PACKAGE LEAFLET: INFORMATION FOR THE USER

Funis®
2,5% + 2,5% cream
Lidocaine and Prilocaine

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Funis®

1.2. Composition:

Active substances: Lidocaine and Prilocaine.
Excipients: Castor oil hydrogenated, Carbomer, Sodium hydroxide, Water purified.

1.3. Pharmaceutical form

Cream.

1.4. Quantitative composition

Each g of cream contains 25 mg (2.5%) lidocaine and 25 mg (2.5%) prilocaine as bases.

1.5. Nature and content of the container

Each aluminum tube, coated inside with protective lacquer contains the named amount of cream and is enclosed in a carton with a package leaflet..
Package containing 5 tubes of 5g, 10 dressings and a leaflet.
Package containing 10 tubes of 5g, 25 dressings and a leaflet.
Package containing 1tube of 15g and a leaflet
Package containing 1tube of 30g and a leaflet
Package containing 1tube of 30g, 15 dressings and a leaflet
Not all packages may be marketed.

1.6. Pharmaceutical group

Local anesthetic.

1.7. Marketing Authorization Holder:

TARGET PHARMA LTD, 54, Menandrou str., 104 31 Athens,
Tel.:30 210 5224830, Fax: 30 210 5224838,
e-mail: info@targetpharma.gr, http://www.targetpharma.gr

1.8. Manufacturer

Pharmaceutical Industry PROEL, 9 Dilou , 12134 Peristeri, Athens.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

All information in this leaflet refers to the medicinal product **Funis®** that your doctor prescribed to you. Please read this carefully. You will receive important information, but not everything can be explained in this document. If you have more questions or if you are not sure about something in this leaflet, ask your doctor of pharmacist.

2.1. General information

Funis® is applied on the skin to cause temporary loss of sensation or numbness at the spot of application. However, sensations such as the feeling of pressure or touch are maintained in the area.
The desired result is achieved about half hour to one hour after application.

2.2. Indication

Topical amaesthesia of the skin in connection with:
- preparation for needle insertion e.g. intravenous or intrarterial catheters or pantures.
- performing superficial surgical procedures on the skin near genitals or genital mucosa, e.g. for the removal of wrists, circumcision or lesions of foreskin.

2.3. Contraindications

Do not use **Funis®**:
- if you allergic in the active substances lidocaine, prilocaine or any other similar topical anaesthetic.
- if you have an allergy or sensitivity to any of the excipients of the cream.
- if you suffer from congenital, acquired or through poisoning methemoglobinemia.
- on infants younger than (3) months old.
- if you suffer from atopic dermatitis.

2.4. Special warnings and precautions for use

2.4.1. General:

Before you use **Funis®**, inform your doctor or pharmacist for any other medicines you may take, including those that you buy without medicinal prescription.
Funis® should be applied only on healthy intact skin. Do not use in areas with inflammation, erythema, cuts scratches or other sores. If you have any of the above consult your doctor or pharmacist before using it.
Do not apply **Funis®** near the eyes, because it can cause irritation.
If **Funis®** accidentally goes to your eyes, rinse them with plenty of lukewarm water.
It should not be applied to the ear in cases where there is puncture or rupture of the tympanic membrane, as absorption in the middle ear may be othotoxic.
Patients with severe liver disease are at greater risk of developing toxic plasma concentrations of lidocaine and prilocaine.
Caution is needed when **Funis®** is applied to patients with dermatitis and in patients with G6PD deficiency.
Funis® should not be used before intradermal injection of vaccines containing live micro-organisms.

Funis® should not be used:
- in infants 3-12 months old, which are under treatment with drugs that may cause methemoglobinemia such as sulfonamides, antimalarials. (see also “possible side effects”)

- before intradermal injection of vaccines containing live micro-organisms e.g BCG, because interaction between active substances of **Funis®** and vaccine cannot be excluded.

2.4.2. Elderly:

See in section "Dosage for Adults".

2.4.3. Pregnancy:

Funis® should be used during pregnancy only if this is absolutely necessary and the expected benefit overcomes possible risk for the embryo.

2.4.4. Lactation:

Lidocaine and possible prilocaine are excreted in human milk, but this excretion is rather small when the recommended doses are used that there is no risk for the newborn. Generally, however, it should be used with caution in nursing women.

2.4.5. Children:

Funis® should not be administered to infants younger than 3 months old.

2.4.6. Effect on the ability to drive or use machines:

There is no effect when the recommended doses are administered.

2.4.7. Special warnings about the excipients:

None.

2.5. Interactions with other medicines or substances

Patients that receive drugs that may induce methemoglobinemia e.g. sulfonamides, antimalarials, **Funis®** may enhance formulation of methemoglobulin (See also "Possible side effects").
Funis® should be used with caution in patients that receive class I antiatythmic drugs (quinidine, procainamide, mexiletine, etc.).

2.6. Posology

Funis® is applied to the skin under occlusive dressing.
Funis® causes topical skin anesthesia. The depth of anesthesia depends on the application time, the quantity used and the point of application.

Area / Age	Surgical procedure	Dosage and application time
Skin		Apply a thick layer of cream to the skin and cover with an occlusive dressing
Adults		Recommended dose: 1.5g/10cm^2 of skin area
	Minor interventions e.g. insertion of needles and surgical	2 g (about half of the 5g tube) Minimum application time 1h,

	treatment of localized lesions	Maximum appl. time 5h [1]
	Interventions in larger areas of the skin e.g. partial skin transplantation.	About 1.5-2 g/10 cm^2 Minimum application time 2h, Maximum appl. time 5h [1]
Children Infants 3-11 months [2] Toddlers 1-5 years Children 6-11 ετών	Minor interventions e.g. insertion of needles and surgical treatment of localized lesions.	About 1.0 g/10 cm^2 Application time: 30 min to 1h. Up to 2.0 g and up to 20 cm^{2} [2,3] Up to 10.0 g and up to 100 cm^2 Up to 20.0 g and up to 200 cm^2
Skin near genitals Adults	Surgical treatment of localized lesions e.g. removal of genital warts (wrinkled warts), circumcision or solution of the foreskin.	Apply approximately 5-10g **Funis®** for 5-10 min. No impermeable dressing is required. The surgery should be done immediately afterwards.

[1] If the application of the cream remains for longer period of time, anesthesia decreases.
[2] Until there is further clinical experience, **Funis®** should not be used in infants up to 12 months of age receiving treatment with methemoglobin-inducing agents.
[3] There was no clinically significant increase in methemoglobin levels after application up to 4 hours on a 16 cm^2 area.

2.7. Overdose – Management

High doses of prilocaine may cause increase in the levels of methemoglobulin, especially when combined with methemoglobulemia causing agents (eg sulfonamides).
However, if systemic toxicity occurs after topical application of **Funis®** to the skin, signs similar to those seen from the administration of local anesthetics through other routes of administration are expected.
Toxicity of local anesthetics manifested by excitation of the nervous system and in serious cases with suppression of the central nervous and cardiovascular system.
Serious neurological symptoms (convulsions, suppression of CNS) should be treated symptomatically, with respiratory support and medication against seizures. Methemoglobinemia can be treated by slow intravenous administration of methylene blue.
Because absorption from intact skin is slow, patients with any signs of toxicity should be monitored for several hours after initial symptom management.

Poison Center Athens, Tel: +30 210 7793777.

2.8. Possible side effects:

Topical reactions such as paleness, erythema and edema caused by **Funis®** at the site of application are common. These reactions are transient and usually mild.
An initial feeling of burning or itching is observed at a lesser frequency.
Allergic reactions (in serious cases anaphylactic shock) in local amide-type anesthetics and increase in methemoglobin levels are rare.
Prilocaine in high doses may cause increase in the levels of methemoglobin. (it has been reported case of methemoglobinemia to an infant of 3 months, that received sulfonamide and received also treatment with high dose of lidocaine+prilocaine (2.5+2.5)% cream on intact skin).
If you notice any uncomfortable or unusual sign during **Funis®** application, stop using the cream and tell your doctor as soon as possible.

In case you experience a side effect caused by this medicine, you should report it to your doctor or pharmacist or any other health care professional or directly to the National Drug Organization (284 Mesogeion Av. 15562, Cholargos, Athens Greece, www.eof.gr).

2.9. What should you know if you miss a dose:

Not applicable.

2.10. What should you know about the expiration date:

This medicine should not be taken if the expiration date mentioned in the container has passed.

2.11. Special precaution for storage

Store below 25˚C. Do not freeze.

2.12. Date of last revision of the text

13 January 2015

3. ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΤΗΝ ΟΡΘΟΛΟΓΙΚΗ ΧΡΗΣΗ ΤΩΝ ΦΑΡΜΑΚΩΝ

- This medicine has been prescribed for you by your doctor only for your particular medical problem. Do not pass it on to others or use it in other medical problems without taking previously advice by your doctor.
- If any problem with the medicine occurs during the treatment contact immediately your doctor or your pharmacist.
- If you have any questions about the information concerning the medicine that you use or you need better advising for your medical problem do not you hesitate to ask this information from your doctor or your pharmacist.
- To be effective and safe the medicine, which is prescribed for you, it must be used according to the given information.
- For your safety and health it is necessary to read carefully any information concerning your prescribed medicine.
- Do not store the medicines in bath lockers, because the heat and moisture can degrade the medicine and make it harmful for your health
- Do not keep the medicine, which you do not need any more or those that have expired.
- Keep all medicines in safe place out of the reach and sight of children.

4. PRESCRIBING INFORMATION

This product is subjected to medicinal prescription.