

Patient Information Leaflet

1. DETERMINATION OF THE PHARMACEUTICAL PRODUCT

1.1 Name: ARFAREL

1.2 Composition:

Active ingredient: Clindamycin phosphate

Excipients: Propylene glycol, Isopropyl alcohol, Purified water.

1.3 Pharmaceutical form: Dermal solution

1.4 Strength: Arfarel dermal solution contains Clindamycin phosphate 12,42mg equivalent to 10 mg Clindamycin per 1 ml of aqueous-alcoholic solution

1.5 Description Packaging: Plastic vial with polyethylene dropper cup containing 30 ml of a transparent, colorless solution in carton box with an instruction leaflet.

1.6 Therapeutical category: Antibiotic.

1.7 Marketing Authorization Holder-Manufacturer: IASIS PHARMA HELLAS S.A
137, Filis Ave., 134 51 Kamatero, Athens GREECE. Tel.: + 30 210 2311031

2. THINGS THAT YOU SHOULD KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

The clindamycin phosphate is an ester of clindamycin and semisynthetic antibiotic. Depending on the sensitivity of the microorganism and the concentration of the antibiotic, clindamycin may be bactericidal or bacteriostatic.

The clindamycin has no fungicidal activity. The clindamycin phosphate is hydrolyzed by phosphatases of the skin to active clindamycin base.

2.1 Therapeutic indications

ARFAREL is indicated for the treatment of acne (especially for the inflammatory).

2.2 Contraindications

Clindamycin (clindamycin phosphate) is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin or to any of the excipients. Also it is contraindicated in individuals with a history of ulcerative colitis or inflammatory bowel disease or enteritis or antibiotics associated colitis.

2.3 Special warnings and precautions for use

2.3.1 General: Most antibiotics, including clindamycin, have been associated with severe diarrhoea and pseudomembranous colitis.

Cases of diarrhea and colitis following the topical use of clindamycin have rarely been reported.

Consequently, the physician should take into account the possible occurrence of diarrhea or colitis associated with antibiotic. If you have diarrhea or if you are allergic person, tell your doctor.

If a severe or prolonged diarrhea occurs, the medication should be discontinued and the appropriate diagnostic procedures and treatment should be applied.

2.3.2 Elderly: The same that apply to adults.

2.3.3 Pregnancy: The safety of administration of clindamycin has not been established yet. Clindamycin can be used during pregnancy only if the physician considers it absolutely necessary.

Lactation: It is not known whether clindamycin is excreted in human milk following use of ARFAREL. As a general rule, you should not breastfeed during the treatment with ARFAREL.

2.3.4 Children: Do not use ARFAREL to children below 12 years old.

2.3.5 Effects on ability to drive and use machines: None.

2.3.6 Special warnings for the excipients: ARFAREL dermal solution contains propylene glycol. This must be taken under consideration in patients with a history of hypersensitivity to propylene glycol.

2.3.7 Incompatibilities: The concomitant administration of topical clindamycin with medicines containing benzoyl peroxide is not recommended.

2.3.8 Interaction with other medicinal products or substances: Tell your doctor if you are taking other medicines. Antagonism has been demonstrated between clindamycin and erythromycin. Clindamycin for topical use may be used successfully in combination with other anti-acne preparations, but their time of application should be different. The clindamycin may potentiate the neuromuscular blockade during general anesthesia. If you're going to have surgery, tell your doctor that you are being treated with this medicine.

2.4 Dosage Mode of use

Route of Administration: Topical (only for external use).

Instructions: The clindamycin for topical use is applied twice daily to the affected area. No rubbing of the skin is needed for the medicine to penetrate.

Caution to the administration: In case of contact in error with sensitive surfaces (eyes, eroded skin, mucous membranes), these surfaces should be washed with large amounts of cool water. The solution has an unpleasant taste and caution should be exercised when this drug is used around the mouth.

2.5 Overdosage

No overdose symptom usually occur following topical application. The accidental ingestion of the drug can cause the same side effects with those reported after administering oral clindamycin. Consult your doctor about the treatment of the symptoms.

2.6 Undesirable effects

The following undesirable effects that have been reported from the topical use of clindamycin are: dryness, erythema, burning, burning/itching, exfoliating, oiliness/oily skin, itching, urticaria, gastrointestinal disorders, abdominal pain, diarrhea and colitis, contact dermatitis, gram negative folliculitis, oiliness of the skin, skin irritation and stinging of the eye. As with any substance applied to the skin, an allergic reaction may occur to any ingredients of ARFAREL.

2.7 Things that you should know if you miss a dose

Should the medicine be administered uninterruptedly and you have missed a dose, you should take the missed dose as soon as possible. If the appropriate time for the next dose administration is close, do not take the dose you have missed, but continue normal treatment instead. Do not double the doses.

2.8 Expiration date of the product

It is indicated on the outer and inner packaging. Do not use this medicine after the expiration date.

2.9 Special precautions for storage: Store in temperature not exceeding 25°C.

2.10 Date of last product information leaflet revision: 1-3-2010

3. INFORMATION ON THE RATIONAL USE OF MEDICINES

- This medicine was prescribed by your doctor for your specific health problem. You should not administer it to others or use it yourself for other health problems, without prior consent from your doctor.
- Inform immediately your doctor or pharmacist if a problem appears during the treatment.
- If you have any questions regarding your health problem, do not hesitate to contact your doctor or pharmacist and ask for additional information.
- The medicine that was prescribed to you is safe and effective only when administered according to your doctor's or pharmacist instructions.
- It is important for your safety and your health to read carefully all information regarding the medicine that was prescribed to you.
- Do not store medicines in bathroom closets since heat and humidity may alter them and render them hazardous for your health.
- Do not store medicines that are no more useful to you or have already expired.
- For more safety keep medicines in a secure place away from children

4. MODE OF ADMINISTRATION

This is a prescription only medicine.