CORE Summary of product characteristics (English)

1. NAME OF THE MEDICINAL PRODUCT

PANNO**CORT** 1% cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of cream contains 10 mg of hydrocortisone acetate (=1%)
Excipients with known effect
1 g of cream contains 135 mg of cetostearyl alcohol and 1 mg of methyl p-hydroxybenzoate.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This is a class IV corticosteroid, i.e. a low potency corticosteroid.

- Allergic dermatoses, pruritic or wet dermatoses.
- Psoriasis, particularly of face and genitals.
- Eczema.

4.2 Posology and method of administration

Rub a small amount of Pannocort (for example the size of a pea) on the painful area and surrounding area.
Massage gently until fully absorbed.
Apply once to twice daily.

4.3 Contraindications

- Infections of the skin (viral, bacterial or fungal).
- Atrophy of the skin, acne vulgaris, acne rosacea.
- Wounds and ulcers.
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Use of corticosteroids may change the appearance of skin lesions, making diagnosis more difficult. If the effect is rapid and pronounced, it is however rarely maintained for a prolonged period of time and recurrence, even with rebound effect and exacerbation of the lesions, may occur upon discontinuation of therapy. This may sometimes result in systemic or local effects.
Do not apply to the mucous membranes and avoid contact with the eyes.

This medicinal product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
This medicinal product contains methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

Visual impairment:
Visual impairment may be reported with systemic and topical use of corticosteroids. If patients develop symptoms such as blurred vision or other visual disturbances, consideration should be given to referring the patient to an ophthalmologist to establish the possible cause including cataract, glaucoma or rare conditions such as central serous chorioretinopathy (CSCR) which have been reported following the use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

No data submitted.

4.6 Fertility, pregnancy and lactation

Pregnancy
Although no harmful effects to the foetus have been observed after topical use of corticosteroids, their harmlessness has not been fully established. Application of large amounts or prolonged use should therefore be avoided in pregnant women.
Breastfeeding
Use of topical corticosteroids is generally not contraindicated during breastfeeding. Caution is however advised when applying Pannocort to the nipple or areola in order to avoid intake of the product by the infant while nursing.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The most severe systemic reaction is inhibition of the hypothalamic-pituitary-adrenal axis due to corticosteroid absorption.
However, this risk is lowest for class IV corticosteroids, to which Pannocort belongs.
Some factors may increase the absorption, including:

- application to large areas
- application under an occlusive dressing
- existing inflammation of the skin
- application of high concentrations

Especially infants and children are very sensitive, which may sometimes lead to Cushing's syndrome-like manifestations and growth inhibition.

Skin and subcutaneous tissue disorders:
The most important local adverse reactions include: atrophy of the skin with striations and telangiectasias, extension or flare-up of existing infections, increased risk of infections, perioral dermatitis, delayed healing of scars, pigmentary changes, subcutaneous atrophy of collagen tissue and hypertrichosis.
Allergic reactions during local therapy are usually caused by one of the excipients.

Eye disorders:
Not known: blurred vision (see also section 4.4)

General disorders and administration site conditions:
Very rare: accumulation of fluid in tissues

Reporting of suspected adverse reactions
Reporting of 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:
Federal agency for medicines and health products
Vigilance department
Mailbox 97
1000 BRUSSELS
Madou
Internet site: www.notifieruneffetindesirable.be
e-mail: adr@fagg-afmps.be

4.9 Overdose

Systemic effects may occur with the use of large amounts.
See section 4.8. Undesirable effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical corticosteroids, class IV, ATC code: D07AA02

The therapeutic activity of hydrocortisone and its derivatives in various dermatoses is mostly based on its anti-inflammatory effect. Its action consists of the inhibition of certain endogenous mediators of inflammation: histamine, quinines, prostaglandins and lysosomal enzymes. It has no causal effect. Conditions may recur upon discontinuation of treatment.

5.2 Pharmacokinetic properties

The systemic absorption of 1% hydrocortisone from a cream is low. The degree of systemic absorption following local application depends on:

- the size of the area treated.
- the duration of treatment: the longer the treatment, the higher the anticipated absorption.
- damage to the epidermis.
- site of administration.
- the absorption is increased when applied under an occlusive dressing.

5.3 Preclinical safety data

No data submitted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol, sodium lauryl sulphate, glycerol, methyl p-hydroxybenzoate, purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
After first opening: 3 months

6.4 Special precautions for storage

Tube: This medicinal product does not require any special storage conditions.
Pot: Do not store above 25°C.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Aluminium tube with PP screw cap containing 5 g, 15 g, 30 g or 60 g of cream.
PP jar with HDPE lid containing 1 kg of cream for use in hospitals and pharmacies.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

Pannoc Chemie NV

Lammerdries-oost 23
2250 OLEN
BELGIUM

8. MARKETING AUTHORISATION NUMBER

Tube: BE053392
Jar: BE511244

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 November 1961
Date of latest renewal: 03 December 2007

10. DATE OF REVISION OF THE TEXT

September 2021

Date of approval: 10/2021