilabial can cause dizziness, drowsiness or confusion. **Do not drive or use machines** if you have any of these symptoms while taking Fenilabial.

### **Important information about other ingredients of Fenilabial**

Fenilabial contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Fenilabial**

Always take this medicine exactly as described in this leaflet or as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

- For the best results start the medicine as soon as possible after the first signs and symptoms appear.
- If you have or have had kidney problems, please refer to your doctor who may recommend you another treatment.

The tablets cannot be split in half. For dose recommendations that are not possible with this product, other medicinal products should be used.

### **Dose for cold sores**

If you have a normal immune system, the recommended dose is three tablets of 500 mg taken together as a single dose.

Clinical efficacy data have not been presented for Fenilabial when administered more than 1 hour after the first symptoms. Therefore Fenilabial tablets should be taken as soon as possible after the first symptoms (e.g. tingling, itching or burning) or signs (e.g. redness or swelling) of a cold sore appear. Do not take the tablets if a hard crust has already formed on the cold sore.

The minimum time interval between two treatments of recurrent cold sores has not been defined. Always take this medicine exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

### **Method of administration**

Swallow each tablet whole with a glass of water. Fenilabial can be taken with or without food. It is not necessary to chew or crush the tablet.

### **If you take more Fenilabial than you should**

If you have taken more than 3 tablets in a single dose, or if someone else accidentally takes your medicine, go to your doctor or hospital for advice immediately. Show them your pack of tablets.

Taking too much Fenilabial may affect the kidneys. In people who already have kidney problems it may, rarely, lead to kidney failure if their dose is not correctly lowered.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Fenilabial can cause side effects, although not everybody gets them. The side effects caused by Fenilabial are usually mild to moderate in intensity.

### Serious side effects of Fenilabial are:

Most of these side effects are rare (may affect up to 1 in every 1,000 people) or uncommon (may affect up to 1 in every 100 people)

- **Severe blistering** of the skin or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (these could be signs of a serious allergic skin reaction).
- **Unexplained bruising**, reddish or purplish patches on the skin or **nosebleeds** (these could be signs of a decrease in the number of blood platelets).
- **Swelling** below the surface of the skin (e.g. facial swelling, swelling around eye, eyelid swelling, throat swelling).
- **Yellowing** of the skin and/or eyes (signs of jaundice).

**Contact a doctor or go to the emergency department at your nearest hospital straight away** if you get any of these effects.

**Some side effects are very common** (may affect more than 1 in 10 people)

- Headache

**Some side effects are common** (may affect up to 1 in 10 people)

- Feeling sick (nausea)
- Vomiting
- Dizziness
- Rash
- Itching
- Liver function test giving abnormal results

**Some side effects are uncommon** (may affect up to 1 in 100 people)

- Confusion
- Drowsiness (usually in older people)
- Itchy rash (urticaria)
- Diarrhoea

**Some side effects are rare** (may affect up to 1 in 1,000 people)

- Hallucinations (seeing or hearing things that are not really there)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

IMB Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.imb.ie](http://www.imb.ie)

e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Fenilabial**

- Keep this medicine out of the sight and reach of children.
- Do not use Fenilabial after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month. Do not store above 25°C.
- Do not use Fenilabial if you notice the pack is damaged or shows signs of tampering.
- 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.

### **6. Further information**

#### **What Fenilabial contains**

The active substance is famciclovir.

One film-coated tablet contains 500 mg famciclovir.

The other ingredients are

#### **Tablet core:**

Lactose anhydrous

Hydroxypropylcellulose

Sodium Starch Glycollate, type A

Magnesium Stearate

#### **Tablet coat:**

Hypromellose

Titanium Dioxide (E171)

Macrogol 4000

Macrogol 6000

#### **What Fenilabial looks like and contents of the pack**

Fenilabial 500 mg film-coated tablets are oval, white-tablets marked 'FV 500' on one side and plain on the reverse side.

They come in blister packs of 3 tablets.

#### **Marketing Authorisation Holder and Manufacturer**

Novartis Consumer Health UK Limited

Trading as Novartis Consumer Health

Watchmoor Park

Camberley, GU15 3YL  
UK

**This leaflet was last approved in June 2015**