EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2015
EMA/727021/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: phenylephrine

Procedure No.: PSUSA/00002378/201501

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised	Legal basis
Colircusi Fenilefrina		34.185	Alcon Cusi, S.A	ES	N/A (authorised in 1960)
Disneumón pernasal		46297	Abbott Laboratories, S.A.	ES	Full application (Article 8(3) of Directive No 2001/83/EC)
Metaoxedrin Minims		5732	Bausch & Lomb UK ltd	NO	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Fenylefrinehydrochloride		RVG 09366	Bausch & Lomb Pharma	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Fenylefrinehydrochloride		RVG 14872	Bausch & Lomb Pharma	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Phenylephrine Chlorhydrate		1999045015	Bausch & Lomb Pharma	LU	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Phenylephrine Chlorhydrate		BE097133	Bausch & Lomb Pharma	BE	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Phenylephrine Hydrochloride		AA147/00112	Bausch & Lomb UK Ltd	MT	Medicinal product authorised according to Article 126a of Directive No 2001/83/EC
Minims Phenylephrine		AA1088/00401	Bausch & Lomb UK Ltd	MT	Medicinal product authorised according to

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised	Legal basis
Hydrochloride					Article 126a of Directive No 2001/83/EC
Minims Phenylephrine Hydrochloride		PL 03468/0076	Bausch & Lomb UK Ltd	GB	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Phenylephrine Hydrochloride		PL 03468/0077	Bausch & Lomb UK Ltd	GB	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Phenylephrine Hydrochloride		PA 555/14/2	Bausch & Lomb UK ltd	IE	Full application (Article 8(3) of Directive No 2001/83/EC)
Minims Phenylephrine Hydrochloride		PA 555/14/1	Bausch & Lomb UK ltd	IE	Full application (Article 8(3) of Directive No 2001/83/EC)
Nasomixin C.M.		AIC 038070013	Teofarma S.R.L.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)
Neo-sinefrina 2,5 mg/ml		9908731	Omega Pharma Portuguesa, Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Neo-sinefrina 5 mg/ml		9908756	Omega Pharma Portuguesa, Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Neo-synephrine		AIC 006769020	Teofarma S.R.L.	IT	Full application (Article 8(3) of Directive No 2001/83/EC)

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised	Legal basis
Neosynephrine Faure		NL 11153	Laboratoires Europhta	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Neosynephrine Faure		NL 11154	Laboratoires Europhta	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Neosynephrine Faure		NL 11800	Laboratoires Europhta	FR	Full application (Article 8(3) of Directive No 2001/83/EC)
Phenylephrine hydrochloride Chauvin		10045	Bausch & Lomb UK ltd	SE	Full application (Article 8(3) of Directive No 2001/83/EC)
VibrocilFen		3870680-3870789	Novartis Consumer Health - Produtos Farmacêuticos e Nutrição, Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
VibrocilFen		3870888-3870987	Novartis Consumer Health - Produtos Farmacêuticos e Nutrição, Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
VibrocilFen		3871084	Novartis Consumer Health - Produtos Farmacêuticos e Nutrição, Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Visadron		6191164.00.00	Alcon Pharma Gmbh	DE	Bibliographic application: 65/65/EWG Art. 4, 8a ii
Visadron		8753	Boehringer Ingelheim Rcv Gmbh & Co Kg	AT	Full application (Article 8(3) of Directive No 2001/83/EC)

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised	Legal basis
Visadron		8914804	Unilfarma Lda.	PT	Full application (Article 8(3) of Directive No 2001/83/EC)
Visadron		RVG 04518	Boehringer Ingelheim B.V.	NL	Full application (Article 8(3) of Directive No 2001/83/EC)
Neosynephrine AP-HP		34009 355 407 0 6	AGEPS	FR	Full application (Article 8(3) of Directive No 2001/83/EC)