



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 June 2026
EMADOC-1700519818-3242613
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): bromhexine

EURD list No. PSUSA/00000437/202509

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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	not available	5472824	LABIALFARMA - LABORATÓRIO DE PRODUTOS FARMACÊUTICOS E NUTRACÊUTICOS, S.A.	BE
BISOLVON 0,2 POUR CENT, solution buvable	not available	6773.00.02	A. NATTERMANN & CIE. GMBH	BE
BISOLVON 0,2 POUR CENT, solution buvable	not available	6773.00.02	A. NATTERMANN & CIE. GMBH	BE
Bisolvon 0,8 mg/ml mikstur, jordbær	not available	6773.00.02	A. NATTERMANN & CIE. GMBH	BE
Bisolvon 0,8 mg/ml mikstur, jordbær	not available	6773.00.02	A. NATTERMANN & CIE. GMBH	BE
Bisolvon 0,8 mg/ml mikstur, jordbær	not available	6773.00.02	A. NATTERMANN & CIE. GMBH	BE
Bisolvon 0,8 mg/ml oraaliliuos	not available	6773.00.02	A. NATTERMANN & CIE. GMBH	BE
Bisolvon 0,8 mg/ml oraaliliuos	not available	8283309	OPELLA HEALTHCARE PORTUGAL UNIPESSOAL LDA.	BE
Bisolvon 0,8 mg/ml oral lösning	not available	45941	EVOLAN PHARMA AB	BE
Bisolvon 0,8 mg/ml oral lösning	not available	55632	EVOLAN PHARMA AB	BE
Bisolvon 0,8 mg/ml oral lösning	not available	RVG 09554	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 0,8 mg/ml oral lösning	not available	RVG 09554	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 0,8 mg/ml oral lösning	not available	RVG 09554	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml mikstur, kirsebær	not available	RVG 09554	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml mikstur, kirsebær	not available	RVG 09554	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml mikstur, kirsebær	not available	9254813	OPELLA HEALTHCARE PORTUGAL UNIPESSOAL LDA.	BE

Bisolvon 1,6 mg/ml mikstur, kirsebær	not available	19661	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml oral lösning	not available	9092	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml oral lösning	not available	9092	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml oral lösning	not available	8805	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 1,6 mg/ml oral lösning	not available	14351	OPELLA HEALTHCARE FRANCE SAS	BE
Bisolvon 2 mg/ml oralna otopina/koncentrat za otopinu za atomizator	not available	43664	OPELLA HEALTHCARE FRANCE SAS	DE
BISOLVON 2 mg/ml soluzione orale	not available	19661	OPELLA HEALTHCARE FRANCE SAS	DE
BISOLVON 4 mg/2 ml soluzione iniettabile	not available	19661	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 4 mg/5 ml Oral Solution	not available	19661	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 4 mg/5 ml Oral Solution	not available	43664	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 4 mg/5 ml Oral Solution	not available	43664	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 4 mg/5 ml sirup	not available	43664	OPELLA HEALTHCARE FRANCE SAS	DE
BISOLVON 8 mg compresse	not available	9092	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 8 mg Comprimido	not available	8805	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 8 mg Comprimido	not available	8805	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 8 mg oppløselige tabletter	not available	8805	OPELLA HEALTHCARE FRANCE SAS	DE
BISOLVON 8 mg tablete	not available	MA1470/00101	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 8 mg tablete	not available	MA1470/00101	OPELLA HEALTHCARE FRANCE SAS	DE

Bisolvon 8 mg tabletter	not available	MA1470/00101	OPELLA HEALTHCARE FRANCE SAS	DE
Bisolvon 8 mg tabletter	not available	66548	OPELLA HEALTHCARE SPAIN, S.L	DE
Bisolvon 8 mg tabletter	not available	5490818	BLUEPHARMA GENÉRICOS - COMÉRCIO DE MEDICAMENTOS, S.A.	DE
Bisolvon 8 mg tabletter	not available	6773.00.00	A. NATTERMANN & CIE. GMBH	DE
Bisolvon 8 mg tabletter	not available	6773.00.00	A. NATTERMANN & CIE. GMBH	DE
Bisolvon 8 mg tabletter	not available	6773.00.00	A. NATTERMANN & CIE. GMBH	DK
Bisolvon 8 mg tabletti	not available	25320.00.00	A. NATTERMANN & CIE. GMBH	DK
BISOLVON 8 mg, comprimé	not available	25320.00.00	A. NATTERMANN & CIE. GMBH	DK
BISOLVON 8 mg, comprimé	not available	25320.00.00	A. NATTERMANN & CIE. GMBH	DK
BISOLVON 8 mg, comprimé dispersible	not available	021004015	OPELLA HEALTHCARE ITALY S.R.L.	DK
Bisolvon 8 mg, liukeneva tabletti	not available	021004179	OPELLA HEALTHCARE ITALY S.R.L.	ES
Bisolvon 8 mg, lösliga tabletter	not available	021004181	OPELLA HEALTHCARE ITALY S.R.L.	ES
BISOLVON 8 mg/5 ml sciroppo	not available	78348	OPELLA HEALTHCARE SPAIN, S.L	FI
BISOLVON 8 mg/5 ml sciroppo	not available	34009 373 606 1 6	OPELLA HEALTHCARE FRANCE SAS	FI
Bisolvon 8 mg/5 mL σιρόπι	not available	34009 373 607 8 4	OPELLA HEALTHCARE FRANCE SAS	FI
Bisolvon 8 mg/5 mL σιρόπι	not available	34009 355 297 0 1	OPELLA HEALTHCARE FRANCE SAS	FI
Bisolvon Citron 8 mg lösliga tabletter	not available	34009 301 300 3 2	OPELLA HEALTHCARE FRANCE SAS	FI

Bisolvon drank voor kinderen met aardbeiensmaak, 4 mg/5 ml	not available	34009 324 859 7 0	OPELLA HEALTHCARE FRANCE SAS	FI
Bisolvon drank voor kinderen met aardbeiensmaak, 4 mg/5 ml	not available	RVG 09246	OPELLA HEALTHCARE FRANCE SAS	FI
Bisolvon drank voor kinderen met aardbeiensmaak, 4 mg/5 ml	not available	5670377	LABORATÓRIOS BASI - INDÚSTRIA FARMACÊUTICA, S.A.	FI
Bisolvon drank voor kinderen met aardbeiensmaak, 4 mg/5 ml	not available	5465828	GENERIS FARMACÊUTICA, S.A.	FI
Bisolvon drank, 8 mg/5 ml.	not available	37241/10/18.04.2011	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD.	FI
Bisolvon drank, 8 mg/5 ml.	not available	37241/10/18.04.2011	OPELLA HEALTHCARE GREECE SINGLE MEMBER LTD.	FI
Bisolvon drank, 8 mg/5 ml.	not available	9254813	OPELLA HEALTHCARE PORTUGAL UNIPESSOAL LDA.	FI
Bisolvon drank, 8 mg/5 ml.	not available	6803	ORION CORPORATION	FI
Bisolvon drank, 8 mg/5 ml.	not available	32956	ORION CORPORATION	FI
Bisolvon Hustensaft 8 mg/5 ml	not available	32956	ORION CORPORATION	FI
Bisolvon Hustensaft 8 mg/5 ml	not available	6803	ORION CORPORATION	FI
Bisolvon Hustensaft 8 mg/5 ml	not available	5606470	CUIDAFARMA, LDA.	FR
Bisolvon Hustentabletten 8 mg/Tablette	not available	12-9050	EVOLAN PHARMA AB	FR

Bisolvon Hustentabletten 8 mg/Tablette	not available	021004039	OPELLA HEALTHCARE ITALY S.R.L.	FR
Bisolvon Hustentabletten 8 mg/Tablette	not available	5411566	LABORATÓRIOS BASI – INDÚSTRIA FARMACÊUTICA, S.A.	FR
Bisolvon Hustentabletten 8 mg/Tablette	not available	21653	OPELLA HEALTHCARE FRANCE SAS	FR
Bisolvon Hustentabletten 8 mg/Tablette	not available	21653	OPELLA HEALTHCARE FRANCE SAS	GR
Bisolvon Hustentabletten 8 mg/Tablette	not available	10436	OPELLA HEALTHCARE FRANCE SAS	GR
Bisolvon Hustentropfen 10 mg/5 ml Tropfen zum Einnehmen, Lösung Wirkstoff: Bromhexinhydrochlorid	not available	10436	OPELLA HEALTHCARE FRANCE SAS	HR
Bisolvon Hustentropfen 10 mg/5 ml Tropfen zum Einnehmen, Lösung Wirkstoff: Bromhexinhydrochlorid	not available	21653	OPELLA HEALTHCARE FRANCE SAS	HR
Bisolvon Hustentropfen 10 mg/5 ml Tropfen zum Einnehmen, Lösung Wirkstoff: Bromhexinhydrochlorid	not available	21653	OPELLA HEALTHCARE FRANCE SAS	HR
Bisolvon Hustentropfen 10 mg/5 ml Tropfen zum Einnehmen, Lösung Wirkstoff: Bromhexinhydrochlorid	not available	13290	OPELLA HEALTHCARE FRANCE SAS	IT
Bisolvon Hustentropfen 10 mg/5 ml Tropfen zum Einnehmen, Lösung Wirkstoff: Bromhexinhydrochlorid	not available	13290	OPELLA HEALTHCARE FRANCE SAS	IT

Bisolvon Hustentropfen 10 mg/5 ml Tropfen zum Einnehmen, Lösung Wirkstoff: Bromhexinhydrochlorid	not available	10437	OPELLA HEALTHCARE FRANCE SAS	IT
Bisolvon Jordgubb 0,8 mg/ml oral lösning	not available	10437	OPELLA HEALTHCARE FRANCE SAS	IT
Bisolvon Jordgubb 0,8 mg/ml oral lösning	not available	10436	OPELLA HEALTHCARE FRANCE SAS	IT
Bisolvon Jordgubb 0,8 mg/ml oral lösning	not available	10436	OPELLA HEALTHCARE FRANCE SAS	IT
Bisolvon Jordgubb 0,8 mg/ml oral lösning	not available	021004027	OPELLA HEALTHCARE ITALY S.R.L.	IT
BISOLVON Linctus 4 mg/5 ml sciroppo Gusto cioccolato-ciliegia	not available	0014314	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
BISOLVON Linctus 4 mg/5 ml sciroppo Gusto fragola	not available	0014295	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
Bisolvon Linctus Adulto 1,6 mg/ml Xarope	not available	0014328	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
Bisolvon Linctus Adulto 1,6 mg/ml Xarope	not available	5314182	OPELLA HEALTHCARE PORTUGAL UNIPESSOAL LDA.	MT
Bisolvon Linctus Criança 0,8 mg/ml Xarope	not available	5790183	OPELLA HEALTHCARE PORTUGAL UNIPESSOAL LDA.	MT
BISOLVON MUCOLÍTICO 1,6 mg / ml jarabe	not available	021004205	OPELLA HEALTHCARE ITALY S.R.L.	MT
Bisolvon Mucolítico infantil 0,8 mg/ml jarabe	not available	021004041	OPELLA HEALTHCARE ITALY S.R.L.	NL
Bisolvon Schleimiger Husten 2 mg/ml Lösung für einen Vernebler	not available	6647	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Schleimiger Husten 2 mg/ml Lösung für einen Vernebler	not available	6647	OPELLA HEALTHCARE FRANCE SAS	NL

Bisolvon Schleimiger Husten 2 mg/ml Lösung für einen Vernebler	not available	6718	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Schleimiger Husten 8 mg Tabletten	not available	19427	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Schleimiger Husten 8 mg Tabletten	not available	6647	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Schleimiger Husten 8 mg Tabletten	not available	H/92/00288/001	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Schleimiger Husten 8 mg/5 ml Sirup	not available	03-2318	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Slijmhoest 2 mg/ml verneveloplossing	not available	09-7270	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Slijmhoest 2 mg/ml verneveloplossing	not available	97-5236	OPELLA HEALTHCARE FRANCE SAS	NL
Bisolvon Slijmhoest 2 mg/ml verneveloplossing	not available	03-2318	OPELLA HEALTHCARE FRANCE SAS	NO
Bisolvon Slijmhoest 8 mg tabletten	not available	6639	OPELLA HEALTHCARE FRANCE SAS	NO
Bisolvon Slijmhoest 8 mg tabletten	not available	09-7270	OPELLA HEALTHCARE FRANCE SAS	NO
Bisolvon Slijmhoest 8 mg tabletten	not available	09-7270	OPELLA HEALTHCARE FRANCE SAS	NO
Bisolvon Slijmhoest 8 mg/5 ml siroop	not available	03-2318	OPELLA HEALTHCARE FRANCE SAS	NO
Bisolvon Strong 1,6 mg/ml oraaliliuos	not available	03-2318	OPELLA HEALTHCARE FRANCE SAS	NO
Bisolvon Strong 1,6 mg/ml oraaliliuos	not available	BE142956	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	NO
Bisolvon Strong 1,6 mg/ml oral lösning	not available	BE142956	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	NO
Bisolvon Strong 1,6 mg/ml oral lösning	not available	BE142956	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	NO

Bisolvon tabletten, 8 mg.	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	NO
Bisolvon Toux grasse 2 mg/ml solution pour inhalation par nébuliseur	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 2 mg/ml solution pour inhalation par nébuliseur	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 2 mg/ml solution pour inhalation par nébuliseur	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 2 mg/ml solution pour inhalation par nébuliseur	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 8 mg comprimés	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 8 mg comprimés	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 8 mg comprimés	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 8 mg comprimés	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 8 mg/5 ml sirop	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon Toux grasse 8 mg/5 ml sirop	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon, opløselige tabletter	not available	BE021305	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT

Bisolvon, oral opløsning	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	PT
Bisolvon, oral opløsning	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	RO
Bisolvon, oral opløsning	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	SE
Bisolvon, tabletter	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	SE
Bisolvon-Linctus Hustensaft 4 mg/5 ml	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	SE
Bisolvon-Linctus Hustensaft 4 mg/5 ml	not available	BE119226	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	SE
Bisolvon-Linctus Hustensaft 4 mg/5 ml	not available	13004/2020/01	LAROPHARM SRL	SE
Bromexina Bluepharma 1,6 mg/ml, xarope	not available	RVG 107255	OPELLA HEALTHCARE FRANCE SAS	SE
Bromexina Farnoz 1,6 mg/ml, xarope	not available	RVG 107255	OPELLA HEALTHCARE FRANCE SAS	SE
Bromexina Flusidon 1,6 mg/ml, xarope	not available	RVG 107255	OPELLA HEALTHCARE FRANCE SAS	SE
Bromheksin Norfri 1,6 mg/ml mikstur.	not available	RVG 107255	OPELLA HEALTHCARE FRANCE SAS	SE
Bromhexin ABECE 1,6 mg/ml oral lösning	not available	5411558	FARMOZ - SOCIEDADE TÉCNICO MEDICINAL, S.A.	SE
Bromhexin Apofri 1,6 mg/ml oral lösning	not available	6424059.00.00	A. NATTERMANN & CIE. GMBH	SE
Holtoss 1,6 mg/ml xarope	not available	6424059.00.00	A. NATTERMANN & CIE. GMBH	SE
Medipekt 0,8 mg/ml oraaliliuos	not available	6424059.00.00	A. NATTERMANN & CIE. GMBH	SE

Medipekt 0,8 mg/ml oral lösning	not available	6424059.00.00	A. NATTERMANN & CIE. GMBH	SE
Medipekt 1,6 mg/ml oraaliliuos	not available	6424059.00.00	A. NATTERMANN & CIE. GMBH	SE
Medipekt 1,6 mg/ml oral lösning	not available	6424059.00.00	A. NATTERMANN & CIE. GMBH	SE
Mucavex 1,6 mg/ml, xarope	not available	HR-H-025912186-01	OPELLA HEALTHCARE FRANCE SAS	SE
Tusexin 12 mg comprimate	not available	HR-H-042974735-01	OPELLA HEALTHCARE FRANCE SAS	SE
Zumux 1,6 mg/ml, xarope	not available	HR-H-667277868-01	OPELLA HEALTHCARE FRANCE SAS	SI