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SUMMARY OF PRODUCT CHARACTERISTICS FOR PHARMACEUTICAL PRODUCTS

1 NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

POSITON CREAM

1.1 Strength

Triamcinolone acetonide 1 mg/g, Neomycin sulphate 2.5 mg/g and Nystatin 100,000 I.U./g

1.2 Pharmaceutical form

Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 *Qualitative declaration*

Triamcinolone acetonide
Neomycin sulphate
Nystatin
Polyoxyl 40 stearate,
Glyceryl monostearate,
White petroleum jelly,
Cetostearyl alcohol,
Aluminium hydroxide,
Titanium dioxide (E 171),
Sorbitol solution,
Propylene glycol,
Ethylenediamine dihydrochloride,
Methyl parahydroxybenzoate (E 218),
Propyl parahydroxybenzoate (E 216),
Sorbic acid (E 200),
Dimethicone,
Water

2.2 *Quantitative declaration*

Triamcinolone acetonide	1.0 mg/g
Neomycin sulphate	2.5 mg/g
Nystatin	100,000.0 I.U./g
Polyoxyl 40 stearate	40.0 mg
Glyceryl monostearate	40.0 mg

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White petroleum jelly	100.0 mg
Cetostearyl alcohol	60.0 mg
Aluminium hydroxide	10.0 mg
Titanium dioxide (E 171)	5.0 mg
Sorbitol solution	50.0 mg
Propylene glicol	50.0 mg
Ethylenediamine dihydrochloride	2.0 mg
Methyl parahydroxybenzoate (E 218)	2.0 mg
Propyl parahydroxybenzoate (E 216)	0.2 mg
Sorbic acid (E 200)	2.0 mg
Dimethicone	10.0 µg
Water	q.s.1.0 g

3 PHARMACEUTICAL FORM

Cream

Light yellow soft smooth evanescent cream without foreign substances or lumps.

4 CLINICAL PARTICULARS

4.1.*Therapeutic indications*

Positon is indicated in the treatment of complicated dermatoses that respond to corticosteroids where there is a risk of bacterial or fungal infection caused by sensitive microorganisms.

Official recommendations regarding the appropriate use of antibacterial agents must be taken into account.

4.2.*Posology and method of administration*

Topical use.

Treatment should not exceed 7 days without medical supervision.

Posology

Adults

Apply a small amount to the affected area as a thin layer, 2 or 3 times a day until an improvement is noted. This improvement may be maintained subsequently with applications once a day or less frequently.

Paediatric population

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This medicinal product should only be used in children and adolescents when its use is considered necessary by a doctor; in this case, a thin layer should be applied once a day and treatment must not exceed 7 days (see section 4.4).
If used in children, the treatment must be carefully controlled by the doctor. This is particularly important if the product is applied to more than 5-10% of the body surface or if using occlusive dressings or a tight nappy (see section 4.5).

Elderly people (over 65 years of age)
Positon can be administered in elderly patients, although care should be taken in cases where kidney function is impaired and there may be significant systemic absorption of neomycin sulphate (see section 4.5).

Renal impairment
The dose should be reduced in patients with renal impairment (see Section 4.5).

4.3.*Method of administration*
Topical use.
Treatment should not exceed 7 days without medical supervision.

4.4.*Contraindications*
- Hypersensitivity to the active substances, to other aminoglycoside antibiotics or to any of the excipients listed in section 6.1.
- Do not use in case of rosacea, tuberculosis, acne vulgaris, perioral dermatitis, atrophic skin diseases, cutaneous reactions to vaccines, perianal and/or genital pruritus or viral skin infections (e.g. herpes simplex, varicella).
- It should not be used in children under the age of 1 year because there is a greater risk of increased absorption.

4.5.*Special warnings and precautions for use*
Whenever possible, prolonged continuous application of a topical treatment should be avoided, especially in children, as it can lead to suppression of the hypothalamic-pituitary-adrenal axis, with or without clinical signs of Cushing's syndrome, even without using occlusive dressings. Should this situation occur, the medicine must be withdrawn gradually (topical corticosteroid) under medical supervision due to the risk of adrenal insufficiency (see sections 4.11 and 4.12).

The administration of more than 7 days of combined steroid and antibiotic treatment should be avoided if there is no clinical improvement, as the effect of the corticosteroid could mask the extent of the infection.

Do not use occlusive dressings or dressings that do not allow the skin to breathe, as this may encourage the development of infections and the corresponding skin irritation. In the event of

irritation in the area of application, discontinue use of the cream and, if necessary, start another suitable treatment.

Care should be taken to ensure that Positon cream does not come into contact with the eyes or mucous membranes. Hands should be washed thoroughly after application. When the cream is used on the face, treatment should be limited to 5 days.

Due to the ototoxic and nephrotoxic potential of neomycin sulphate, it is not recommendable to use Positon in large amounts or on extensive areas for prolonged periods of time due to the possible risk of systemic absorption.

Continued or recurrent application may increase the risk of contact sensitivity.

In cases of renal impairment, the plasma clearance of neomycin is reduced (see section 4.2).

Visual disturbances

Visual disturbances can occur with topical and systemic corticosteroids. If a patient experiences symptoms such as blurred vision or other visual disturbances, an ophthalmologist should be consulted to assess the possible causes, including cataracts, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR), which has been reported after use of systemic and topical corticosteroids.

Warning about excipients:

This medicinal product may cause local skin reactions (such as contact dermatitis) because it contains cetostearyl alcohol and sorbic acid (E 200).

This medicine contains propylene glycol, which may irritate the skin.

This medicinal product may induce allergic reactions (possibly of a delayed nature) because it contains methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216).

In patients with moderate or severe renal impairment coadministration of bilastine with P-glycoprotein inhibitors, such as e.g, ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem, may increase plasmatic levels of bilastine and therefore increase the risk of adverse reactions of bilastine. Therefore, coadministration of bilastine and P-glycoprotein inhibitors should be avoided in patients with moderate or severe renal impairment.

4.6. *Interaction with other medicinal products and others forms of interaction*

Treatments of extensive areas of skin or long-term treatments with corticosteroids can lead to similar interactions to those caused by systemic treatment as a result of absorption.

In the case of concomitant treatment with systemic aminoglycosides, the possibility of cumulative neomycin-induced toxicity should be considered.

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4.7. *Additional information on special populations*

Paediatric population

This medicinal product should only be used in children and adolescents when its use is considered necessary by a doctor; in this case, a thin layer should be applied once a day and treatment must not exceed 7 days (see section 4.4).

If used in children, the treatment must be carefully controlled by the doctor. This is particularly important if the product is applied to more than 5-10% of the body surface or if using occlusive dressings or a tight nappy (see section 4.5).

Elderly people (over 65 years of age)

Positon can be administered in elderly patients, although care should be taken in cases where kidney function is impaired and there may be significant systemic absorption of neomycin sulphate (see section 4.5).

Renal impairment

The dose should be reduced in patients with renal impairment (see Section 4.5).

4.8. *Fertility, pregnancy and lactation*

There is very limited information demonstrating the possible effect of neomycin in pregnancy and breastfeeding. Given that neomycin can cross the placental barrier and its presence in the mother's blood can cause toxicity, the use of Positon cream is not recommended during pregnancy or breastfeeding.

4.9. *Effects on ability to drive and use machines*

Positon cream has no or negligible influence on the ability to drive and use machines.

4.10. *Undesirable effects*

a) Summary of the safety profile

Adverse reactions are listed according to the medDRA convention by frequency, using the following classification:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); frequency not known (cannot be estimated from the available data).

b) Tabulated list of adverse reactions

Immune system disorders	
Very frequent	Hypersensitivity reactions (especially if used for prolonged periods), which include: contact dermatitis, burning, erythema, rash and urticaria.

Rare	Anaphylactic reactions.

Endocrine disorders	
Rare	Hypercorticism, adrenocortical suppression

Eye disorders	
Unknown frequency	Blurred vision.

Skin and subcutaneous tissue disorders	
Common	Mild to moderate burning sensation at the application site, pruritis, local skin atrophy, pain, stinging, irritation, inflammation or erythema of the skin at the application site, which does not usually require the treatment to be discontinued.
Uncommon	Stretch marks, secondary infection, papular rosacea, ecchymosis, folliculitis, erythema, pruritis, burning sensation.
Rare	Hypertrichosis, sensitisation, hyper/hypopigmentation, telangiectasias, perioral dermatitis, systemic activity, contact dermatitis. In rare cases, the treatment of psoriasis with corticosteroids can lead to the pustular form of the disease.
Other adverse effects include: purpura, acne (especially in prolonged treatments).	

e) Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via National Pharmacovigilance System for Medicinal Products for Human Use.

4.11. Overdose

An acute overdose is unlikely; however, excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, causing secondary adrenal insufficiency and symptoms of hypercorticism, including Cushing's syndrome (see section 4.11), as well as symptoms such as hypertension, oedema, hyperglycaemia, glycosuria and hyperthyroidism.

In this situation, the application of topical steroids should be stopped gradually and under medical supervision (see section 4.5), and auditory acuity and renal and neuromuscular function must be monitored.

Appropriate symptomatic treatment should be applied.

In patients treated with neomycin on skin ulcers or over large areas of bare skin or for long periods of time, the following may occur: ototoxicity, nephrotoxicity and neuromuscular blockade; rare

cases of severe dermatitis have been reported with topical neomycin treatment that has progressed to exfoliative dermatitis, which can be a potentially fatal reaction.

Cutaneous absorption of nystatin is negligible, so when applied to the skin in patients who have not shown hypersensitivity reactions, systemic effects are not expected with overdose or overdose or prolonged treatments.

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: corticosteroids, moderately potent, combinations with antibiotics. Triamcinolone and antibiotics. ATC code: D07CB01.

Triamcinolone acetonide is a fluorinated corticosteroid with known cutaneous effects. It has a powerful local action on inflammatory processes of the skin, superior to that shown with hydrocortisone acetate, which helps reduce inflammatory phenomena and contributes to the subjective well-being of the patient. It has also been noted that local application to the skin results in vasoconstriction, which aids the local anti-inflammatory effect.

Neomycin sulphate is an antibiotic of the aminoglycoside family that has bactericidal actions when administered topically and orally. Neomycin is effective against gram-positive microorganisms, including staphylococci and a wide range of gram-negative microorganisms. Strains of Pseudomonas aeruginosa are resistant to neomycin, as are fungi and viruses. The mechanism of action consists of the antibiotic irreversibly binding to segment 30S of the ribosome, which brings about a biocidal effect. Its efficacy is not reduced by the presence of pus.

Nystatin is an antifungal drug obtained from Streptomyces noursei. Nystatin has in vitro fungistatic and fungicidal properties against a wide range of yeast and related fungi. It acts by binding to sterols in the cell membrane of sensitive species of Candida (Candida albicans and other species) and forming ion channels in them, leading to changes in the permeability of the membrane and the consequent leakage of intracellular components.

During repeated subcultures at increasing concentrations of nystatin, Candida albicans does not develop resistance. Patients do not generally develop resistance to nystatin during treatment. Nystatin has no activity against bacteria, protozoa and viruses.

5.2. Pharmacokinetic properties

Small amounts of topical corticosteroids can be absorbed through the skin.
The extent of percutaneous absorption is dependent upon a number of factors, such as the vehicle used, skin integrity, area of application and use of occlusive dressings. They can be absorbed through intact skin. Inflammation and high body temperature increase percutaneous absorption.

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Following absorption, topical corticosteroids show pharmacokinetic characteristics similar to those of oral corticosteroids (plasma protein binding, metabolism in the liver and excretion via the kidneys).

Neomycin is not absorbed or is only absorbed in minimal quantities through intact skin, but it is rapidly absorbed through bare skin or excoriated areas of skin that have lost a layer of keratin, such as wounds, burns or ulcers. The use of extensive areas in these places can lead to absorption and a substantial increase in plasma concentrations. Neomycin binds to kidney tissue, where the highest concentration is found in the renal cortex, from which it is slowly released over several weeks after treatment is discontinued.

Nystatin is not absorbed through intact skin or mucous membranes.

5.3. Preclinical safety data

There are no preclinical data on the safety of Positon cream in topical use.
Animal studies have shown that topical corticosteroids can cause embryotoxic or teratogenic effects after exposure to doses considered higher than the maximum human dose.
No long-term studies have been performed on animals to evaluate the carcinogenicity of topical corticosteroids.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Polyoxyl 40 stearate,
Glyceryl monostearate,
White petroleum jelly,
Cetostearyl alcohol,
Aluminium hydroxide,
Titanium dioxide (E 171),
Sorbitol solution,
Propylene glycol,
Ethylenediamine dihydrochloride,
Methyl parahydroxybenzoate (E 218),
Propyl parahydroxybenzoate (E 216),
Sorbic acid (E 200),
Dimethicone,
Water

6.2. Incompatibilities

Not applicable.

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6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store below 30ºC

6.5. Nature and contents of container

Collapsible aluminium tube with interior epoxy resin coating, closed with a polypropylene cap.
Pack containing a 30 g tube of cream.

6.6. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORISATION HOLDER

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MANUFACTURER

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8 MARKETING AUTHORISATION NUMBER

48.825

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 20 February 1970
Date of latest renewal: 20 February 2010

10 DATE OF REVISION OF THE TEXT

February 2018

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