**SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE**

## SCHEDULING STATUS

**S3**

## PROPRIETARY NAME AND DOSAGE FORM

**ILOTYCIN-A CREAM**

## COMPOSITION

Each 1 g of ILOTYCIN-A CREAM contains 0,5 mg Vitamin A acid (tretinoin).

*Excipients:*

Adeps lanae anhydrous, butylhydroxytoluol, cetostearyl alcohol, complex acid salt of a monoalkyl phosphoric acid with diethylanolamine, dimethyl polysiloxane, glycerol monostearate, magnesium sulphates, oleic acid decyl ester, perfume, purified water, sorbitol solution

## CATEGORY AND CLASS

A 13.11 Acne preparations

## PHARMACOLOGICAL ACTION

### Pharmacodynamic properties

The primary target tissue for successful local acne therapy is the follicular epithelium. Consequently, a deep rather than superficial action is needed for the true effectiveness of a locally applied acne preparation. Tretinoin stimulates proliferation and modifies differentiation as well as cornification of the epidermis, the follicular epithelium and of the

epithelium of the acne comedos. It increases the production of loose noncoherent horny cells in the follicular epithelium and loosens the acne comedo from its bed. The comedos are subsequently ejected by the increasing stream of loose horny cells via excretory follicular ducts. In this manner the prerequisites are met for regeneration of the follicular epithelium and for healing of acne without the formation of residual scars.

## INDICATIONS

Acne vulgaris.

## CONTRAINDICATIONS

Acute dermatitis, particularly acute eczema and rosacea.

## WARNINGS AND SPECIAL PRECAUTIONS

ILOTYCIN-A CREAM is for external use only.

During the first weeks of therapy an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication on deep, previously unseen acne comedos.

The severeness of these accompanying symptoms depends on the dose and frequency of application of ILOTYCIN-A CREAM and on the patient's individual sensitivity. The symptoms usually decrease or disappear during further treatment. In cases where it is necessary temporarily to discontinue the therapy or to reduce the frequency of application, regular treatment may be resumed when the patient is again able to tolerate the treatment.

Therapeutic results are noticed as a rule after two to three weeks of treatment; optimal results (complete disappearance of acne comedos and efflorescence) may be expected after approximately six to seven weeks of therapy.

ILOTYCIN-A CREAM should be kept away from the eyes, the mouth and mucous membranes.

## INTERACTIONS

Concomitant topical medication with other medicines should be used with caution because of possible interactions with tretinoin.

Particular caution should be exercised in using preparations containing peeling agents (such as sulphur, resorcinol, benzoyl peroxide or salicylic acid). Extensive exposure to sunlight, including sun lamps, should be avoided during use of ILOTYCIN-A CREAM. Medicated or abrasive soaps or cleansers as well as cosmetics that have a strong drying effect or products with high concentrations of alcohol or astringents (shaving lotions) should not be used during treatment with ILOTYCIN-A CREAM.

## HUMAN REPRODUCTION

Not known.

## DOSAGE AND DIRECTIONS FOR USE

Unless otherwise prescribed by the doctor, ILOTYCIN-A CREAM should be applied twice daily (morning and evening) to the skin, using enough to lightly cover the entire affected area. Prior to application the skin should preferably be cleaned with lukewarm water and a mild, non-irritating soap.

## SIDE EFFECTS

The application of ILOTYCIN-A CREAM may cause a transitory reddening of the skin and a feeling of warmth or slight stinging.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

### Symptoms

Symptoms mentioned under “SIDE EFFECTS” may occur.

### Treatment

Treatment is supportive and symptomatic.

## IDENTIFICATION

Light yellow, homogenous off-white emulsion with a pleasant odour.

## PRESENTATION

20 g is packed into aluminium tubes with inner protection lacquer on epoxy-phenol basis.

## STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

## REGISTRATION NUMBER

H/13.12/171

## NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead; 2191

## DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 30 August 1977

Date of the most recent amendment to the professional information as approved by the Authority: 17 August 1998

Namibia: NS2 90/13.12/00986

**ZA_ILOTCRM_9808_02**

**SUID-AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK**

**SKEDULERINGSTATUS**

**S3**

**EIENDOMSNAAM EN DOSEERVORM**

**ILOTYCIN-A CREAM** (room)

**SAMESTELLING**

Elke 1 g ILOTYCIN-A CREAM bevat 0,5 mg Vitamien A suur (tretinoïen).

*Eksipiënte:*

Anhidriese adeps lanae, butielhidroksitoluol, setostеariel alkohol, komplekse suursout van ’n mono-alkiel fosforsuur met diëtielanolamien, dimetiel polisiloksaan, gliserol monostearaat, magnesiumsulfaat, oleïensuur desielester, parfuum, gesuiwerde water, sorbitol oplossing

**KATEGORIE EN KLAS**

A 13.12 Aknee-preparate

**FARMAKOLOGIESE WERKING**

**Farmakodinamiese eienskappe**

Die primêre teikenweefsel vir die suksesvolle plaaslike aknee terapie, is die follikulêre epiteel. Gevolglik is ’n diep, eerder as ’n oppervlakkige werking nodig vir ware doeltreffendheid van ’n aknee preparaat wat plaaslik aangewend word. Tretinoïen stimuleer proliferasie en wysig differensiasie asook kornifikasie van die epidermis, die follikulêre epiteel en van die epiteel van die aknee-komedo. Dit verhoog die produksie van los nie-

samehangende horingagtige selle in die follikulêre epiteel en maak die aknee-komedo los van sy bedding. Die komedo's word daarna deur die toenemende stroom van los horingagtige selle via uitskeidings follikulêre kanale uitgewerp.

Op hierdie wyse word aan die voorvereistes voldoen vir die herstel van die follikulêre epiteel en vir die genesing van aknee sonder die vorming van residuele littekens.

**INDIKASIES**

Aknee vulgaris.

**KONTRA-INDIKASIES**

Akute dermatitis, veral akute ekseem en rosacea.

**WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**

ILOTYCIN-A CREAM is slegs vir uitwendige gebruik.

Gedurende die eerste weke van terapie kan 'n skynbare verergering van inflammatoriese letsels voorkom. Dit is as gevolg van die werking van die medikasie op diep, voorheen onsigbare aknee-komedo's. Die erns van hierdie gepaardgaande simptome hang af van die dosis en hoe dikwels ILOTYCIN-A CREAM aangewend word, asook die individuele sensitiwiteit van die pasiënt. Die simptome neem gewoonlik af of verdwyn gedurende verdere behandeling. In gevalle waar dit nodig is om die terapie tydelik te staak of om die frekwensie van aanwending te verminder, kan gereelde behandeling hervat word wanneer die pasiënt weer in staat is om die behandeling te verdra.

Terapeutiese resultate word as 'n reël na twee tot drie weke opgemerk; optimale resultate (algehele verdwyning van aknee-komedo's en veluitslag) kan na ongeveer ses tot sewe weke van terapie verwag word.

ILOTYCIN-A CREAM moet weg van die oë, die mond en slymvliese gehou word.

## INTERKASIES

Meegaande topikale medikasie met ander medisyne moet met versigtigheid gebruik word as gevolg van die moontlike interaksies met tretinoïen.

Besondere versigtigheid moet uitgeoefen word wanneer preparate wat vervelmiddels bevat (soos swawel, resorsinol, bensoïelperoksied of salisielsuur), gebruik word. Grootskaalse blootstelling aan sonlig, sonlampe ingesluit, moet vermy word gedurende gebruik van ILOTYCIN-A CREAM. Medisinale- of skuurseep of skoonmaakmiddels asook skoonheidsmiddels wat ’n sterk uitdroog effek het, of produkte met hoë konsentrasies alkohol of saamtrekmiddels (naskeermiddels) moenie tydens behandeling met ILOTYCIN-A CREAM gebruik word nie.

## MENSLIKE VOORTPLANTING

Onbekend.

## DOSIS EN GEBRUIKSAANWYSINGS

Tensy anders voorgeskryf deur die dokter, moet ILOTYCIN-A CREAM twee keer per dag (soggens en saans) aan die vel aangewend word, deur genoeg te gebruik om liggies die hele aangetaste area te bedek. Voor aanwending, moet die vel verkieslik met louwarm water en ’n ligte nie-irriterende seep skoongemaak word.

## NEWE-EFFEKTE

Die aanwending van ILOTYCIN-A CREAM kan veroorsaak dat die vel tydelik rooi word en ’n gevoel van warmte of effense prikkeling kan voorkom.

## BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

### Simptome

Simptome soos onder “NEWE-EFFEKTE” genoem kan voorkom.

### Behandeling

Behandeling is ondersteunend en simptomaties.

**IDENTIFIKASIE**

Ligte geel, homogeniese naaswit emulsie met aangename reuk.

**AANBIEDING**

20 g word verpak in aluminiumbuise met innerlike lakbeskerming op epoksie-fenol basis.

**BERGINGSAANWYSINGS**

Bêre teen of benede 25 °C.

Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.

**HOU BUITE BEREIK VAN KINDERS.**

**REGISTRASIENOMMER**

H/13.12/171

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE**

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead;2191

**DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK**

Datum van registrasie: 30 Augustus 1977

Datum van die mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 17 Augustus 1998

Namibië: NS2 90/13.12/00986

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