



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 June 2017
EMA/367573/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: bromhexine

Procedure no.: PSUSA/00000437/201609



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
Basiflux 1,6 mg/ml xarope		5411566	LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.	PT
Bisolvon 0.8 mg/ml oral lösning		9092	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE
Bisolvon 1.6 mg/ml oral lösning		19661	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE
BISOLVON 2 mg/ml peroralna raztopina/inhalacijska raztopina za nebulator		H/92/00288/002	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SI
BISOLVON 2 mg/ml peroralna raztopina/inhalacijska raztopina za nebulator		5363-I-1488/11	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SI
Bisolvon 2 mg/ml solução oral		8254912	UNILFARMA LDA.	PT
Bisolvon 2 mg/ml solução oral		8254920	UNILFARMA LDA.	PT
Bisolvon 2 mg/ml solução oral		8254938	UNILFARMA LDA.	PT
BISOLVON 4 mg/5 ml sirup		H/92/00288/003	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SI
BISOLVON 4 mg/5 ml sirup		5363-I-2513/10	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SI
BISOLVON 8 MG COMPRIMIDO		9254813	UNILFARMA LDA.	PT
Bisolvon 8 mg comprimido dispersível		3231297	UNILFARMA LDA.	PT
Bisolvon 8 mg comprimido dispersível		3231396	UNILFARMA LDA.	PT
Bisolvon 8 mg comprimido dispersível		5005301	UNILFARMA LDA.	PT
Bisolvon 8 mg oral lösning i dospåse		50678	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE

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BISOLVON 8 MG TABLETE		5363-I-1489/11	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SI
Bisolvon 8 mg tabletter		8805	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE
Bisolvon 8 mg töflur		671024	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	IS
Bisolvon Citron 8 mg lösliga tabletter		14351	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE
Bisolvon drank in sachet, 8 mg		RVG 111840	BOEHRINGER INGELHEIM B.V.	NL
Bisolvon drank voor kinderen met aardbeiensmaak 4 mg/5 ml		RVG 107255	BOEHRINGER INGELHEIM B.V.	NL
Bisolvon drank voor kinderen, 4 mg/5 ml		RVG 06053	BOEHRINGER INGELHEIM B.V.	NL
Bisolvon drank, 8 mg/5 ml		RVG 09554	BOEHRINGER INGELHEIM B.V.	NL
Bisolvon druppels voor kinderen, 2 mg/ml		RVG 20431	BOEHRINGER INGELHEIM B.V.	NL
Bisolvon Jordgubb 0,8 mg/ml oral lösning		43664	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE
Bisolvon Linctus Adulto 1,6 mg/ml Xarope		5314182	UNILFARMA LDA.	PT
Bisolvon Linctus Adulto, 1,6 mg/ml, Xarope		5790183	UNILFARMA LDA.	PT
Bisolvon Linctus Criança 0,8 mg/ml Xarope		8283309	UNILFARMA LDA.	PT

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BISOLVON MUCOLÍTICO 1,6 MG/ ML JARABE		66.548	BOEHRINGER INGELHEIM ESPANA S.A.	ES
Bisolvon mucolítico 8 mg comprimidos solubles		74.772	BOEHRINGER INGELHEIM ESPANA S.A.	ES
Bisolvon mucolítico 8 mg jarabe en sobres		78834	BOEHRINGER INGELHEIM ESPANA S.A.	ES
BISOLVON MUCOLITICO INFANTIL 0,8 MG/ML JARABE		78348	BOEHRINGER INGELHEIM ESPANA S.A.	ES
Bisolvon tabletten, 8 mg		RVG 09246	BOEHRINGER INGELHEIM B.V.	NL
Bisolvon, opløselige tabletter		19427	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	DK
Bisolvon, oral opløsning		6647	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	DK
Bisolvon, tabletter		6718	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	DK
Bisolvon® - Lösung		1-13241	BOEHRINGER INGELHEIM RCV GMBH & CO KG	AT
Bisolvon® Hustenlöser - Saft		1-14179	BOEHRINGER INGELHEIM RCV GMBH & CO KG	AT
Bisolvon® Hustensaft 8 mg/5 ml		25320.00.00	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG	DE
Bisolvon® Hustentabletten 8 mg/Tablette		6773.00.02	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG	DE
BISOLVON® HUSTENTROPFEN 10 mg/5 ml Tropfen zum Einnehmen, Lösung		6424059.00.00	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG	DE

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Bisolvon-Linctus® Hustensaft 4 mg/5 ml		6773.00.00	BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG	DE
Bromexina Bluepharma 1,6 mg/ml, xarope		5490818	BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.	PT
Bromexina Farmoz 1,6 mg/ml, xarope		5411558	FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.	PT
Bromexina Generis 1,6 mg/ml, xarope		5465828	GENERIS FARMACÊUTICA, S.A.	PT
Bromexina Gide, 1,6 mg/ml, xarope		5606470	LABESFAL GENÉRICOS, S.A.	PT
Bromhexin Apofri 1,6 mg/ml oral lösning		45941	APOFRI AB	SE
Bromocal, 0,8 mg/ml, xarope		5314265	CALDEIRA & METELO LDA.	PT
Medipekt 0,8 mg/ml oraaliliuos		6803	ORION OYJ	FI
Medipekt 0,8 mg/ml oral lösning		6803	ORION OYJ	FI
Medipekt 1,6 mg/ml oraaliliuos		32956	ORION OYJ	FI
Medipekt 1,6 mg/ml oral lösning		32956	ORION OYJ	FI
Pectodil 2 mg/ml solución inyectable y para perfusión		44.612	BOEHRINGER INGELHEIM ESPANA S.A.	ES
PECTODIL 2 mg/ml solución oral o concentrado para solución para inhalación por nebulizador		39.295	BOEHRINGER INGELHEIM ESPANA S.A.	ES
MUCOVIN 0,8 mg/ml - oraaliliuos		6798	Takeda Oy, Finland	FI