

Fusidic Acid / Betamethasone (as Valerate)  
cream (2+0,1)%

## 1. DETERMINATION OF THE MEDICINAL PRODUCT

### 1.1 Name: SENSIBIO

**1.2 Composition:** Active ingredients: Fusidic Acid & Betamethasone (as valerate)

Excipients: Cetomacrogol 1000, Cetostearyl alcohol, Chlorocresol, Sodium phosphate monobasic, Paraffin liquid, White soft paraffin, Sodium hydroxide, Purified water

**1.3 Pharmaceutical form:** Cream for external use.

**1.4 Content:** Each gram (1g) of cream contains 20mg Fusidic acid & 1mg of Betamethasone.

**1.5 Description – Packaging:** Each box contains an aluminum tube containing 15g of white-off white smooth cream with polyethylene safety cap and a leaflet.

**1.6 Pharmacotherapeutical group:** Cream, combination of antibiotic with corticosteroid for topical use  
**ATC D07CC01**

**1.7 Manufacturer:** IASIS PHARMACEUTICALS HELLAS ABEE,  
137, Filis Ave., 134 51 Kamatero, Attiki, Greece. Tel: +30 210 23 11 031

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

**2.1 General information:** SENSIBIO combines the strong topical antimicrobial activity of fusidic acid with anti-inflammatory and antipruritic action of betamethasone.

SENSIBIO has an intense antimicrobial efficacy against a number of Gram+ microorganisms. Staphylococci, including the strains that are resistant to penicillin or other antibiotics, are particularly sensitive to SENSIBIO.

The therapeutical efficacy of topically applied SENSIBIO is due to its intense antimicrobial action against microorganisms responsible for cutaneous infections, to the unique property of this antibiotic to penetrate intact skin and finally to the combination with Betamethasone Valerate which guarantees anti-inflammatory and antipruritic action.

Fusidic acid is active at low concentrations against staphylococci, including strains resistant to penicillin or other antibiotics. Topically used, fusidic acid is also effective against streptococci, corynebacteria, neisseria and some clostridia.

### 2.2 Indications:

SENSIBIO cream is indicated in inflammatory dermatoses where bacterial infection is present or likely to occur.

The inflammatory dermatoses include:

- Atopic eczema,
- Discoid eczema,
- Seborrheic dermatitis,
- Contact dermatitis,
- Chronic lichenoid eczema,
- Psoriasis,
- Discoid lupus erythematosus.

**2.3 Contraindications:** Hypersensitivity to any component of the product. The topical use of corticosteroids is contraindicated in tuberculous, fungal and viral skin infections. Also, topical corticosteroids should not be used in case of undiagnosed skin condition. Also, their use should be avoided in cases of acne, perioral dermatitis in leg ulcers, and burns because they hinder healing.

### 2.4 Special warnings and precautions for use

#### 2.4.1 General:

- a. Avoid long-term use in children. Children and adolescents are more prone to systemic adverse effects with topical corticosteroids, because larger amount of the drug may be absorbed, due to greater skin surface area relative to body weight. Also, long-term therapy should be avoided in infants and toddlers.
- b. When applying occlusive dressing, patients should be advised to clear their skin to avoid possible contamination.
- c. Do not use topical corticosteroids beyond 3 weeks without a follow -up by a dermatologist.
- d. After repeated application, at least 10-15 days, temporary decrease or loss of efficacy of corticosteroids (especially fluorinated), due tachyphylaxis, can be observed. This phenomenon is restored after stopping use for a few days or weeks.
- e. In psoriasis corticosteroids can be granted sparingly and under supervision of an expert, because, beyond the temporary benefit, there is a risk of worsening disease long-term after the discontinuation of therapy.
- f. Due to adverse effects from possible absorption caution is required, when applied to large surfaces of skin or in prolonged administration, especially in children and patients with severe kidney disease, bleeding diathesis and upcoming vaccinations.
- g. Generally, the less potent corticosteroid that is effective for the intended indication should be chosen

and in case of poor results, another of the same or greater potency-class should be administered.

h. SENSIBIO may cause cataracts and glaucoma when used in the area of the eyes for prolonged periods. If you use the medicine topically to eyelids, caution is required so as the drug not to come into contact with the eye.

i. Suppression of adrenal cortical axis may occur in cases of not covered wounds.

**2.4.2 Pregnancy and lactation:** There are insufficient data about safety of topical corticosteroids when used in pregnant women. Topical administration of potent corticosteroids to pregnant animals has caused abnormalities in foetal development. For this reason, topical corticosteroids may be administered during pregnancy only if the potential benefit justifies the potential risk to the foetus. In such cases, topical corticosteroids should not be administered in large quantities or for long periods. When corticosteroid use during breast feeding is necessary, the quantities of medication and duration of therapy should be minimized.

**2.4.3 Effects on ability to drive and use machines:** Not reported.

**2.4.4 Special warnings regarding the excipients:** No particular warnings regarding the excipients have been reported so far except cases where the patient has a declared hypersensitivity to any of them.

**2.5 Interaction with other medicinal products and other forms of interaction:** Not reported.

**2.6 Posology and method of administration:**

Non occluded areas: SENSIBIO cream is applied 2-3 times daily on the affected area.

Occluded areas: less frequent applications may be adequate.

**2.7 Overdose:** Not reported.

**2.8 Undesirable effects:** Rare topical hypersensitivity reactions.

**Topical after long term topical use:**

The undesirable effects that have been reported with potent topical corticosteroids in their positions of application are: Burning, itching, irritation, dryness, folliculitis, hypopigmentation, thinning skin, telangiectasias.

Alteration of clinical presentation on misuse (fungal infections, scabies).

Secondary infection, local bacterial infection (latent infection initiation or aggravation evolving), fungal infections, facilitating the entry of molluscum contagiosum and genital warts. Inhibition of wound healing, acne, pustules, heat rash, perioral dermatitis, rash in the form of acne rosacea, relapse of pustular psoriasis after treatment discontinuation (Rebound Phenomenon), skin atrophy in form of scar, linear streaks, spider veins, purple rash, diffuse erythema, atypical papillo-vesicular rashes, allergic hypersensitivity, localized hypertrichosis.

**If symptoms of hypersensitivity appear, the administration should be stopped immediately.**

These side effects are not common, but may occur more frequently with the use of occlusive dressings or after long-term topical use.

**General after long-term topical use:**

Suppression of the function of adrenal-cortical axis, lowering of plasma cortisol levels – CUSHING syndrome.

**2.9 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.

**2.10 Expiration of the product:** It is indicated on the outer and inner packaging. Do not use this drug after the expiration date.

**2.11 Special precautions for storage:** SENSIBIO cream must be stored at temperature below 30°C, in a dry place, protected from light.

**2.12 Date of last product information leaflet revision:** 12-2014.

### 3. INFORMATION ON THE RATIONAL USE OF DRUGS

- 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 the medicine that you are taking or you need further information on 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 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 have already expired or are no more useful to you.

- For more safety keep medicines in a secure place away from children

### 4. MODE OF ADMINISTRATION

This medicine may only be administered with a doctor's prescription