SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

ILOTYCIN A GEL

COMPOSITION

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

Excipients:

Butylated hydroxytoluene, carbopol, cremophor, isopropyl alcohol, methyl hydroxybenzoate, purified water, sodium propyl hydroxybenzoate, softigen

Preservatives:

Methyl hydroxybenzoate	0,06 % *m/m*
Sodium propyl hydroxybenzoate	0,04 % *m/m*

CATEGORY AND CLASS

A 13.11 Acne preparations

PHARMACOLOGICAL ACTION

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 GEL is for external use only.

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

Particular caution should be exercised in using preparations containing peeling agents (such as sulphur, resorcinol, benzoyl peroxide or salicylic acid). 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 GEL.

Extensive exposure to sunlight, including sun lamps, should be avoided during use of ILOTYCIN A GEL.

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

INTERACTIONS

Concomitant topical application of other medicines should be done with caution because of possible interactions with tretinoin.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Unless otherwise prescribed by the physician, ILOTYCIN A GEL 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 GEL may cause a transitory reddening of the skin and a feeling of warmth or slight stinging. During the first weeks of therapy an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication on the skin, previously unseen acne comedos. The severity of these accompanying symptoms depends on the dose and frequency of application of ILOTYCIN A GEL and on the patients' 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms mentioned under SIDE EFFECTS may occur. Treatment is supportive and symptomatic.

IDENTIFICATION

A light yellow clear gel.

PRESENTATION

20 g is packed in a printed aluminium tube.

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/13.12/172

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: 30 August 1977

Botswana BOT0901543 S2

Namibia NS2 90/13.12/00987

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SUID AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

ILOTYCIN A GEL (jel)

SAMESTELLING

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

Eksipiënte:

Gebutileerde hidroksitolueen, karbopol, kremofor, isopropielalkohol, metielhidroksibensoaat, gesuiwerde water, natriumpropiel-hidroksibensoaat, “softigen”

Preserveermiddels:

Metielhidroksibensoaat	0,06 % *m/m*
Natriumpropiel-hidroksibensoaat	0,04 % *m/m*

KATEGORIE EN KLAS

A 13.11 Aknee-preparate

FARMAKOLOGIESE WERKING

Die follikulêre epiteel is die primêre teikenweefsel vir suksesvolle plaaslike aknee terapie.

Gevolglik is ’n diep, eerder as ’n oppervlakkige werking nodig vir die ware doeltreffendheid van ’n plaaslik aangewende aknee preparaat. Tretinoïen stimuleer proliferasie en wysig differensiasie asook kornifikasie van die epidermis, die follikulêre epiteel en van die epiteel van die aknee-komedo’s. Dit verhoog die produksie van los, nie-saamklewende horingagtige selle in die follikulêre epiteel en maak die aknee-komedo van sy bed los. Die komedo’s word daarna deur die toenemende stroom van los horingagtige selle, deur middel van follikulêre uitskeidingsbuise 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

Acne vulgaris.

KONTRA-INDIKASIES

Akute dermatitis, veral akute ekseem en rosacea.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

ILOTYCIN A GEL is slegs vir uitwendige gebruik.

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

Sorg moet veral uitgeoefen word met die gebruik van preparate wat afskilferingsmiddels (soos swael, resorsinol, bensoïelperoksied of salisielsuur) bevat. Gemedisineerde of skurende sepe of reinigers, sowel as skoonheidsmiddels wat ’n sterk uitdrogende effek het, of produkte met hoë konsentrasies van alkohol of saamtrekmiddels (skeermiddels) moenie gedurende behandeling met ILOTYCIN A GEL gebruik word nie.

Oormatige blootstelling aan sonlig, insluitend sonlampe, moet gedurende die gebruik van ILOTYCIN A GEL vermy word.

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

INTERKASIES

Gepaardgaande plaaslike aanwending van ander medisyne moet versigtig gedoen word as gevolg van moontlike interaksies met tretinoïen.

MENSLIKE VOORTPLANTING

Onbekend.

DOSIS EN GEBRUIKSAANWYSINGS

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

NEWE-EFFEKTE

Die aanwending van ILOTYCIN A GEL kan ’n verbygaande verrooiing van die vel en ’n gevoel van warmte of effense branderigheid veroorsaak. Gedurende die eerste weke van terapie kan ’n skynbare verergering of inflammatoriese letsels voorkom. Dit is as gevolg van die werking van die medikasie op die vel, voorheen onsigbare aknee-komedo’s. Die ernstigheid van hierdie gepaardgaande simptome hang van die dosis en frekwensie van aanwending van ILOTYCIN A GEL en van die pasiënt se individuele sensitiwiteit af. Die simptome verminder of verdwyn gewoonlik gedurende verdere behandeling. In gevalle waar

dit nodig is om die terapie tydelik te staak of om die frekwensie van aanwending te verminder, kan gewone behandeling hervat word wanneer die pasiënt weer die behandeling kan verdra.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

Simptome wat onder NEWE-EFFEKTE genoem word, kan voorkom. Behandeling is ondersteunend en simptomaties.

IDENTIFIKASIE

'n Liggeel deursigtige jel.

AANBIEDING

20 g word in 'n gedrukte aluminiumbuis verpak.

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/13.12/172

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: 30 Augustus 1977

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