SUMMARY PRODUCT CHARACTERISTIC

HYDROCORTISONE
1% ointment for topical use

1.NAME OF THE MEDICINAL PRODUCT – 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
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
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
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
Medical advice should be sought if the condition does not improve.
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 which may include cataract, glaucoma or rare conditions such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.
Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

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

No clinically significant interactions known.

4.6. Fertility, pregnancy and lactation
This product should not be used in pregnancy without medical advice. There is no information about effects during lactation.

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

4.8. Undesirable effects
Hydrocortisone Ointment 1% is usually well tolerated but if hypersensitivity occurs discontinue use.
Eye disorders:
Frequency not known: blurred vision (see also section 4.4)

Skin and subcutaneous tissue disorders:
Not known (cannot be estimated from available data): Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

4.9. Overdose
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 and subsequently the systemic circulation. Absorption may be markedly increased when the skin has lost its keratin layer and can be increased by inflammation or diseases of the epidermal barrier. Hydrocortisone is absorbed to a greater degree 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°C.

6.5. Nature and contents of container
Hydrocortisone 1% topical ointment is supplied in an aluminum tube (10 g), inserted with leaflet in cardboard box.
Hydrocortisone 1% 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
Kotayk Marz, Abovyan, 2204, 2nd Micro-District, 19 Building, Republic of Armenia Tel.: (374) 222 21703 Fax: (374) 222 21924

8. MARKETING AUTHORIZATION HOLDER
"ARPIMED" LLC
Kotayk Marz, Abovyan, 2204, 2nd Micro-District, 19 Building, 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