



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2020
EMA/374512/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): flurbiprofen

Procedure No.: PSUSA/00001450/201911



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
Froben, 2,5 mg/ml suuloputuslahus	EE/H/0217/001	913716	MYLAN IRE HEALTHCARE LIMITED	EE
Froben 2,5 mg/ml solution pour bain de bouche	EE/H/0217/001	2016110297	MYLAN EPD BVBA/SPRL	LU
Froben 2,5 mg/ml Mundwasser	EE/H/0217/001	2016110297	MYLAN EPD BVBA/SPRL	LU
Froben 2,5 mg/ml solution pour bain de bouche	EE/H/0217/001	BE494595	MYLAN EPD BVBA/SPRL	BE
Froben 2,5 mg/ml mondspoeling	EE/H/0217/001	BE494595	MYLAN EPD BVBA/SPRL	BE

Froben 2,5 mg/ml Mundwasser	EE/H/0217/001	BE494595	MYLAN EPD BVBA/SPRL	BE
Froben 2,5 mg/ml solução para lavagem da boca	EE/H/0217/001	5707435	BGP PRODUCTS UNIPESSOAL, LDA.	PT
Froben 2,5mg/ml διάλυμα για στοματικές πλύσεις	EE/H/0217/001	12112/14-02-2017	BGP PRODUCTS S.LTD	GR
Froben 2,5 mg/ml otopina za ispiranje usta	EE/H/0217/001	HR-H-101595452	MYLAN HRVATSKA D.O.O.	HR
TANTUM VERDEDOL 8,75 mg Pastiglie gusto Limone e Miele	not available	042810010	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
TANTUM VERDEDOL 8,75 mg Pastiglie gusto Limone e Miele	not available	042810022	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT

KETODOL GOLA 8,75 mg Pastiglie gusto Limone e Miele	not available	041512031	EPIFARMA S.R.L.	IT
KETODOL GOLA 8,75 mg Pastiglie gusto Limone e Miele	not available	041512043	EPIFARMA S.R.L.	IT
KETODOL GOLA 0,25% Collutorio	not available	041512017	EPIFARMA S.R.L.	IT
KETODOL GOLA 0,25% Spray per mucosa orale	not available	041512029	EPIFARMA S.R.L.	IT
FLURBIPROFENE FG 8,75 mg Pastiglie gusto Limone e Miele	not available	042814018	FG S.R.L.	IT

FLURBIPROFENE FG 8,75 mg Pastiglie gusto Limone e Miele	not available	042814020	FG S.R.L.	IT
FLURBIPROFENE TEVA 0,25% Collutorio	not available	043509013	TEVA ITALIA S.R.L.	IT
FLURBIPROFENE TEVA 0,25% Spray per mucosa orale	not available	043509025	TEVA ITALIA S.R.L.	IT
Froben, 2,5 mg/ml suuõõnesprei, lahus	EE/H/0217/002	913616	MYLAN IRE HEALTHCARE LIMITED	EE
Froben 2,5 mg/ml solution pour pulvérisation buccale	EE/H/0217/002	2016110298	MYLAN EPD BVBA/SPRL	LU
Froben 2,5 mg/ml Spray, Lösung zur Anwendung in der Mundhöhle	EE/H/0217/002	2016110298	MYLAN EPD BVBA/SPRL	LU

Froben 2,5 mg/ml solution pour pulvérisation buccale	EE/H/0217/002	BE494604	MYLAN EPD BVBA/SPRL	BE
Froben 2,5 mg/ml spray voor oromucosaal gebruik, oplossing	EE/H/0217/002	BE494604	MYLAN EPD BVBA/SPRL	BE
Froben 2,5 mg/ml Spray, Lösung zur Anwendung in der Mundhöhle	EE/H/0217/002	BE494604	MYLAN EPD BVBA/SPRL	BE
Froben 2,5mg/ml στοματικό εκνέφωμα, διάλυμα	EE/H/0217/002	12113/14-02-2017	BGP PRODUCTS S.LTD	GR
Froben 2,5 mg/ml solução para pulverização bucal	EE/H/0217/002	5707443	BGP PRODUCTS UNIPESSOAL, LDA.	PT
Faremyl 2,5 mg/ml oralno pršilo, raztopina	EE/H/0217/002	H/16/02175/001	MYLAN IRE HEALTHCARE LIMITED	SI

Froben 2,5 mg/ml sprej za usnu sluznicu, otopina	EE/H/0217/002	HR-H-091625115	MYLAN HRVATSKA D.O.O.	HR
Polovox 8,75 mg/devā aerosols izsmidzināšanai mutes dobumā, šķīdums	ES/H/0520/001	19-0015	POLPHARMA	LV
Faringo Intensiv 8,75 mg/dozā spray bucofaringian, soluție	ES/H/0520/001/DC	11527/2019/01	TERAPIA S.A.	RO
PoloVox spray, 8,75 mg/dawkę, aerosol do stosowania w jamie ustnej, roztwór	ES/H/0520/001	25231	POLPHARMA	PL
PoloVox 8,75 mg/dozėje burnos gleivinės purškalas (tirpalas)	ES/H/0520/001	LT/1/19/4375/001	POLPHARMA	LT

SORENEX 8,75 mg/dosis solución para pulverización bucal	ES/H/0520/001	83997	ITALFARMACO S.A.	ES
Flurbiprofen 100 mg coated tablets	not available	PL 46302/0012	MYLAN PRODUCTS LIMITED	UK
Froben Tablets 100 mg	not available	PL 46302/0012	MYLAN PRODUCTS LIMITED	UK
Flurbiprofen 50 mg coated tablets	not available	PL 46302/0013	MYLAN PRODUCTS LIMITED	UK
Froben Tablets 50 mg	not available	PL 46302/0013	MYLAN PRODUCTS LIMITED	UK
KAVOFLOG 0,25% Collutorio	not available	041794013	POOL-PHARMA S.R.L.	IT

CORYFIN GOLA DOLORE 2,5 mg/ml collutorio	not available	041827015	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
FLUIBRON GOLA 0,25% Spray per mucosa orale	not available	042000024	CHIESI FARMACEUTICI S.P.A.	IT
FLUIBRON GOLA 0,25% Collutorio	not available	042000012	CHIESI FARMACEUTICI S.P.A.	IT
Flubilarin 8,75 mg zuigtabletten	NL/H/3513/001	BE501724	SANDOZ N.V.	BE
Flurbiprofeno Sandoz care 8,75 mg pastillas para chupar sabor naranja	NL/H/3513/001	81995	SANDOZ FARMACÉUTICA, S.A.	ES

Flurbiangin akut 8,75 mg – Lutschtabletten	NL/H/3513/001	137526	SANDOZ GMBH	AT
Flurbiprofeno Sandoz 8.75 mg Pastilha	NL/H/3513/001	5717665	SANDOZ FARMACÊUTICA LDA.	PT
Flurbiprofeno Sandoz 8.75 mg Pastilha	NL/H/3513/001	5717715	SANDOZ FARMACÊUTICA LDA.	PT
Formitrol Gola	NL/H/3513/001	045235013	SANDOZ S.P.A.	IT
Formitrol Gola	NL/H/3513/001	045235025	SANDOZ S.P.A.	IT

Formitrol Gola	NL/H/3513/001	045235049	SANDOZ S.P.A.	IT
Formitrol Gola	NL/H/3513/001	045235052	SANDOZ S.P.A.	IT
Formitrol Gola	NL/H/3513/001	045235064	SANDOZ S.P.A.	IT
Formitrol Gola	NL/H/3513/001	045235076	SANDOZ S.P.A.	IT
Formitrol Gola	NL/H/3513/001	045235088	SANDOZ S.P.A.	IT

Formitrol Gola	NL/H/3513/001	045235037	SANDOZ S.P.A.	IT
Flurbiprofen Sandoz sinaasappel suikervrij 8,75 mg, zuigtabletten	NL/H/3513/001	RVG 117524	SANDOZ B.V.	NL
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/01	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/02	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/03	S.C. SANDOZ S.R.L.	RO

Dolips cu aromă de portocală 8,75 mg pastile Flurbiprofen	NL/H/3513/001	9589/2017/04	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/05	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/06	S.C. SANDOZ S.R.L.	RO
Dolips cu aromă de portocală 8,75 mg pastile Flurbiprofen	NL/H/3513/001	9589/2017/07	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/08	S.C. SANDOZ S.R.L.	RO

DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/09	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/10	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/11	S.C. SANDOZ S.R.L.	RO
DOLIPS cu aroma de portocala 8,75 mg PASTILE	NL/H/3513/001	9589/2017/12	S.C. SANDOZ S.R.L.	RO
АНГАЛ Интензив 8,75 mg таблетки за смучене, отляти	NL/H/3513/001	20160384	SANDOZ PHARMACEUTICALS D.D.	BG

FLURBIPROFENE SANDOZ CONSEIL 8,75 mg ORANGE SANS SUCRE, pastille édulcorée au sucralose	NL/H/3513/001	34009 300 814 8 8	SANDOZ	FR
FLURBIPROFENE SANDOZ CONSEIL 8,75 mg ORANGE SANS SUCRE, pastille édulcorée au sucralose	NL/H/3513/001	34009 300 814 9 5	SANDOZ	FR
FLURBIPROFENE SANDOZ CONSEIL 8,75 mg ORANGE SANS SUCRE, pastille édulcorée au sucralose	NL/H/3513/001	34009 300 815 0 1	SANDOZ	FR
Flurbiprofen Sandoz Orange 8.75 mg τροχισκοι	NL/H/3513/001	022722	SANDOZ GMBH	CY
NEO BOROCILLINA GOLA DOLORE "8,75 mg pastiglie senza zucchero gusto menta"	not available	035760065	ALFASIGMA S.P.A.	IT

NEO BOROCILLINA GOLA DOLORE "8,75 mg pastiglie senza zucchero gusto menta"	not available	035760077	ALFASIGMA S.P.A.	IT
NEO BOROCILLINA GOLA DOLORE "8,75 mg pastiglie senza zucchero gusto menta"	not available	035760040	ALFASIGMA S.P.A.	IT
NEO BOROCILLINA GOLA DOLORE "8,75 mg pastiglie senza zucchero gusto limone e miele"	not available	035760103	ALFASIGMA S.P.A.	IT
NEO BOROCILLINA GOLA DOLORE "8,75 mg pastiglie senza zucchero gusto limone e miele"	not available	035760127	ALFASIGMA S.P.A.	IT
NEO BOROCILLINA GOLA DOLORE "8,75 mg pastiglie senza zucchero gusto limone e miele"	not available	035760115	ALFASIGMA S.P.A.	IT

NEO BOROCILLINA GOLA DOLORE “8,75 mg pastiglie senza zucchero gusto arancia e miele”	not available	035760139	ALFASIGMA S.P.A.	IT
NEO BOROCILLINA GOLA DOLORE “8,75 mg pastiglie senza zucchero gusto arancia e miele”	not available	035760141	ALFASIGMA S.P.A.	IT
NEO BOROCILLINA GOLA DOLORE “8,75 mg pastiglie senza zucchero gusto arancia e miele”	not available	035760154	ALFASIGMA S.P.A.	IT
OCUFEN 0,12 mg/0,4 ml, collyre en récipient unidose	not available	34009 334 433 2 0	HORUS PHARMA	FR
OCUFEN 0,12 mg/0,4 ml, collyre en récipient unidose	not available	34009 334 434 9 8	HORUS PHARMA	FR
OCUFEN 0,12 mg/0,4 ml, collyre en récipient unidose	not available	34009 335 026 1 4	HORUS PHARMA	FR

INOVOX Ultra smak miętowy, 8,75 mg, pastylki twarde	ES/H/0365/001	23979	US PHARMACIA SP. Z O.O.	PL
Ocuflur O.K.	not available	27168.00.00	OMNIVISION GMBH	DE
Transact Lat, 40 mg, penso impregnado	not available	5109582	AMDIPHARM LIMITED	PT
Transact Lat, 40 mg, penso impregnado	not available	2338283	AMDIPHARM LIMITED	PT
FLURACTIVE 0,25% Collutorio	not available	041514011	FG S.R.L.	IT
FLURACTIVE 0,25% Spray per mucosa orale	not available	041514023	FG S.R.L.	IT

PN-LEMOS 2,5 mg/mL στοματικό εκνέφωμα, διάλυμα	not available	30323/29-03-2019	NASSINGTON LTD	GR
FLURBIPROFENE Pensa 0,25% Collutorio	not available	043510015	FG S.R.L.	IT
FLURBIPROFENE Pensa 0,25% Spray per mucosa orale	not available	043510027	FG S.R.L.	IT
ASPI GOLA 8,75 mg Pastiglie gusto Limone e Miele	not available	041513033	BAYER SPA	IT
CEBUTID LP 200 mg, gélule à libération prolongée	not available	34009 331 990 8 1	ALMIRALL, S.A.	FR

TANTUM VERDE GOLA 250mg/100ml collutorio.	not available	034015014	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
TANTUM VERDE GOLA 250mg/100ml spray per mucosa orale, soluzione.	not available	034015026	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
ASPI GOLA 0,25% Spray per mucosa orale	not available	041513021	BAYER SPA	IT
Faringo Intensiv 8,75 mg pastile	ES/H/0365/001	9891/2017/01	TERAPIA S.A.	RO
Faringo Intensiv 8,75 mg pastile	ES/H/0365/001	9891/2017/02	TERAPIA S.A.	RO

Faringo Intensiv 8,75 mg pastile	ES/H/0365/001	9891/2017/03	TERAPIA S.A.	RO
Faringo Intensiv 8,75 mg pastile	ES/H/0365/001	9891/2017/04	TERAPIA S.A.	RO
Faringo Intensiv 8,75 mg pastile	ES/H/0365/001	9891/2017/05	TERAPIA S.A.	RO
Mentocaína Anti-Inflam 8,75 mg pastilhas	ES/H/0365/001	5714654	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Mentocaína Anti-Inflam 8,75 mg pastilhas	ES/H/0365/001	5714662	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT

Mentocaína Anti-Inflam 8,75 mg pastilhas	ES/H/0365/001	5714670	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Mentocaína Anti-Inflam 8,75 mg pastilhas	ES/H/0365/001	5714704	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Mentocaína Anti-Inflam 8,75 mg pastilhas	ES/H/0365/001	5714647	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Flurbiprofene Geiser 8,75 mg pastiglie	ES/H/0365/001	175/2017	GEISER PHARMA, S.L	IT
Angifen 8,75 mg pastillas para chupar sabor menta	ES/H/0365/001	81.911	ALFASIGMA ESPAÑA, S.L.	ES

ASPI GOLA 0,25% Collutorio	not available	041513019	BAYER SPA	IT
KAVOFLOG 0,25% Spray per mucosa orale	not available	041794025	POOL-PHARMA S.R.L.	IT
CORYFIN GOLA DOLORE 2,5 mg/ml spray per mucosa orale	not available	041827027	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
FLURBIPROFENE EG 0,25% Collutorio	not available	041815010	EPIFARMA S.R.L.	IT
FLURBIPROFENE EG 0,25% Spray per mucosa orale	not available	041815022	EPIFARMA S.R.L.	IT

Flugalin 100 mg bevont tabletta	not available	OGYI-T-1641/02	MYLAN EPD KFT.	HU
Flugalin 50 mg bevont tabletta	not available	OGYI-T-1641/01	MYLAN EPD KFT.	HU
FROBEN GOLA 250mg/100ml Collutorio	not available	042822015	MYLAN ITALIA S.R.L.	IT
FROBEN GOLA 250mg/100ml Spray per mucosa orale	not available	042822027	MYLAN ITALIA S.R.L.	IT
FROBEN 100 mg compresse rivestite	not available	024284034	MYLAN ITALIA S.R.L.	IT
FROBEN 100 mg compresse rivestite	not available	024284162	MYLAN ITALIA S.R.L.	IT
FROBEN 5mg/ml sciroppo	not available	024284073	MYLAN ITALIA S.R.L.	IT

Froben 100 mg comprimidos revestidos	not available	5550884	BGP PRODUCTS UNIPESOAL, LDA.	PT
Froben 100 mg comprimidos revestidos	not available	5550983	BGP PRODUCTS UNIPESOAL, LDA.	PT
Flugalin 50 mg obalené tablety	not available	29/0391/92-S	MYLAN IRE HEALTHCARE LIMITED	SK
ANTADYS 100 mg, comprimé pelliculé	not available	34009 326 767 2 9	THERAMEX IRELAND LIMITED	FR
ANTADYS 100 mg, comprimé pelliculé	not available	34009 554 616 9 2	THERAMEX IRELAND LIMITED	FR
Flurbiprofen 50mg Tablets	not available	PL 17907/0324	BRISTOL LABORATORIES LTD (BERKHAMSTED)	UK

Flurbiprofen 100 mg Tablets	not available	PL 17907/0325	BRISTOL LABORATORIES LTD (BERKHAMSTED)	UK
TRANSACT Lat 40 mg cerotti medicati	not available	028741015	AMDIPHARM LIMITED	IT
TRANSACT Lat 40 mg cerotti medicati	not available	028741039	AMDIPHARM LIMITED	IT
TANTUM VERDE GOLA 0,25 % spray per mucosa orale gusto camomilla e miele.	not available	034015038	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.P.A.	IT
Flurbiprofen EG 8,75 mg pastilles	ES/H/0371/001	BE505031	EUROGENERICS N.V./S.A.	BE

Flurbiprofen EG 8,75 mg Lutschtabletten	ES/H/0371/001	BE505031	EUROGENERICS N.V./S.A.	BE
Flurbiprofen EG 8,75 mg zuigtabletten	ES/H/0371/001	BE505031	EUROGENERICS N.V./S.A.	BE
Flurbiprofen HTP mint 8,75 mg, zuigtabletten	ES/H/0371/001	RVG 117674	HEALTHYPHARM B.V.	NL
Flurbifex, 8,75 mg, pastylki twarde	ES/H/0371/001	23978	STADA ARZNEIMITTEL AG	PL
Flurbiprofen EG 8,75 mg pastilles	ES/H/0371/001	2017070225	EUROGENERICS N.V./S.A.	LU

Flurbiprofen AL 8,75 mg Lutschtabletten	ES/H/0371/001	95778.00.00	ALIUD PHARMA GMBH	DE
FLURBIPROFENE EG LABORATORI EUROGENERICI 8,75 mg pastiglie gusto menta	ES/H/0371/001	044446021	EG S.P.A.	IT
FLURBIPROFENE EG LABORATORI EUROGENERICI 8,75 mg pastiglie gusto menta	ES/H/0371/001	044446045	EG S.P.A.	IT
FLURBIPROFENE EG LABORATORI EUROGENERICI 8,75 mg pastiglie gusto menta	ES/H/0371/001	044446033	EG S.P.A.	IT
FLURBIPROFENE EG LABORATORI EUROGENERICI 8,75 mg pastiglie gusto menta	ES/H/0371/001	044446058	EG S.P.A.	IT

FLURBIPROFENE EG LABORATORI EUROGENERICI 8,75 mg pastiglie gusto menta	ES/H/0371/001	044446019	EG S.P.A.	IT
Buccostad flurbiprofeno 8,75 mg pastillas para chupar	ES/H/0371/001	81.925	LABORATORIO STADA, S.L.	ES
FROBENPRET 8,75 mg Pastiglie gusto Limone e Miele	not available	042807014	MYLAN S.P.A.	IT
FROBENPRET 8,75 mg Pastiglie gusto Limone e Miele	not available	042807026	MYLAN S.P.A.	IT
Flurbiprofen Geiser Pharma 8,75 mg pastilky	ES/H/0369/001	69/ 682/15-C	GEISER PHARMA, S.L	CZ

Flurbiprofen Geiser Pharma 8,75 mg tvrdé pastilky	ES/H/0369/001	69/0091/17-S	GEISER PHARMA, S.L	SK
Geiserfen 8,75 mg zuigtabletten	ES/H/0369/001/DC	BE527306	GEISER PHARMA, S.L	BE
Polovox 8,75 mg/devā aerosols izsmidzināšanai mutes dobumā, šķīdums	ES/H/0520/001	19-0015	POLPHARMA	LV
PoloVox spray, 8,75 mg/dawkę, aerosol do stosowania w jamie ustnej, roztwór	ES/H/0520/001	25231	POLPHARMA	PL
PoloVox 8,75 mg/dozėje burnos gleivinės purškalas (tirpalas)	ES/H/0520/001	LT/1/19/4375/001	POLPHARMA	LT

DOLAUT GOLA 0,25% spray per mucosa orale	not available	036497028	NEOPHARMED GENTILI SPA	IT
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