

**SUMMARY OF PRODUCT CHARACTERISTICS****1) NAME OF MEDICINAL**

Sterozinil 0,1% + 0,1% cream

**2) QUALITATIVE AND QUANTITATIVE COMPOSITION**

100 g of cream contain:

<u>Active substances:</u>	Gentamicin	0,1 g (come gentamicin sulphate)
	Betamethasone	0,1 g (come bethametasone valerate)

For the excipients: see 6.1

**3) PHARMACEUTICAL FORM**

Cream

**4) CLINICAL INFORMATION****4.1) THERAPEUTIC INDICATIONS**

Topical treatment of allergic dermatitis or secondarily infected inflammations, or risk of infection. Conditions include: eczema (atopic, infantile, nummular), anus-genital and senile pruritus, dermatitis from contact, seborrheic dermatitis, neuro-dermatitis, intertrigin, sun erythema, peeling dermatitis, dermatitis from radiation, dermatitis from stasis and psoriasis.

**4.2) POSOLOGY AND METHOD OF ADMINISTRATION**

Apply a small quantity of cream to the area concerned 2 – 3 times per day.

Refractory psoriasis lesions and deep, secondarily infected dermatitis may respond better to therapy with corticosteroids and local antibiotics when used with the occlusive bandaging technique, described here as follows.

*Occlusive bandaging technique:*

- 1) apply a consistent layer of cream over the entire surface of the lesion under light gauze and cover with transparent, waterproof and flexible material, extending over the edges of the treated zone;
- 2) seal the edges onto the healthy skin with a plaster or other means;
- 3) leave the medication "*in situ*" for 1-3 days and repeat the procedure 3-4 times according to need.

With this method we often observe a considerable improvement in a few days. In rare cases, military folliculitis eruptions develop on the skin under the medication, making removal of the plastic covering necessary.

**4.3) CONTRAINDICATIONS**

Cutaneous tuberculosis, herpes simplex, as well as in the presence of viral illnesses with cutaneous localization. The product is also not recommended in patients with hypersensitivity to the active substances or to any of the excipients.

**4.4) SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

In case of irritation or sensitization related to the use of the product, treatment should be suspended and a suitable therapy begun. All undesired effects described for systemic

corticosteroids, including adrenal insufficiency, may occur also with topical corticosteroids, above all in infants.

Systemic absorption of topical corticosteroids increases with the treatment of extensive skin surfaces or with the use of occlusive medication. In these cases, or when prolonged treatment is foreseen, suitable precautions are required, especially in infants.

Sometimes the use of topical antibiotics permits the proliferation of insensitive organisms, including mycetes. In this case, or whenever irritation, sensitization or super-infection develop, treatment with Gentamicin must be suspended and a suitable specific therapy begun.

Use in infants: infants may prove to be more sensitive than adults to the fall in the hypothalamus-hypophysis-surrene axis induced by topical cortisones and the effects of exogenous corticosteroids, given the greater absorption due to the high ratio between cutaneous surface area and body weight.

In children treated with topical corticosteroids, depression of the hypothalamus-hypophysis-surrene, Cushing syndrome, delayed stature and weight growth and endocranic hypertension have been reported. In children, adrenal insufficiency manifestations include low cortisolemia levels and a lack of response to stimulation with ACTH. Endocranic hypertension manifestations include fontanel tension, headache and bilateral papilledema.

The drug contains chlorocresol which may cause allergic reactions.

The drug also contains cetostearylic alcohol which may cause local cutaneous reactions (e.g. contact dermatitis).

The product cannot be used for ophthalmic use.

#### Visual disturbances

Visual disturbances may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR), which have been reported after use of systemic and topical corticosteroids.

#### **4.5) INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION**

None known to date.

#### **4.6) PREGNANCY AND LACTATION**

The safety of topical corticosteroids has not been established in gestating women; therefore, the use of drugs belonging to this class must be limited to cases in which the expected benefit justifies the potential risk to the foetus. These drugs are not used intensively in pregnant patients, at high doses or for long periods of time.

It is not known if the topical administration of corticosteroids may determine sufficient systemic absorption to produce measurable concentrations in maternal milk. Therefore, decisions as to interrupting lactation or to suspending the therapy must be taken considering the importance of the drug to the mother.

#### **4.7) EFFECTS ON ABILITY TO DRIVE AND USE MACHINERY**

The medicinal product does not alter the state of mental alertness.

#### **4.8) SIDE EFFECTS**

The following undesired effects have been described correlated with the use of topical corticosteroids: burning sensation, itching, irritation, dry skin, folliculitis, hypertrichosis, acne eruptions, hypo-pigmentation, perioral dermatitis, dermatitis from allergy contact.

If occlusive medication is adopted, undesired effects such as skin maceration, secondary infections, cutaneous atrophy, striae and miliary may occur with greater frequency.

Treatment with Gentamicin can produce temporary irritation (erythema and pruritus) which do not normally require treatment suspension.

Blurred vision (see also section 4.4).

#### **4.9) OVERDOSAGE**

Symptoms: the excessive or prolonged use of topical corticosteroids can depress hypophysis-surrene function, causing secondary adrenal insufficiency and manifestations of hypercorticism including Cushing syndrome.

One single overdose episode of Gentamicin should not produce any symptoms. Excessive and prolonged use of topical Gentamicin can lead to the formation of lesions due to mycetes and insensitive bacteria.

Treatment: the appropriate symptomatic treatment is recommended. Acute hypercorticism symptoms are generally reversible. If necessary, treat the electrolytic imbalance. In the case of mycetes and bacteria proliferation we recommend an appropriate anti-fungus or anti-bacteria therapy.

### **5) PHARMACOLOGICAL PROPERTIES**

#### **5.1) PHARMACODYNAMIC PROPERTIES**

Pharmacotherapeutic Group: Active corticosteroids associations with antibiotics, ATC: D07CC01

The product combines the broad-spectrum antibacterial action of gentamicin topical anti-inflammatory, anti-allergic and anti-itching of betamethasone 17-valerate.

The therapeutic effects of the two components are described separately below.

Gentamicin: gentamicin is produced by the fermentation of *Micromonospora purpurea* and is obtained as an amorphous white powder, soluble in water and stable to heat.

This broad-spectrum antibiotic has proved to be highly effective in the topical treatment of primary and secondary bacterial infections of the skin. Among the bacteria susceptible to gentamicin are included *Staphylococcus aureus* (coagulase-positive strains, coagulase-negative and penicillinase-producing), the Gram-negative bacteria, *Pseudomonas aeruginosa*, *Aerobacter aerogenes*, *Escherichia coli*, *Proteus vulgaris* and *Klebsiella pneumoniae*) and also streptococci (beta-hemolytic and group A alpha-hemolytic). The results of the reaction tests on skin carried out in clinical, have shown that gentamicin is not a primary irritant; moreover gentamicin has a low index of skin sensitization.

Betamethasone 17-valerate: this ester of betamethasone is highly effective in the topical treatment of dermatoses that respond to corticosteroid therapy.

The suppression of the inflammatory reaction produces a ready and prolonged control of itching, erythema and infiltration.

The reduction of the treatment decreases the probability of exacerbation of the injury and the onset of secondary infections. Clinical studies in different localized and systemic diseases, sensitive to corticosteroids, indicate that betamethasone 17-valerate causes a rapid and effective response in most patients.

#### **5.2) Pharmacokinetics properties**

The transcutaneous absorption of topical corticosteroids is usually negligible, however, it may increase if large areas of skin are treated or the technique of occlusive bandage is used. In the

child transcutaneous absorption is normally higher. Percutaneous absorption of gentamicin is usually absent.

**5.3) Preclinical safety data**

Preclinical data have little clinical significance in light of the extensive experience with use on humans of the active ingredients in the medicinal product.

**6) PHARMACEUTICAL INFORMATION****6.1) LIST OF EXCIPIENTS**

Chlorocresol, macrogol cetostearylether, cetostearyl alcohol, white soft paraffin, liquid paraffin, sodium mono-basic phosphate, phosphoric acid, purified water.

**6.2) INCOMPATIBILITIES**

None.

**6.3) SHELF LIFE**

2 years.

**6.4) SPECIAL PRECAUTIONS FOR CONSERVATION**

No special precaution.

**6.5) NATURE AND CONTENT OF CONTAINER**

Aluminium tube internally coated with epoxy resins, 30 g closed by polyethylene cap.

**6.6) INSTRUCTIONS FOR USE AND HANDLING**

No special instruction.

The unused product and waste derived from this medicine should be disposed of in compliance with local requirements.

**7) MARKETING AUTHORIZATION HOLDER**

Aesculapius Farmaceutici S.r.l. – Via Cefalonia, 70 – 25124 Brescia

**8) MARKETING AUTHORIZATION NUMBER**

Sterozinil 0,1% + 0,1% cream –30 g tube      MA n° 036274025

**9) DATE OF FIRST AUTHORIZATION/ RENEWAL OF AUTHORIZATION**

Renewal date: August 2010

**10) DATE OF REVISION OF THE TEXT**

November 2017