Scheduling status: S4

Proprietary name: **EFUDIX®**

Proprietary name and dosage form:
Efudix Ointment

COMPOSITION
Efudix ointment is an oil-in-water emulsion containing as active substance 50mg/g fluorouracil, a fluorinated pyrimidine belonging to the antimetabolite group of drugs. Contains 0,025 % methylhydroxybenzoate and 0,015 % propylhydroxybenzoate.

PHARMACOLOGICAL CLASSIFICATION
A: 13.8 Keratolytics.

PHARMACOLOGICAL ACTION
Efudix, a cytostatically active preparation exerts a beneficial therapeutic effect on neoplastic and pre-neoplastic skin lesions. When the preparation is applied to such lesions, the action of fluorouracil produces the following pattern of response: first erythema, then usually vesiculation, erosion, ulceration, necrosis and epithelialization.

INDICATIONS
Solar and senile keratoses, Bowen's disease, single or multiple superficial basal-cell carcinomas; premalignant conditions and superficial basal-cell carcinomas in radiation damaged skin. Nodular basal-cell and squamous-cell carcinoma do not respond to Efudix treatment.

CONTRAINDICATIONS
Efudix should not be used during pregnancy, nor where pregnancy cannot be excluded. It is likewise contraindicated in patients with known hypersensitivity to Efudix.

WARNINGS AND SPECIAL PRECAUTIONS
The total area of skin being treated with **EFUDIX** at any one time should not exceed 500 cm^2 (approx. 23 x 23 cm). Larger areas should be treated a section at a time. The ointment should not be allowed to come into contact with mucous membranes or the eyes. The hands should be carefully washed after applying **Efudix**.

DOSAGE AND DIRECTIONS FOR USE
Efudix should only be used under strict medical supervision. In cases of senile and solar keratoses a thin layer of the ointment is applied to the affected areas once or twice daily, generally without a dressing. In the treatment of other conditions (including keratosis palmaris) a fresh occlusive dressing should be applied daily. Treatment should be continued up to the ulceration stage in the case of basal-cell carcinoma and up to the erosion stage in the case of other types of lesions. Duration of therapy is usually 3–4 weeks, but it may prove necessary to exceed this on occasion.

SIDE EFFECTS
Efudix is well tolerated. The healthy skin surrounding the area being treated may occasionally become reddened, but soon resumes its normal colour on cessation of treatment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Systemic symptoms of overdosage have to date not been reported or observed because of the negligible cutaneous absorption. Local signs may range from mild to severe skin irritation (erythema to ulceration). Treatment consists of withdrawal of drug and supportive measures to promote healing which may include the application of an antihistaminic or steroid ointment and possibly a systemic antibacterial agent to prevent local infection in ulcerated areas.

IDENTIFICATION
White ointment.

PRESENTATION
Ointment 50 mg/g – 20 g

STORAGE INSTRUCTIONS
Store at or below 25°C.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER
D/13.8/122

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Mylan (Pty) Ltd
4 Brewery Street, Isando, Johannesburg,
South Africa, 1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT
03 November 1994

NAMIBIA
NS2
04/13.8/105

Mylan
www.mylansa.co.za

Skeduleringstatus: S4

Eiendomsnaam: **EFUDIX®**

Eiendomsnaam en doseervorm:
Efudix Salf

SAMESTELLING
Efudix salf is 'n olie-in-water-emulsie wat as aktiewe bestanddeel 50 mg/g fluorourasiel, 'n gefluorineerde pirimidien wat aan die antimetabolietgroep geneesmiddels behoort, bevat. Bevat 0,025 % metielhidroksiebensoaat en 0,015 % propielhidroksiebensoaat.

FARMAKOLOGIESE KLASSIFIKASIE
A: 13.8 Keratolitikum.

FARMAKOLOGIESE WERKING
Efudix, 'n sitostaties-aktiewe preparaat, oefen 'n voordelige terapeutiese uitwerking op neoplastiese en preneoplastiese huidletsels uit. Wanneer die preparaat op sulke letsels aangewend word, lewer die werking van fluorourasiel die volgende reaksiepatroon: eers eriteem, dan gewoonlik vesikulasie, erosie, ulserering, nekrose en epitelialisering.

INDIKASIES
Solare en seniele keratose, Bowen se siekte en enkel- of veelvoudige oppervlakkige basaalselkarsinome, pre-maligne toestande asook oppervlakkige basaalselkarsinome van die vel wat deur bestraling beskadig is. Nodulêre basaalsel- en plaveiselselkarsinome reageer nie op Efudix terapie nie.

KONTRA-INDIKASIES
Efudix moet nie gedurende swangerskap, of waar die moontlikheid van swangerskap nie uitgesluit kan word, gebruik word nie. Dit is ook teenaangedui in pasiënte met 'n bekende hipersensitiwiteit vir Efudix.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Die totale veloppervlakte wat te enige tyd met **EFUDIX** behandel word, moet nie 500 cm² (ongeveer 23 x 23 cm) oorskry nie. Groter oppervlaktes moet 'n gedeelte op 'n keer behandel word. Die salf moet nie toegelaat word om met die slymvliese of die oë in aanraking te kom nie. Die hande moet deeglik gewas word, nadat **EFUDIX** aangewend is.

DOSIS EN GEBRUIKSAANWYSINGS
Efudix moet slegs onder streng mediese toesig gebruik word. In gevalle van senieleen solare keratose word 'n dun lagie van die salf een- of twee keer per dag op die aangetaste dele aangewend, gewoonlik sonder 'n verband. In die behandeling van ander toestande (insluitende keratosis palmaris) moet 'n nuwe verband daagliks aangewend word.

Behandeling moet volgehou word tot op die ulsereringstadium in die geval van basaalselkarsinoom, en tot op die erosiestadium in die geval van ander soorte letsels. Duur van terapie is normaalweg 3 – 4 weke, dog dit mag nodig blyk te wees om dit in sekere gevalle te verleng.

NEWE-EFFEKTE
Efudix word goed verdra. Die gesonde vel wat die deel wat behandel word omring, kan soms rooi word, dog neem spoedig na staking van behandeling weer sy normale kleur aan.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Sistemiese simptome van oordosis is tot dusver nog nie aangemeld of waargeneem nie vanwee die onbeduidende kutane absorpsie. Plaaslike verskynsels wissel van matige tot ernstige irritasie van die vel (eriteem tot ulkusvorming). Behandeling behels onttrekking van die middel en ondersteunende maatreëls om genesing te bevorder. Dit kan die aanwending van 'n antihistaminiese of steroïed-salf insluit en moontlik 'n sistemiese antibakteriële middel om plaaslike infeksie in geulsereerde gebiede te voorkom.

IDENTIFIKASIE
Wit salf.

AANBIEDING
Salf 50mg/g – 20g

BERGINGSAANWYSINGS
Bewaar teen of benede 25°C.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
D/13.8/122

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
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Mylan

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Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.	**ULOTKA PIL**				
Nazwa produktu Product Name	**EFUDIX** /Fluorouracilum/		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	**ZA**		Nr wykrojnika Spec No	**-**	
Opracowane przez Designed by	**Katarzyna Wojdanowska**		Kod Wytwórcy Manufacturer code	**-**	
Nr korekty Proof No	**3**	Data Date **14-02-2020**	Kod farmaceutyczny Pharmacode	**13**	
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Krój czcionki Font used	Gill Sans font family		Gramatura papieru Paper weight	**50 g/m²**	

Komentarze Comments (Reason for the change)

– Update the logos on the packs to reflect the Mylan Logo, update from MEDA to MYLAN and Regulation updates to bring in line with the latest
– PMR_ICN-19-1189

Akceptacja Techniczna Technical Approval

Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval

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