

PATIENT INFORMATION LEAFLET



ASIVIRAL® 5% Cream

For external use

- **Active Ingredient:** Each 1 gr cream contains 50 mg acyclovir.
- **Inactive Ingredients:** Nipagin M (Methylparaben), cetostearyl alcohol, sodium lauryl sulfate, propylene glycol, deionized water.

Read all of this LEAFLET carefully before you start using 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, please ask to your doctor or pharmacist.
- This medicine is prescribed only for you. Do not pass it on to others.
- If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.
- Please strictly follow instructions in this prescribing leaflet. Do not take **lower or higher dose** than recommended dose.

What is in this leaflet:

1. What is ASIVIRAL and what it is used for?
2. What you need to know before you use ASIVIRAL.
3. How to use ASIVIRAL?
4. What are possible side effects?
5. How to store ASIVIRAL?

1. What is ASIVIRAL and what it is used for?

ASIVIRAL is an antiviral medicine that is effective to Herpes Simplex Virus (HSV) type I and II and Varicella zoster infection.

ASIVIRAL contains acyclovir as active ingredient and presented as 10 g aluminum tube.

ASIVIRAL is used for treatment of Herpes Simplex skin infections (herpes) including the first and recurrent Herpes genitalis and Herpes labialis.

2. What you need to know before you use ASIVIRAL DO NOT USE ASIVIRAL in following cases;

- If any allergic reaction happens while using ASIVIRAL (rash, regional pain or swelling) stop using the medicine and talk to your doctor.
- Do not use this medicine if you are allergic to acyclovir, valacyclovir (an antiviral medicine), propylene glycol or any of the other ingredients.

TAKE SPECIAL CARE with ASIVIRAL in following cases;

- Since it might irritate, it is not recommended for ASIVIRAL to be applied on areas such as mouth, eyes or vagina. Take special care not to contact with eyes.
- If you suffer from severe immune weakness (for example, AIDS disease or bone marrow transplantation), oral forms of ASIVIRAL may be considered.
- If you have such kind of disease, you should consult your doctor for treatment of any infection.
- Cetostearyl alcohol contained in ASIVIRAL might cause local skin infections (ex. contact dermatitis)
- Due to its special base, ASIVIRAL shouldn't be diluted or used for dilution of other medicines.

If such warnings addresses you, even for any period at past, please contact your doctor.

Taking ASIVIRAL with food and drink

Not applicable.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant or you thing that you might be pregnant, please tell this to your doctor. ASIVIRAL can be used during pregnancy, only if the benefits are higher than the risks.

If you notice that you are pregnant during your treatment, immediately contact your doctor or pharmacist.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

When cream form of ASIVIRAL is used during breastfeeding, amount that passes to the baby from milk is not considered as important.

Driving and using machines

No data about effect on ability to drive or use machines.

Important information about some of the inactive ingredients of ASIVIRAL

Since it contains propylene glycol, it may cause skin rash. Cetostearyl alcohol contained in ASIVIRAL might cause local skin infections (ex. contact dermatitis). Always wash your hands before and after applying cream.

Taking other medicines

ASIVIRAL shouldn't be mixed with other creams or ointments.

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

3. How to use ASIVIRAL?

Instructions for appropriate usage and dosing/administration frequency:

- Follow instructions of your doctor for application of ASIVIRAL.
- Apply ASIVIRAL 5 times a day with 4-hour intervals, by skipping night dose.
- Apply ASIVIRAL to the affected area as soon as possible after commencement of indications or infection (intuition about reddening or disease). You can start treatment during following symptoms (swelling or blisters). Treatment should continue minimum 4 days for herpes labialis, and minimum 5 days for genital herpes. If there is no healing, treatment may continue for 10 days.

ÜRÜN ADI	ASIVIRAL 5% Cream-ing MYFARMA KT	ORJİNAL	NUMUNE	ÇALIŞMA NO.	2
DEĞİŞİKLİK TARİHİ	9 ŞUBAT 2022	EBAT	160 x 270 mm	BIÇAK NO.	
HAZIRLAYAN	RENKLER	MALZEME CİNSİ	1.hamur 60 g	AÇIKLAMA 8 punto ile çalışılmalıdır	
Nazife Uygur	Black	FARMA KOD			
		KONTROL NO	502001 017.001		

Application Method:
Apply a small amount on affected area.

- Different age groups:**
- **Use in Children:** No data is available
 - **Use in Elderly:** No data is available

Special Application: No data is available

If you have impression for effect of the ASIVIRAL for being too strong or weak, consult to your doctor or pharmacist.

If you use more ASIVIRAL than you should:
No adverse effect is expected. However, in cases where acyclovir is taken orally repetitively by mistake; it caused gastro-intestinal (nausea and vomiting) and neurologic (headache and confusion) effects. Acyclovir might be cleaned with hemodialysis (treatment administered for cleaning blood).

If you use more ASIVIRAL than your prescribed dose, contact a doctor or pharmacist.

If you forget to use ASIVIRAL:
Do not apply a double dose to make up for forgotten doses.

Possible effects after completion of ASIVIRAL treatment
Do not stop using medicine without consulting your doctor.

4. What are possible side effects?
Like all medicines, ASIVIRAL can have side effects on persons who are sensitive to the materials in its content.

STOP using ASIVIRAL and IMMEDIATELY contact your doctor or go to emergency service of the nearest hospital if any of the following happens: Hypersensitivity reactions

- Allergic reactions such as rash, itching or hives,
- Swelling of the face, lips, tongue or other parts of body. Hypersensitivity reactions are very rare.

Side effects are classified as following categories:
Very common: minimum 1 in 10 patients are affected
Common: fewer than 1 in 10, but more than 1 in 100 patients are affected
Uncommon: fewer than 1 in 100, but more than 1 in 1000 patients are affected
Rare: fewer than 1 in 1000 patients are affected
Very rare: fewer than 1 in 10,000 patients are affected
Not known: frequency cannot be estimated from the available data

Uncommon side effects:

- Mild burning or stinging on skin
- Mild dryness and peeling on skin
- Itching

Rare side effects:

- Reddening
- Contact dermatitis (a kind of skin disease)

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting of Side Effects
If you get any side effects listed or not listed in this leaflet, please give information to your doctor, pharmacist or nurse. You can also report side effects directly to Turkish Pharmacovigilance Center (TÜFAM) by calling 0 800 314 00 08 or by clicking “Medicine Side Effect Notice” icon at www.titck.gov.tr. By reporting the occurred side effects, you can help provide more information on the safety of this medicine.

5. How to store ASIVIRAL?
Keep ASIVIRAL out of sight and reach of children, and store in its package.
Keep this medicine at room temperature lower than 25°C. Protect from light and humidity.
Use in accordance with the expiration date.
Do not use ASIVIRAL after the expiry date, which is stated on the package.

Registration Holder: Terra İlaç ve Kimya Sanayi ve Ticaret A.Ş.
Ümraniye/İstanbul - TURKEY
Manufacturer: Myfarma İlaç San. ve Tic. A.Ş.
Tuzla/İSTANBUL-TURKEY

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