



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 September 2016
EMA/606912/2016
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): Flumazenil

Procedure No.: PSUSA/00001413/201512



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
Anexate		1-18341	Roche Austria Gmbh	Austria
Anexate		1-18342	Roche Austria Gmbh	Austria
Anexate		BE140226	N.V. Roche S.A.	Belgium
Anexate		20020817	Roche Bulgaria Eood	Bulgaria
Anexate		UP/I-530-09/11-02/120	Roche D.O.O.	Croatia
Anexate		19/202/87 – C	Roche S.R.O.	Czech Republic
Anexate		355 757-1 & 355 758-8 & 355 759-4 & 355 761-9 & 355 762-5	Roche	France
Anexate		355 760-2 & 355 763-1 & 355 764-8 & 355 765-4 & 355 766-0 & 355 767-7 & 355 768-3	Roche	France
Anexate		14747.00.00	Roche Pharma Ag	Germany
Anexate		14747.01.00	Roche Pharma Ag	Germany
Anexate		89475/27.10.2014	Roche (Hellas) Sa	Greece
Anexate		OGYI/21307/2014	Roche (Magyarország) Kft	Hungary
Anexate		PA 50/72/1	Roche Products Ltd	Ireland
Anexate		026749010	Roche S.P.A.	Italy
Anexate		026749034	Roche S.P.A.	Italy
Anexate		0178/03/06/7440	N.V. Roche S.A.	Luxembourg
Anexate		RVG 12857	Roche Nederland B.V.	Netherlands
Anexate		7320	F. Hoffmann-La Roche Ag	Norway
Anexate		R/0962	Roche Polska Sp.O.O.	Poland
Anexate		8681809	Roche Farmacêutica Química, Lda.	Portugal
Anexate		8681817	Roche Farmacêutica Química, Lda.	Portugal
Anexate		8409/2015/01	Roche Romania Srl	Romania
Anexate		19/0202/87-C/S	Roche Slovensko S.R.O.	Slovakia
Anexate		5363-I-87/11	Roche Farmaceutvska Družba D.O.O.	Slovenia

Anexate		57.806	Roche	Spain
Anexate		57.807	Roche	Spain
Lanexat		10757	Roche Ab	Sweden
Flumazenil B. Braun	NL/H/0915/001	1-26938	B. Braun Melsungen Ag	Austria
Flumazenil B. Braun	NL/H/0915/001	BE296222	B. Braun Melsungen Ag	Belgium
Flumazenil B. Braun	NL/H/0915/001	BE296231	B. Braun Melsungen Ag	Belgium
Flumazenil B. Braun	NL/H/0915/001	22559	B. Braun Melsungen Ag	Finland
Flumazenil B. Braun	NL/H/0915/001	64945.00.00	B. Braun Melsungen Ag	Germany
Flumazenil B. Braun	NL/H/0915/001	IS/1/10/088/01	B. Braun Melsungen Ag	Iceland
Flumazenil B. Braun	NL/H/0915/001	37756032, 37756020, 37756044 37756018	B. Braun Melsungen Ag	Italy
Flumazenil B. Braun	NL/H/0915/001	0667/07090088	B. Braun Melsungen Ag	Luxembourg
Flumazenil B. Braun	NL/H/0915/001	RVG 32038	B. Braun Melsungen Ag	Netherlands
Flumazenil B. Braun	NL/H/0915/001	14618	B. Braun Melsungen Ag	Poland
Flumazenilo B. Braun	NL/H/0915/001	5019005 & 5019013 & 5019021 & 5019039	B. Braun Melsungen Ag	Portugal
Flumazenil B. Braun	NL/H/0915/001	69020	B. Braun Melsungen Ag	Spain
Flumazenil B. Braun	NL/H/0915/001	24357	B. Braun Melsungen Ag	Sweden
Flumazenilo Fresenius Kabi	NL/H/0639/001	67.260	Fresenius Kabi España S.A.U.	Spain