SUMMARY PRODUCT CHARACTERISTIC

HYDROCORTISONE
1% ointment for topical use

1.1.TRADE NAME - Hydrocortisone
1.2. INTERNATIONAL NON-PROPERTY NAME–Hydrocortisone

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Hydrocortisone, 1%topical ointment, contains:
active ingredient: hydrocortisone acetate – 10 mg;
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment for topical use.
White homogenous ointment with weak odor.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

POM: For the treatment of mild to moderate inflammatory skin disorders such as eczema, including atopic, infantile, discoid and stasis eczema; seborrhoeic dermatitis, intertrigo, otitis externa, contact dermatitis, neurodermatitis flexural psoriasis and lichen simplex.
P: For the relief of irritant contact dermatitis, allergic contact dermatitis, insect bite reactions and mild to moderate eczema.

4.2. Posology and method of administration

POM: For adults and children: Apply sparingly twice a day.
P: For adults, the elderly and children over 10 years of age: Apply sparingly to a small area, once or twice a day, for a maximum of 7 days.
Children under 10 years of age: Not recommended except under medical supervision.
For topical application.

4.3. Contraindications

POM: Should not be used if allergic to any of the ingredients or on untreated, infected lesions, ulcerative conditions, rosacea, perioral dermatitis or acne.
P: The product should not be used if allergic to any of the ingredients or on the eyes or face, the anogenital area or on broken or infected skin including impetigo, cold sores, acne or athlete's foot.

4.4. Special warnings and precautions for use

POM: Avoid prolonged, continuous use, particularly in children and especially on the face, as adrenal suppression may occur.
P: Medical advice should be sought if the condition does not improve.
Contains Propylparaben, whichmay cause allergic reactions (possibly delayed).

4.5. Interaction with other medicinal products and other forms of interaction

P and POM: No clinically significant interactions known.

4.6. Pregnancy and lactation

POM: There is inadequate evidence of safety in human pregnancy. Topical application of corticosteroids to pregnant animals can cause abnormalities of foetal development. There may, therefore, be a very small risk of such effects in the human foetus.
P: This product should not be used in pregnancy without medical advice. There is no information about effects duringlactation.

4.7. Effects on ability to drive and use machines
P and POM: No adverse effects known.

4.8. Undesirable effects
POM: The product is usually well tolerated, but if hypersensitivity occurs use of the product should be discontinued.
Epidermal thinning, telangectasia and striae may occur in areas of high absorption such as skin folds, the face and thenappy area and where occlusive dressings are used. Sufficient systemic absorption may occur at these sites toproduce features of suppression of the HPA (hypothalamopituitaryadrenal) axis after prolonged treatment.
P: Hydrocortisone Ointment 1% is usually well tolerated but if hypersensitivity occurs discontinue use.

4.9. Overdose
POM: Acute overdosage is very unlikely to occur. In the case of chronic overdosage or misuse the features ofhypercorticism may appear and in this situation, topical steroids should be discontinued.
P: No special precautions or antidotes are likely to be needed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
ATC code/pharmacological group:D07AA02.
Hydrocortisone is a corticosteroid which has antiinflammatory activity.

5.2. Pharmacokinetic properties
Following topical application to most areas of normal skin, only minimal amounts of the drug reach the dermis andsubsequently the systemic circulation. Absorption may be markedly increased when the skin has lost its keratin layerand can be increased by inflammation or diseases of the epidermal barrier. Hydrocortisone is absorbed to a greaterdegree from the scrotum, axilla, eyelid, face and scalp than from the forearm, knee, elbow, palm and sole.

5.3. Preclinical safety data
There are no preclinical data of relevance to the prescriber which are additional to that already included.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Paraffin liquid,
Propylparaben (E216),
Petrolatum (vaseline) white,
Ethanol.

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
3 years.
Shelf life 6 months from date of first opening.

6.4. Special precautions for storage
Store in a dry place, out of the reach of children. At temperature not higher than 15^{o}C.

6.5. Nature and contents of container
Hydrocortisone 1%topical ointmentis supplied in an aluminum tube (10 g), inserted with leaflet in cardboard box.
Hydrocortisone1% topical ointment is supplied in an aluminum tube (15 g), inserted with leaflet in cardboard box.

6.6. Special precautions for disposal and other handling
No special requirements.

7. MANUFACTURER
"ARPIMED" LLC
Bldg. 19, mcr 2^{-nd}, Abovyan, KotaykiMarz,Republic of Armenia
Tel.: (374) 222 21703 Fax: (374) 222 21924

8. MARKETING AUTHORIZATION HOLDER
"ARPIMED" LLC
Bldg. 19, mcr 2-nd, Abovyan, KotaykiMarz, Republic of Armenia
Tel.: (374) 222 21703 Fax: (374) 222 21924

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
27.12.2002 (DATE OF FIRST AUTHORISATION)

10. DATE OF REVISION OF THE TEXT