SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Carplexil 10 mg/g Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 10 mg of Hydrocortisone.
Contains 16 mg of Cetyl alcohol, 3 mg of methyl parahydroxybenzoate and 4 mg of propyl parahydroxybenzoate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Carplexil is used in the treatment of several skin disorders in adults, such as dermatitis, sunburn reaction or insect bite. It is also used in all the cases in which the use of a corticosteroid is indicated, such as inflammatory and pruritic manifestations caused by dermatosis.
Carplexil, due to its refreshing and drying action, is indicated in the acute and exudative situations.

4.2 Posology and method of administration

Posology

Carplexil is applied twice or three times daily, in the affected areas.
Maximum treatment duration: 7 days, after which, if there is no improvement, the doctor should be consulted.

Method of administration

Carplexil is a medicinal product for cutaneous use.
As a rule, a dressing should not be done on the application site. The use of an impermeable dressing produces occlusion and increases the effectiveness of the medicinal product, but also produces side effects. It should only be made by medical indication and under his/her surveillance.

It should not be used for more 7 days, after which, if there is no improvement, the doctor should be consulted

Paediatric population
It should not be used in children, except if expressly medical indicated

4.3 Contraindications

- Carplexil is contraindicated in dermatosis of tuberculosis or systemic and cutaneous viral aetiology (for example chickenpox and herpes simplex), on the wounded skin, on lip lupus or on the genital area.
- It should not be used near the eyes, on the face or infected areas
- It should not be used in children, except if expressly medical indicated.
- Hypersensitivity to the active substance (hydrocortisone) or to any of the excipients.
- Pregnancy and/or breast-feeding, unless expressly medical indicated.

4.4 Special warnings and precautions for use

Carplexil is usually well-tolerated, but if signs of sensitisation appear, such as burning sensation, irritation or dryness of the skin, the applications should be suspended.

Considering the statute of the medicinal product (medicinal product not subject to medical prescription of dispense exclusively in pharmacy), the medicinal product should not be provided in the situations described below, except by medical indication:
- Diabetes mellitus
- Infections, wounds at the treatment site or ulcerated areas
- Severe changes of the peripheral circulation
- History of peptic ulcer

Before using this medication the doctor must consider the potential risks against the benefit, and he/she should consider the following:
- Allergies to corticosteroids or to other substances as preservatives, food or inks.
- It should not be used in children for long periods of time or in very extensive areas unless under medical surveillance.
- The use of topical corticosteroids should be avoided in curatives of extensive exudative lesions with occlusive plastic materials, given the higher tendency to systemic absorption, occurrence of thermolysis and local hypersensitive reactions.

Athletes should be warned that this medicinal product contains an ingredient that may have a positive result in the “antidoping” control.

Cetyl alcohol, present in the formulation, may cause local skin irritation (for example contact dermatitis). Parabens (methyl parahydroxybenzoate and propyl parahydroxybenzoate), present in the formulation, may cause allergic reactions (possible delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Glucocorticoids decrease the action of the oral hypoglycaemics and insulin hypoglycaemic activity. In high doses they can cause hypokalaemia and increase this effect in thiazides and in some diuretics; they can increase the ulcerogenic potential of the non-steroidal anti-inflammatory drugs; they can decrease the salicylates plasma levels and they can decrease or increase the prothrombopenic anticoagulant effects.

4.6 Fertility, pregnancy and lactation

In case of pregnancy or breast-feeding, it should not be used in very extensive areas and for long periods of time, since the cutaneous corticosteroids may be systemically absorbed.

4.7 Effects on ability to drive and use machines

There are no known effects on the ability to drive and use machines.

4.8 Undesirable effects

As with all other cutaneous use corticosteroids, when used according the occlusive method in very extensive areas and for a long time, one should always consider the possibility of systemic effects (such as arterial hypertension, water retention, psychiatric changes such as euphoria and depression, adrenal suppression, hyperglycaemia, hypokalaemia, growth suppression, cataracts, gastrointestinal changes, osteoporosis and higher susceptibility to infections).

Some side effects may occur that do not require medical observation and that disappear with the continuation of the treatment, however a doctor should be consulted if the following side effects persist: burning sensation, dryness, irritation, pruritus or skin erythema; increase of the erythema or desquamation of the skin of the wounds and skin rash.

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 directly to INFARMED, I.P.:

INFARMED, I.P.
Direção de Gestão do Risco de Medicamentos
Parque da Saúde de Lisboa, Av. Brasil 53
1749-004 Lisboa
Tel: +351 21 798 73 73
Line of the Medicinal Product: 800222444 (free)
Fax: + 351 21 798 73 97
Internet website: http://www.infarmed.pt/web/infarmed/submissaoram

E-mail: farmacovigilancia@infarmed.pt

4.9 Overdose

In case of chronic cutaneous overdose, since there is no specific antidote, the treatment is symptomatic and

consists in discontinue the corticosteroid therapy, being gradually suppressed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Dermatologicals. Corticosteroids, dermatological preparations. Corticosteroids, weak (group I)
ATC Code: D07AA02

Corticosteroids (hydrocortisone) diffuse through the cellular membranes and bind to specific cytoplasmic receptors. These complexes enter then in the cellular nucleus, binding to DNA (chromatin) and stimulating the transcription of the messenger RNA (mRNA) and subsequent protein synthesis of the various enzymes inhibitors responsible for the anti-inflammatory effects of cutaneous use corticosteroids.

5.2 Pharmacokinetic properties

Hydrocortisone due to the 17-hydroxyl group is resistant to the local metabolism of the skin, being systemically absorbed and then metabolised in the liver.

5.3 Preclinical safety data

Hydrocortisone is a substance that, under a toxicological point of view, can be administered to humans, not revealing problems that need special measures or that prevent its use as a therapeutic agent.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl monostearate, isopropyl myristate, cetyl alcohol, stearic acid, liquid paraffin, glycerol, dexpanthenol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, trolamine and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

The cream must be used within 7 days after opening the tube.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium tubes internally coated with epoxy varnish with high density polyethylene cap.
Each tube contains 30g of cream.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratórios Basi - Indústria Farmacêutica, S.A
Parque Industrial Manuel Lourenço Ferreira, Lote 15
3450-232 Mortágua
Portugal

8. MARKETING AUTHORISATION NUMBER(S)

Registration no.: 06551/08065/REN/2021 10 mg/g, Alu/Alu tube.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 February 2009

10. DATE OF REVISION OF THE TEXT

September, 2017