Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette **No. 9971** *Regulasiekoerant*

Vol. 576 **Pretoria, 10 June Junie 2013** **No. 36551**

AIDS HELPLINE: 0800-0123-22 Prevention is the cure

CONTENTS

INHOUD

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 409 **10 June 2013**

NO C 58

EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

I, **Mandisa Hela, 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 Medicines Control Council held on **28 February 2013** the medicines listed in the schedule hereto from the operation of the therein listed provisions of the regulations promulgated by Government Notice No R510 of 10 April 2003.

.....
MANDISA HELA
REGISTRAR OF MEDICINES

No. R. 409 **10 Junie 2013**

NR C 58

UITSLUITING VAN SEKERE MEDISYNE VAN DIE TOEPASSING VAN SEKER BEPALINGS VAN DIE WET OP DIE BEHEER VAN MEDISYNE EN VERWANTE MIDDELS 1965 (WET 101 VAN 1965)

Ek, **Mandisa Hela, Registrateur van Medisyne**, handelend kragtens 'n delegasie ingevolge artikel 34A van die Wet op Medisyne en Verwante Middels, 1965 (Wet 101 van 1965), en op eenparige aanbeveling van die lede van die Medisynebeheerraad teenwoordig in 'n vergadering gehou op **28 Februarie 2013**, sluit hierby uit, kragtens Artikel 36 van die Wet 101 van 1965, die medisyne in die bylae hiervan vermeld van die toepassing van die daarinvermelde bepalings van die regulasies afgekondig by Goewermentskennisgewing Nr. R.510 van10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.

.....
MANDISA HELA
REGISTRATEUR VAN MEDISYNE

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGSVORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITNG	APPLICANT/ APPLIKANT
Unregistered	TPN Solutions	Solutions	Section 14(1): Sale of medicines that is subjected to registration and which is not registered.	Provided that: *A Section 21 application be submitted to Council for compounded TPN Solutions;* An annual report be submitted to the Medicines Control Council on the safety and quality of these compounded preparations; *The Product complies with the labelling requirements as per Section 14(4) of the Medicines and Related Substances Act (Act 101 of 1965);* and No advertising of the TPN solutions are done.	Fresenius Kabi (Pty) Ltd
32/26/0111	Gliadel Wafers	Wafer	Regulation 8: Label on the immediate container and the outer container: Regulation 8(1): Bilingualism; Regulation 8(1)(a): Scheduling number; Regulation 8(1)(c): Registration number of the medicine; Regulation 8(1) (p): "the name of the holder of the certificate of registration of the said medicine". Regulation 9: Package Insert and Information to appear on the Package Insert: Regulation 9(1): Bilingualism; Regulation 9(1)(a): Scheduling number; Regulation 9(1)(d): Pharmacological Classification; Regulation 9(1)(n): Identification; Regulation 9(1)(p): Keep out of reach of children; Regulation 9(1)(q): Registration number of the medicine; Regulation 9(1)(r): Name and business address of the holder of certificate of registration; Regulation 9(1)(s): Date of publication of the package. Insert. Regulation 10: Patient Information leaflet to be included in the packaging.		Pharmaplan

REGISTRATION NO/ REGISTRASIE NR	NAME OF MEDICINE/ NAAM VAN MEDISYNE	FORM OF PREPARATION/ BEREIDINGSVORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARDES VIR UITSLUITNG	APPLICANT/ APPLIKANT
44/32.2/0546	Mozobil Injection	Solution for Injection.	Regulation 8: Label on the immediate container label (injection label): Regulation 8(1): Bilingualism; Regulation 8(1)(p): "the name of the holder of certificate of registration of the said medicine" Regulation 8: Label on the outer container (Carton label): Regulation 8(1): Bilingualism; Regulation 8(1)(a): Scheduling number; Regulation 8(1)(c): Registration number of the medicine; Regulation 8(1)(p): "the name of the holder of certificate of registration of the said medicine" Regulation 8(1)(q): "the name of the holder of certificate of registration of the said medicine". Regulation 9: Package Insert and information to appear of the Package Insert: Regulation 9(1): Bilingualism; Regulation 9(1)(a): Scheduling number; Regulation 9(1)(d): Pharmacological classification; Regulation 9(1)(q): Registration number of the medicine; Regulation 9(1)(r): Name and business address of the holder of certificate of registration; Regulation 9(1)(s): Date of publication of the package insert. Regulation 10: Patient Information Leaflet to be included in the packaging.	Provided that: The exemption is only applicable for 8 units, Batch number: J0002H15; Expiry date: February 2014.	Genzyme
43/31/0745	Myozyme	Powder for Injection.	Section 22G(3)(a) Transparent Pricing System; and Regulation 6 Transparent Pricing System.	Provided that: The exemption is solely for the sale at no cost to one A Vahed at the prescribed dose of his treating Physician.	Genzyme

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531