

## PATIENT INFORMATION LEAFLET

### AKNEFLOKS 1% cream

For topical use.

**Active substance(s):** Each 1 gram cream contains 10 mg nadifloxacin.

**Excipient(s):** Methyl paraben, phenylethyl alcohol, triethanolamine, glycerin, cetyl alcohol, stearyl alcohol, cetostearyl alcohol, oleic acid, ethyl alcohol, deionized water.

**Read 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

#### In this leaflet:

1. ***What AKNEFLOKS is and what it is used for?***
2. ***Before you use 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 a cream for topical use and presented in aluminum tubes of 30 g. The main active substance is nadifloxacin and it has bacterial and germicidal properties.

AKNEFLOKS is used for topical (application to body surfaces) treatment of inflammatory acne and superficial skin infections

#### **2 – Before you use AKNEFLOKS**

**Do not use AKNEFLOKS in the following conditions**

If:

- You are allergic (hypersensitivity) to nadifloxacin or any of the other ingredients of AKNEFLOKS,
- As AKNEFLOKS is not tested in children under 14 years old, do not use this medicine in the treatment of acne in children under 14 years old.

#### **TAKE SPECIAL CARE WITH AKNEFLOKS in the following conditions:**

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, blisters, cyst or any severe condition occur, stop using the product and consult your doctor.

Do not apply to areas where there are open wounds

Please consult your doctor, even if these statements were applicable to you at any time in the past.

**Using AKNEFLOKS with food and drink:**

There is no interaction with food and drinks.

**Pregnancy:**

*Ask your doctor or pharmacist for advice before using the medicine.*

Consult your doctor before using AKNEFLOKS, if you are pregnant or likely to be pregnant,

*If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.*

**Breastfeeding:**

*Ask your doctor or pharmacist for advice before using the medicine.*

AKNEFLOKS cream should not be used during breastfeeding.

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

**Effects on ability to drive and use machines:**

Any effect on ability to drive and use machines of AKNEFLOKS has not shown.

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

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

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

**Using with other medicines**

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.

*Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.*

**3 – How to use AKNEFLOKS?**

**Instructions for appropriate method and dose/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 and method of administration:**

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 under 14 years old.

**Use in elderly:**

There is no special usage.

**Special populations:****Kidney/Liver failure:**

There is no special usage.

*If you have the impression that the effect of AKNEFLOKS is too strong or too weak, talk to your doctor or pharmacist.*

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 have used more AKNEFLOKS than you should:**

*If you may have taken more AKNEFLOKS than you should, talk to a doctor or pharmacist.*

**If you forget to use AKNEFLOKS:**

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

**If you stop using AKNEFLOKS:**

Not applicable.

**4 - Possible side effects?**

Like all medicines, side effects can occur in people sensitive to the contents of AKNEFLOKS.

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

- Itching
- Pustule
- Dryness
- Skin irritation
- Burning sensation
- Redness
- Blistering
- Decolorization of skin

These are mild side effects of AKNEFLOKS.

*If you notice any side effects not mentioned in this leaflet, 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 in the original package and out of the reach and sight of children.*

Store in room temperature under 25°C.

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

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

Do not use AKNEFLOKS if you notice any damage to the product and/or package.

### ***Marketing Authorization Holder:***

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