Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cortopin 1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The cream contains Hydrocortisone 1% w/w.
Also contains 7.2% w/w Cetostearyl alcohol and 0.1% w/w Chlorocresol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth, white, homogenous oil in water cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

It can be used to treat contact and allergic dermatitis irritant, insect bite reactions and mild to moderate eczema.

4.2 Posology and method of administration

For topical use.

Adults and children over 12 years:
For use on the skin only. Hands should be washed before and after use. Apply sparingly once or twice a day to the affected area, or as directed by the physician. Do not use for more than 7 days.

Children:
Do not use on children under 12 years of age unless under medical supervision. If symptoms persist consult your doctor.

Do not use on the anal or genital region, or on broken or infected skin.

Do not use on the face except if the doctor has advised you. Do not get the cream in your eyes.

4.3 Contraindications

Use in the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.
Use in acne vulgaris, acne rosacea or in perioral dermatoses.

4.4 Special warnings and precautions for use

Side effects include local irritation, hypersensitivity and intercurrent infections.

Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression or of growth suppression.

Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings including napkin may suppress adrenocortical function.

Continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation, particularly on the face.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out co-administered systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

This product should not be used in pregnancy unless considered essential by the physician.
Topical administrations of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.
There is no evidence against use in lactating women. However caution should be exercised when Hydrocortisone Cream is administered to nursing mothers. In this event, the product should not be applied to the chest area.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Rarely, local sensitivity may occur, requiring discontinuation of treatment.
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail: medsafety@hpra.ie.

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone is the major glucocorticoid secreted by the adrenal cortex. It is released in to the circulation under the influence of adrenocorticotrophic hormone (ACTH). The half-life is normally 60-90 minutes. One percent of secreted cortisol is excreted unchanged in urine, 20% converted to cortisone in the liver and the remainder inactivated by conversion to tetrahydrocortisol by 3-hydroxy steroid dehydrogenase also in the liver.

5.2 Pharmacokinetic properties

Absorption: Topically applied steroids are absorbed to a significant extent only if applied to broken skin, to very large areas, or under occlusive dressings.

Distribution: Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk.

Metabolism: Hydrocortisone is metabolised mainly in the liver, but also the kidney, to various degraded and hydrogenated forms such as tetrahydrocortisone.

Elimination: Hydrocortisone is excreted in the urine, mostly conjugated as glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data

Adverse effects of Hydrocortisone are due to its effects on electrolyte balance, metabolism and particularly adrenal suppression. Topical use of Hydrocortisone has only rarely been associated with systemic side effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl alcohol
White soft paraffin
Liquid paraffin
Chlorocresol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Keep the container tightly closed.

6.5 Nature and contents of container

Aluminium tube with polypropylene cap.

Pack size 30 g, 100 g and 400 g – as a prescription-only medicine.

Pack size 15 g – for over the counter sale through pharmacies only for indications stated on the label.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd.
Ballymacarbry
Clonmel
Co Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 281/71/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 July 1989

Date of last renewal: 17 July 2009

10 DATE OF REVISION OF THE TEXT

July 2016