

## PATIENT INFORMATION LEAFLET

### AKNEFLOKS 1% cream

#### For external use.

- **Active substance:** Each 1 gram cream contains 10 mg nadifloxacin.
- **Excipients:** Methyl paraben (E218), phenylethyl alcohol, triethanolamine, glycerin, cetyl alcohol, stearyl alcohol, cetostearyl alcohol, oleic acid, ethyl alcohol, and purified water.

**Read all of this PATIENT INFORMATION 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher** or **lower** dose other than the recommended to you.*

#### What is in this leaflet:

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

#### **1. What AKNEFLOKS is and what it is used for?**

- AKNEFLOKS is an almost white colored cream marketed in aluminum tubes containing 30 grams of cream and used externally.  
The main active substance is nadifloxacin and it has bacterial and germicidal properties.
- AKNEFLOKS is used for the topical (application to body surfaces) treatment of inflammatory acne and superficial skin infections.

#### **2. What you need to know before you AKNEFLOKS**

##### **DO NOT use AKNEFLOKS**

If you are allergic (hypersensitive) to nadifloxacin or any of the other ingredients of the AKNEFLOKS

As AKNEFLOKS is not tested in children below 14 years of age, do not use to treat acne in this age group.

#### **Warnings and precautions:**

Avoid contact with the eyes, mouth and nose of AKNEFLOKS.

In case of accidental contact with your eyes, mouth or nose, rinse the contacted area thoroughly with plenty of water. Wash your hands after applying AKNEFLOKS to prevent accidental applying to other areas.

Although no effect was observed in studies, avoid contact with sunlight of administration site and avoid from ultraviolet radiation, sunbathing and solarium during use, as for as possible.

If itching, discomfort, pustule, cyst or any severe condition occur, stop using the product and consult your doctor.

Do not apply to areas where there are open wounds.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

**AKNEFLOKS with food and drink:**

There is no interaction with food and drinks.

**Pregnancy:**

*Consult your doctor or pharmacist before taking this medicine.*

Tell your doctor before using AKNEFLOKS, if you are pregnant or there is a possibility that you may be pregnant.

*Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.*

**Breast-feeding:**

*Consult your doctor or pharmacist before taking this medicine.*

AKNEFLOKS cream should not be used during breast-feeding.

AKNEFLOKS cream should not be applied to the breast area during lactation.

**Driving and using machines:**

Any effect on driving and using machines of AKNEFLOKS has not shown.

**Important information about some of the excipients of AKNEFLOKS**

AKNEFLOKS contains cetyl alcohol, stearyl alcohol and cetostearyl alcohol which may lead to local skin reactions (e.g. contact dermatitis; a skin disease that occurs with contacting).

This medicinal product contains methyl paraben (E218) which may cause allergic reactions which can possibly be delayed.

**Other medicines with AKNEFLOKS**

It should be considered that concomitant use of AKNEFLOKS with products which act by peeling the skin or products (alcohol, aromatic agents) containing ingredients that generate damage may increase the skin irritation.

AKNEFLOKS is suitable for use with other acne treatments.

*If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.*

### **3. How to use AKNEFLOKS?**

- **Instructions for use and dosage/frequency of administration:**

AKNEFLOKS is a topical cream. Apply AKNEFLOKS to affected area twice per day in the morning and at bedtime. The treatment duration is generally eight (8) weeks. Your doctor will tell you on the appropriate duration of treatment with AKNEFLOKS. Do not interrupt treatment without obtaining the desired result.

- **Route of administration and method:**

Carefully wash and dry your skin before applying the cream. Apply the cream by using cotton to prevent any possible infection. Avoid contact with eyes and lips of the cream. Wash your hands after applying.

- **Different age groups:**

**Use in children:**

AKNEFLOKS should not be used in children below 14 years of age.

**Use in elderly:**

There is no special usage.

**Special cases of use:**

**Kidney/Liver failure:**

There is no special usage.

*If you have impression that the effect of AKNEFLOKS is very strong or weak, tell a doctor or pharmacist.*

**If you use more AKNEFLOKS than you should:**

AKNEFLOKS is not to be taken orally and is for topical use only. If the medication is applied excessively and repeatedly, no more rapid or better results will be obtained and marked redness and discomfort may occur.

Unless the amount accidentally ingested is small, an appropriate method of gastric emptying should be considered

*If you take more AKNEFLOKS than you should, tell your doctor or pharmacist.*

**If you forget to use AKNEFLOKS:**

*Do not take a double dose to make up for a forgotten dose.*

**If you stop using AKNEFLOKS:**

Not applicable.

### **4 . Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you notice any of the following, please tell your doctor:**

- Itching
- Pustule
- Dryness
- Skin irritation
- Burning sensation

- Redness
- Hives (urticaria)
- Decolorization of skin

These represent mild side effects of AKNEFLOKS.

*If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.*

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website [www.titck.gov.tr](http://www.titck.gov.tr) or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store AKNEFLOKS**

*Keep this medicine out of the sight and reach of children in the original package.*

Store at room temperature below 25°C.

#### **Use in accordance with expiry date.**

*Do not use AKNEFLOKS after the expiry date which is stated on the packaging or tube.*

Do not use AKNEFLOKS if you notice any damage on product and/or packaging.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism

#### ***Marketing authorization holder:***

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

[info@berko.com.tr](mailto:info@berko.com.tr)

#### ***Manufacturer:***

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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