

GOVERNMENT NOTICES  
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

No 885

№ 885

EXCLUSION OF CERTAIN MEDICINES FROM THE  
OPERATION OF CERTAIN PROVISIONS OF THE  
MEDICINES AND RELATED SUBSTANCES ACT, 1965 ACT  
NO  
101 OF 1965)

*Humphrey Zukisa Zokufa, Registrar of Medicines*, acting by virtue of a delegation in terms of section 34A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), hereby exclude in terms of Section 36 of Act 101 of 1965, on the unanimous recommendation of the members present at a meeting of the Medicine Control Council held on 11 February 2005 the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No. R.510 of 10 April 2003.

  
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HUMPHREY ZUKISA ZOKUFA  
REGISTRAR OF MEDICINES

DEPARTMENT VAN GESONDHEID

No 885

№ 885

UITSLUITING VAN SEKERE MEDISYNE VAN DIE  
TOEPASSING VAN SEKERE BEPALING VAN DIE WET OP DIE  
BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1965  
(WET NR. 101 VAN 1965)

Ek, *Humphrey Zukisa Zokufa, Registrateur van Medisyne*, handelend kragtens 'n delegasie ingevoelge artikel 34A van die Wet op Medisyne en Verwante Stowwe, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op 11 Februarie 2005, sluit hierby uit, kragtens Artikel 36 van Wet 101 van 1965, die medisyne in die Bylae hiervan vermeld van die toepassing van die daarinvermelde bepalings van die regulasies afgekondig by Goewermentskennisgewing No. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in the Bylae

  
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HUMPHREY ZUKISA ZOKUFA  
REGISTRATEUR VAN MEDISYNE

REGISTRATION NO/ REGISTRASIE NO	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITING	APPLICANT/ APPLIKANT
27/26/0181	Immukine 0,1mg	Tablets	Regulation 8(1): Information to appear on the immediate container label: Bilingualism, (a) Scheduling status, (b) Proprietary name, (q) Registration number, (r) Name of Holder of certificate of Registration		Ingelheim Pharmaceutical (Pty) Ltd
S/16.4/144	Strepsils Orange-C	Tablets	Regulation 9 Bilingualism Regulation 9(1): inclusion of a package insert.	Provided that the packaging of all carton packs of 2, 4, 6, 8 or 24 complies with the requirements of Regulation 10(1) to contain a patient information leaflet	Booths Healthcare (Pty) Ltd
S/16.4/144	Strepsils Orange-C (Aluminium packaging of 2's)	Tablets	Regulation 9 Bilingualism Regulation 9(1): inclusion of a package insert and Regulation 10(1): inclusion of a patient information leaflet	Provided that the Aluminium packaging of 2's complies with the requirements of an abbreviated PIL Regulation 10(1) and that the reference to "insect bites" be removed from the text under the heading "what this medicine is used for" of the Patient Information Leaflet.	Booths Healthcare (Pty) Ltd
E/16.4/46	Strepsils Soothing Honey & Lemon	Tablets	Regulation 9: Bilingualism Regulation 9(1): inclusion of a package insert	Provided that the packaging of all carton packs of 2, 4, 6, 8 or 24 complies with the	Booths Healthcare (Pty) Ltd

E/16.4/46	Strepsils Soothing Honey & Lemon (Aluminium packaging of 2's)	Tablets	Regulation 9: Bilingualism Regulation 9(1): inclusion of a package insert and Regulation 10(1): inclusion of a patient information leaflet	requirements of Regulation 10(1) to contain a patient information leaflet.	Provided that the Aluminium packaging of 2's complies with the requirements of an abbreviated PIL Regulation 10(1) and that the storage condition of the medicine be identified as to include reference to "below 25°C"	Booths Healthcare (Pty) Ltd
29/34/0037	Oxygen	Gasses	Regulation 8(1): Bilingualism		Provided that the name of the medicine remains "Oxygen" and that the wording "may cause fire and explosion" be added under the heading "Risk"	Afrox
29/34/0044	Nitrous Oxide	Gasses	Regulation 8(1): Bilingualism		Provided that the name of the medicine remains "Nitrous Oxide" and that the wording "may cause fire and explosion" be added under the heading "Risk"	Afrox