

DEPARTMENT OF HEALTH

No 590

9 June 2006

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DEPARTMENT VAN GESONDHEID

9 Junie 2006

<p>NO C15 2006</p> <p>EXCLUSION OF CERTAIN MEDICINES FROM THE OPERATION OF CERTAIN PROVISIONS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (AOT NO 101 OF 1965)</p> <p>1. <i>Mandisa Hela, Registrar of Medicines</i>, 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 7 April 2006 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.</p> <p style="text-align: right;">..... MANDISA HELA REGISTRAR OF MEDICINES</p>	<p>NO C15 2006</p> <p>UITSluiting van sekere medisyne van die toepassing van sekere bepaling van die wet o die beheer van medisyne en verwante stowwe, 1965 (Wet Nr. 101 van 1965)</p> <p>Ek, <i>Mandisa Hela, Registrateur van Medisyne</i>, handelend kragtens 'n delegasie ingevolge 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 7 April 2006, sluit hierby uit, kragtens Artikel 36 van Wet 101 van 1965, die medisyne in die Bylae hiervan vermeld van die toepassing van die daarinvermelde bepaling van die regulasies afgekondig by Goewermentskennisgewing No. R.510 van 10 April 2003, onderworpe aan die voorwaardes ingelys in die Bylae vermeld.</p> <p style="text-align: right;">..... MANDISA HELA REGISTRATEUR VAN MEDISYNE</p>
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REGISTRATION NO/ REGISTRASIE NO	NAME OF MEDICINE/ NAAAM VAN MEDISYNE	FORM OF PREPARATIO N/ BEREIDINGS VORM	PROVISIONS FROM WHICH EXCLUDED/ BEPALINGS WAARVAN UITGESLUIT	CONDITIONS OF EXCLUSION/ VOORWAARD ES VIR UITSLUITING	APPLICANT/ APPLIKANT
B/2.9/1113 P/2.9/22	Grand Pa Headache Powders Grand Pa Headache Tablets	Powder Tablet	Regulation 9 Package Insert	1. When packed as a single dose pack (2 tablets) 2. Abbreviated package insert be printed on the sachets	Glaxo SmithKline
A39/35/0016	Zevalin		Regulation 8(1): Bilingualism (c) registration number (p) name of the Holder of Certificate Registration on the outer container label (carton) Regulation 8(1): Bilingualism (a) scheduling number (c) registration number (p) name of the Applicant on the label on the Formulation buffer (10ml) Regulation 8(1): Bilingualism (c) registration number (e) approved name of active ingredient and quantity thereof (p) name of the Applicant		Schering Plough
320044	Infanrix injection		Regulation 8(1): Bilingualism (p) Name of the Holder of the Certificate		Glaxo SmithKline

H/20.1.1/46	Palacos R with Garamycin (Bone Cement)		Regulation 8(1): (a) scheduling status (c) registration number (p) Name of the Holder of the Certificate	1. The RSA proprietary name be changed to the international proprietary name	Schering Plough
A400322	Onicit		Regulation 8(1):	Bilingualism	Pfizer Global Pharmaceuticals