PACKAGE LEAFLET:INFORMATION FOR THE USER

Fubecot®
2% + 0,1% cream
Fusidic acid + Betamethasone (as valerate)

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Fubecot®

1.2. Composition

Active substances: Fusidic acid and Betamethasone valerate.
Excipients: White soft paraffin, Cetostearyl alcohol, Paraffin liquid, Cetomacrogol 1000, Sodium dihydrogen phosphate, Chlorocresol, Sodium hydroxide, Water purified.

1.3. Pharmaceutical form

Cream for external use.

1.4. Quantitative composition

Each g of **Fubecot®** cream contains 20 mg fusidic acid and 1 mg betamethasone.

1.5. Nature and contents of the container

- Each box contains one tube of 15 g cream for external use and a leaflet.
- Each box contains one tube of 30 g cream for external use and a leaflet.

1.6. Pharmacotherapeutic group

Antibioitc and corticosteroid combination (ATC: D07CC01).

1.7. Marketing Authorization Holder

ΤΑΡΓΚΕΤ ΦΑΡΜΑ, 54 Μενάνδρου st, 104 31 Athens Greece,
Tel.: +30 210 5224830, Fax: +30 210 5224838,
E-mail: info@targetpharma.gr, http://www.targetpharma.gr

1.8. Manufaturer

Pharmaceutical Industry PROEL Epam. G. Koronis S.A., Athens, Greece

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General

Fubecot® combines the potent topical antibacterial action of fucidic acid with anti-inflammatory and antipruritic effects of betamethasone.

Fucidic acid is effective in low concentration against *Staphylococci sp.* including strains that are resistant to penicillin and other antibiotics.
When used topically, fucidic acid is effective against also *Streptococci sp., Corynebacterium sp., Neisseria sp. and Clostridium sp.*

2.2. Indications

Fubecot® is indicated in inflammatory dermatitis, in the presence of bacterial infection or where bacterial infection is likely to occur.
Inflammatory dermatitis includes atopic eczema, nummular eczema, stasis eczema, seborrhoic eczema, contact eczema, lichen simplex chronicus, psoriasis, nummular lupus erythematosus.

2.3. Contraindications

Hypersensitivity to any of the components of the medicine.
Topical corticosteroids should not be used in cases of undiagnosed dermatitis. the use should also be avoided in conditions such as: acne, perioral dermatitis, ulcerative ulcers and also burns due to the possible delay in healing.

2.4. Special warnings and precautions for use

2.4.1. General

a. Long-term continuous treatment should be avoided in children.
   Children are more susceptible to side effects due to the corticosteroids, as it is more likely to absorb higher quantities of the medicine, due to higher skin surface vs. body weight ratio.
b. If occlusion is needed, recommendation should be made to clean the skin thoroughly, to avoid possible superinfection.
c. Duration of corticosteroid use should be limited to up to 3 weeks, unless a dermatologist suggests continuing.
d. In continuous use of 10-15 days, it may be reported that the effectiveness of corticosteroid (especially fluorinated), is deceased or lost due to tachyphylaxis. This effect will be reversed after discontinuation of few days or weeks.
e. In psoriasis corticosteroids should be used only under medical supervision, as despite the short term benefit, after discontinuation of the treatment there is high risk of recurrence.
f. Due to possible side effects as a result of increased absorption, caution is needed when the application is on extended skin areas or in long term use especially in children, patients with renal dysfunctions, patients with bleeding tendency, and in prior vaccination.
g. In general the less potent corticosteroid that is considered effective for the indication should be the first line of choice and if there is poor response then a higher potency corticosteroid should be chosen.
h. In long term treatment near the eyes it is possible to induce cataract or glaucoma. In case of topical palpebral use, caution is needed to avoid contact with the eyes.

2.4.2. Pregnancy and lactation

Safety of topical corticosteroids during pregnancy has not been established. Topical administration of corticosteroids in animals during pregnancy has caused abnormalities in the developing fetus.

For this reason corticosteroids should be avoided during pregnancy unless the expected benefit outweighs the possible risk for the fetus. In such cases, high quantities should be avoided and the duration of the treatment should not be long term.
If the administration of a corticosteroid is necessary during lactation, the quantity and the duration of the treatment should be the minimum possible.

2.4.3. Effects on the ability to drive and use machines.

None.

2.5. Interactions with other medicines or substances

None.

2.6. Dosage and method of administration

Without occlusion: 2-3 times a day.
Under occlusion: less often use is sufficient.

2.7. Overdose - Management

Overdose may occur, presenting local and systemic symptoms, related to high corticosteroid levels. If overdose symptoms occur, treatment should not be discontinued at once, gradual decrease of the dose is needed. Adrenal insufficiency may be treated via intravenous administration of hydrocortisone. It should be noted that overdose with topical corticosteroids is unlike to occur, except of cases of misuse or prolonged use.

2.8. Possible side effects

Topical after prolonged external use
The side effects that have been reported with potent corticosteroids on the site of application are:
Burning sensation, itching, irritation, dryness, folliculitis, depigmentation, thinning of epidermis, teleangiectasia.
Alteration of clinical condition due to misuse (mycoses, scabies).
Secondary infection, topical bacterial infection (new latent infection or worsening of current),fungal infections, molluscum contatiosum and warts.
Impaired wound healing, ance, pustulae, heat rash, prioral dermatitis, rosacea-like rash, recurrence of pustular psoriasis on discontinuation (rebound phenomenon), scar-like skin atrophy, striae, teleangiectasia, purpura, extended rash, vesiculo-papular eruptions, hypersensitivity, hypertrichosis.
If any symptoms of hypersensitivity occur, the treatments should be discontinued immediately.
The above mentioned side effects are not common, but may occur under occlusion or in prolonged use.

General after prolonged topical use
Suppression of the coronary-adrenal axis function, decreased cortisol plasma levels, Cushing's syndrome.

Poison Center Athens Tel.: +30 210 7793777

If you get any side effects, please talk to your doctor or pharmacist or any other health care provider or directly to the National Medicines Agency (284 Mesogion Av., 15562, Cholargos, Athens, Greece www.eof.gr).

2.9. What you should know in case you forget to take one dose

If you forget to use your medicine, apply the next dose as soon as you remember. If it is about the time for your next dosage, do not use the forgotten dosage, continue your treatment as planned. Do not double dosages.

2.10. What should the patient know about the expiration date

Expiration date is mentioned in outer and immediate container. Do not use after the expiration date.

2.11. Special warnings about the storage of the product

Store at temperature below 25ºC and keep away from children.

2.12. Date of last revision of this leaflet

14-12-2012

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This medicine is subjected to medicinal prescription.