



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2022
EMA/156898/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: lactulose

Procedure no.: PSUSA/00001821/202105

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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
Duphalac Fruit 667 mg/ml - Lösung zum Einnehmen	AT/H/0242/001	1-28716	MYLAN ÖSTERREICH GMBH	AT
DUPHALAC FRUIT 10 g/15 ml Sirup	not available	BE238892	MYLAN EPD BVBA/SPRL	BE
DUPHALAC 667 mg/ml Sirup	not available	BE148617	MYLAN EPD BVBA/SPRL	BE
DUPHALAC 667 mg/ml Sirup	not available	BE071836	MYLAN EPD BVBA/SPRL	BE
DUPHALAC FRUIT 10 g / 15 ml siroop	not available	BE238892	MYLAN EPD BVBA/SPRL	BE
DUPHALAC FRUIT 10 g /15 ml sirop	not available	BE238892	MYLAN EPD BVBA/SPRL	BE

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
DUPHALAC 667 mg/ml sirop	not available	BE148617	MYLAN EPD BVBA/SPRL	BE
DUPHALAC 667 mg/ml sirop	not available	BE071836	MYLAN EPD BVBA/SPRL	BE
DUPHALAC 667 mg/ml Sirop	not available	BE148617	MYLAN EPD BVBA/SPRL	BE
DUPHALAC 667 mg/ml Sirop	not available	BE071836	MYLAN EPD BVBA/SPRL	BE
Bifiteral 667 mg/ml sirop	not available	BE071811	MYLAN EPD BVBA/SPRL	BE
BIFITERAL 667 mg/ml sirop	not available	BE071811	MYLAN EPD BVBA/SPRL	BE

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
Bifiteral 667 mg/ml Sirup	not available	BE071811	MYLAN EPD BVBA/SPRL	BE
Дуфалак 67 g/100 ml перорален разтвор	not available	20000353	MYLAN EOOD	BG
Duphalac®, oral solution, 3.335g/5ml	not available	7547	MYLAN IRE HEALTHCARE LIMITED	CY
Duphalac se švestkovou příchutí 667 mg/ml perorální roztok	AT/H/0242/001	61/713/09-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Duphalac 667 mg/ml perorální roztok	not available	80/141/92-S/C	MYLAN IRE HEALTHCARE LIMITED	CZ
Bifiteral® 667 g/l Sirup	not available	3003413.00.00	MYLAN HEALTHCARE GMBH	DE

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
Bifiteral® 667 g/l Sirup	not available	6424869.00.00	MYLAN HEALTHCARE GMBH	DE
Bifiteral® mit Pflaumenaroma 667 mg/ml Lösung zum Einnehmen	AT/H/0242/001	99807.00.00	MYLAN HEALTHCARE GMBH	DE
Bifiteral® Sachet Sirup 10 g/15 ml, Sirup	not available	96785.00.00	MYLAN HEALTHCARE GMBH	DE
Duphalac, 667 mg/ml suukaudne lahus	not available	118395	MYLAN HEALTHCARE SIA	EE
Duphalac Fruit 667 mg/ml, suukaudne lahus	AT/H/0242/001	647309	MYLAN IRE HEALTHCARE LIMITED	EE
DUPHALAC 667 mg/ml oraaliliuos	not available	9871	MYLAN HEALTHCARE B.V.	FI

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
Duphalac 950 mg/g jauhe	not available	11611	MYLAN HEALTHCARE B.V.	FI
Duphalac 667 mg/ml oral lösning	not available	9871	MYLAN HEALTHCARE B.V.	FI
Duphalac 950 mg/g oralt pulver	not available	11611	MYLAN HEALTHCARE B.V.	FI
Levolac 670 mg/ml - oraaliliuos	not available	6863	TAKEDA OY	FI
Duphalac® Fruit 667 mg/ml, oraaliliuos	AT/H/0242/001	25288	MYLAN IRE HEALTHCARE LIMITED	FI
Duphalac® Fruit 667 mg/ml, oral lösning	AT/H/0242/001	25288	MYLAN IRE HEALTHCARE LIMITED	FI

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
LACTULOSE BIPHAR 66,5 %, solution buvable	IE/H/0140/001	34009 373 738 5 2	MYLAN S.A.S	FR
LACTULOSE BIPHAR 66,5 %, solution buvable	IE/H/0140/001	34009 373 739 1 3	MYLAN S.A.S	FR
LACTULOSE BIPHAR 66,5 %, solution buvable	IE/H/0140/001	34009 373 741 6 3	MYLAN S.A.S	FR
LACTULOSE BIPHAR 66,5 %, solution buvable	IE/H/0140/001	34009 373 737 9 1	MYLAN S.A.S	FR
LACTULOSE BIOGARAN 66,5 %, solution buvable	not available	3400955523888	BIOGARAN	FR

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
LACTULOSE BIOGARAN 66,5 %, solution buvable	not available	3400932838080	BIOGARAN	FR
DUPHALAC 10 g/15 ml, solution buvable en sachet	not available	34009 555 668 2 3	MYLAN MEDICAL SAS	FR
DUPHALAC 66,5 POUR CENT, solution buvable en flacon	not available	34009 352 353 7 3	MYLAN MEDICAL SAS	FR
DUPHALAC 66,5 POUR CENT, solution buvable en flacon	not available	34009 352 354 3 5	MYLAN MEDICAL SAS	FR
DUPHALAC 66,5 POUR CENT, solution buvable en flacon	not available	34009 352 351 4 5	MYLAN MEDICAL SAS	FR
DUPHALAC 66,5 POUR CENT, solution buvable en flacon	not available	34009 352 352 0 6	MYLAN MEDICAL SAS	FR

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
DUPHALAC 10 g/15 ml, solution buvable en sachet	not available	34009 329 244 0 0	MYLAN MEDICAL SAS	FR
DUPHALAC 10 g/15 ml, solution buvable en sachet	not available	34009 276 931 9 9	MYLAN MEDICAL SAS	FR
LAXARON 10 g/15 ml, solution buvable en sachet	not available	34009 347 579 0 7	P&G HEALTH FRANCE	FR
LAXARON 10 g/15 ml, solution buvable en sachet	not available	34009 341 937 2 9	P&G HEALTH FRANCE	FR
LACTULOSE BIPHAR 10 g/15 ml, solution buvable en sachet-dose	not available	34009 326 370 5 8	MYLAN MEDICAL SAS	FR
LACTULOSE BIPHAR 10 g/15 ml, solution buvable en sachet-dose	not available	34009 337 798 7 2	MYLAN MEDICAL SAS	FR

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
LACTULOSE BIPHAR 10 g/15 ml, solution buvable en sachet-dose	not available	34009 301 283 9 8	MYLAN MEDICAL SAS	FR
Duphalac® πόσιμο διάλυμα (σιρόπι), 3,335g/5ml	not available	41602/07/06-06-2008	BGP PRODUCTS S.LTD	GR
Duphafruit 667 mg/ml πόσιμο διάλυμα	AT/H/0242/001	14489/17/09-02-2018	BGP PRODUCTS S.LTD	GR
Duphalac 667 mg/ml sirup	not available	HR-H-833932438	MYLAN HRVATSKA D.O.O.	HR
Duphalac Effect 667 mg/ml sirup	not available	HR-H-686529569	MYLAN HRVATSKA D.O.O.	HR
Duphalac 667 mg/ml belsőleges oldat	not available	OGYI-T-8337/02	MYLAN EPD KFT.	HU

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
Duphalac 667 mg/ml belsőleges oldat	not available	OGYI-T-8337/01	MYLAN EPD KFT.	HU
Lactecon 3.335g/5ml oral solution	IE/H/0140/001	PA 2010/14/1	MYLAN IRE HEALTHCARE LIMITED	IE
Duphalac 3.335 g / 5 ml Oral Solution	not available	PA 2010/9/1	MYLAN IRE HEALTHCARE LIMITED	IE
Lactulose 3.335 g/5 ml oral solution	IE/H/0955/001	PA 22749/011/001	BRILLPHARMA (IRELAND) LIMITED	IE
EPALFEN EPS 12 g granulato per soluzione orale	not available	024409120	ZAMBON ITALIA S.R.L.	IT
EPALFEN EPS 6 g granulato per soluzione orale	not available	024409118	ZAMBON ITALIA S.R.L.	IT

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
LATTULOSIO SANDOZ 66,7 % sciroppo, flacone da 180 ml	not available	027668019	SANDOZ S.P.A.	IT
NORMASE 66,7% sciroppo flacone 200 ml	not available	029144019	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPALFEN 12 g granulato per soluzione orale	not available	029119056	ZAMBON ITALIA S.R.L.	IT
EPALFEN 3 g granulato per soluzione orale	not available	029119029	ZAMBON ITALIA S.R.L.	IT
EPALFEN 6 g granulato per soluzione orale	not available	029119031	ZAMBON ITALIA S.R.L.	IT
EPALFEN 65 g/100 ml sciroppo	not available	029119017	ZAMBON ITALIA S.R.L.	IT

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
EPALFEN 9 g granulato per soluzione orale	not available	029119043	ZAMBON ITALIA S.R.L.	IT
NORMASE EPS 66,7% sciroppo	not available	023535180	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
NORMASE EPS 66,7% sciroppo	not available	023535166	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
LATTULOSIO ZENTIVA 66,7 g/100 ml sciroppo	not available	029160025	ZENTIVA ITALIA SRL	IT
EPALFEN EPS 65% sciroppo, flacone 200 ml	not available	024409132	ZAMBON ITALIA S.R.L.	IT
EPALFEN EPS 65% sciroppo, flacone 400 ml	not available	024409144	ZAMBON ITALIA S.R.L.	IT

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
Laevolac EPS 66,7 g/100 ml sciroppo	not available	022711129	CHIESI ITALIA S.P.A.	IT
Laevolac EPS 66,7 g/100 ml sciroppo	not available	022711131	CHIESI ITALIA S.P.A.	IT
DUPHALAC 66,7 g/100 ml sciroppo	not available	022512014	MYLAN ITALIA S.R.L.	IT
ZENAS - 66,7 g/100 ml sciroppo	not available	032880015	S.F. GROUP SRL	IT
LAEVOLAC 66,7 g/100 ml sciroppo	not available	029565013	CHIESI ITALIA S.P.A.	IT
LAEVOLAC 10 g granulato	not available	029565025	CHIESI ITALIA S.P.A.	IT

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
Duphalac Fruit 667 mg/ml geriamasis tirpalas	AT/H/0242/001	LT/1/09/1746/002	MYLAN IRE HEALTHCARE LIMITED	LT
Duphalac Fruit 667 mg/ml geriamasis tirpalas	AT/H/0242/001	LT/1/09/1746/003	MYLAN IRE HEALTHCARE LIMITED	LT
Duphalac Fruit 667 mg/ml geriamasis tirpalas	AT/H/0242/001	LT/1/09/1746/004	MYLAN IRE HEALTHCARE LIMITED	LT
Duphalac Fruit 667 mg/ml geriamasis tirpalas	AT/H/0242/001	LT/1/09/1746/005	MYLAN IRE HEALTHCARE LIMITED	LT
Duphalac Fruit 667 mg/ml geriamasis tirpalas	AT/H/0242/001	LT/1/09/1746/006	MYLAN IRE HEALTHCARE LIMITED	LT

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
Duphalac Fruit 667 mg/ml geriamasis tirpalas	AT/H/0242/001	LT/1/09/1746/001	MYLAN IRE HEALTHCARE LIMITED	LT
DUPHALAC FRUIT 10 g/15 ml Sirup	not available	2005040027	MYLAN EPD BVBA/SPRL	LU
DUPHALAC 667 mg/ml Sirup	not available	2001126509	MYLAN EPD BVBA/SPRL	LU
DUPHALAC FRUIT 10 g / 15 ml sirop	not available	2005040027	MYLAN EPD BVBA/SPRL	LU
DUPHALAC 667 mg/ml sirop	not available	2001126509	MYLAN EPD BVBA/SPRL	LU
Bifiteral 667 mg/ml sirop	not available	1994063491	MYLAN EPD BVBA/SPRL	LU

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
Bifiteral 667 mg/ml Sirup	not available	1994063491	MYLAN EPD BVBA/SPRL	LU
Duphalac 667 mg/ml šķīdums iekšķīgai lietošanai	not available	99-0641	MYLAN HEALTHCARE SIA	LV
Duphalac Fruit 667 mg/ml šķīdums iekšķīgai lietošanai	AT/H/0242/001	09-0375	MYLAN IRE HEALTHCARE LIMITED	LV
NORMASE 66.7% syrup 200-ml bottle	not available	AA500/00401	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	MT
Duphalac 3.335 g / 5 ml Oral Solution	not available	MA 1187/00101	MYLAN IRE HEALTHCARE LIMITED	MT
Lactulose Sandoz 670 mg/ml, stroop	NL/H/2354/001	RVG 109595	SANDOZ B.V.	NL

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
Duphalac, stroop 667 mg/ml	not available	RVG 01467	ABBOTT B.V. (NETHERLANDS)	NL
Duphalac lactulosesiroop, stroop 667 mg/ml	not available	RVG 20869	ABBOTT B.V. (NETHERLANDS)	NL
Lactulose Sandoz 670 mg/ml, stroop	NL/H/2325/001	RVG 109594	SANDOZ B.V.	NL
Duphalac Fruit 667 mg/ml, stroop	AT/H/0242/001	RVG 102976	ABBOTT B.V. (NETHERLANDS)	NL
Etos Laxeerdrank Lactulose 667 mg/ml, stroop	not available	RVG 122648=19268	ETOS B.V.	NL

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
Lactulose SAM 667 mg/ml, stroop	not available	RVG 127565=19268	NEDERLANDSE SERVICE APOTHEEK BEHEER B.V.	NL
Laxeerdrank HTP Lactulose 667 mg/ml, stroop	not available	RVG 19268	HEALTHYPHARM B.V.	NL
Duphalac 667 mg/ml mikstur, oppløsning	not available	5562	MYLAN IRE HEALTHCARE LIMITED	NO
Duphalac 667 mg/ml mikstur, oppløsning med fruktsmak	AT/H/0242/001	08-6099	MYLAN IRE HEALTHCARE LIMITED	NO
Duphalac, 667 mg/ml, roztwór doustny	not available	R/3048	MYLAN HEALTHCARE SP. Z.O.O.	PL

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
Duphalac Fruit, 667 mg/ml, roztwór doustny	AT/H/0242/001	16192	MYLAN IRE HEALTHCARE LIMITED	PL
DUPHALAC 667 g/L, xarope	not available	8310227	BGP PRODUCTS UNIPESOAL, LDA.	PT
Duphalac 10 g/15 ml xarope	not available	5649116	BGP PRODUCTS UNIPESOAL, LDA.	PT
Lactulose Sandoz 670 mg/ml Solução oral	NL/H/2325/001	5470521	SANDOZ FARMACÊUTICA LDA.	PT
Lactulose Sandoz 670 mg/ml Solução oral	NL/H/2325/001	5470513	SANDOZ FARMACÊUTICA LDA.	PT

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
Lactulose Sandoz 670 mg/ml Solução oral	NL/H/2325/001	5470505	SANDOZ FARMACÊUTICA LDA.	PT
Duphalac Ameixa 667 mg/ml solução oral	AT/H/0242/001	5733308	BGP PRODUCTS UNIPessoal, LDA.	PT
Duphalac Ameixa 667 mg/ml solução oral	AT/H/0242/001	5733274	BGP PRODUCTS UNIPessoal, LDA.	PT
Duphalac Fruit 667 mg/ml soluție orală	AT/H/0242/001	8291/2015/01	MYLAN HEALTHCARE GMBH	RO
Duphalac Fruit 667 mg/ml soluție orală	AT/H/0242/001	8291/2015/04	MYLAN HEALTHCARE GMBH	RO

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
Duphalac Fruit 667 mg/ml soluție orală	AT/H/0242/001	8291/2015/03	MYLAN HEALTHCARE GMBH	RO
Duphalac Fruit 667 mg/ml soluție orală	AT/H/0242/001	8291/2015/02	MYLAN HEALTHCARE GMBH	RO
Duphalac Fruit 667 mg/ml soluție orală	AT/H/0242/001	8291/2015/05	MYLAN HEALTHCARE GMBH	RO
Duphalac Fruit 667 mg/ml soluție orală	AT/H/0242/001	8291/2015/06	MYLAN HEALTHCARE GMBH	RO
Lactecon 667 g/l soluție orală	not available	12942/2020/01	MYLAN HEALTHCARE B.V.	RO

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
Lactecon 667 g/l soluție orală	not available	12942/2020/03	MYLAN HEALTHCARE B.V.	RO
Lactecon 667 g/l soluție orală	not available	12942/2020/04	MYLAN HEALTHCARE B.V.	RO
Lactecon 667 g/l soluție orală	not available	12942/2020/02	MYLAN HEALTHCARE B.V.	RO
Lactecon 667 g/l soluție orală	not available	12942/2020/05	MYLAN HEALTHCARE B.V.	RO
Laktulos Meda oralt pulver	not available	16691	MEDA AB	SE
Laktulos Meda 10 g oralt pulver, dospåse	not available	16080	MEDA AB	SE

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
Laktulos Meda 670 mg/ml oral lösning	not available	10293	MEDA AB	SE
Duphalac 670 mg/ml oral lösning	not available	10212	BGP PRODUCTS AB	SE
Lactecon 3,335 g/5 ml peroralna raztopina	IE/H/0140/001	H/05/00868/001	MYLAN IRE HEALTHCARE LIMITED	SI
Lactecon 3,335 g/5 ml peroralna raztopina	IE/H/0140/001	H/05/00868/002	MYLAN IRE HEALTHCARE LIMITED	SI
Lactecon 3,335 g/5 ml peroralna raztopina	IE/H/0140/001	H/05/00868/003	MYLAN IRE HEALTHCARE LIMITED	SI

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
Lactecon 3,335 g/5 ml peroralna raztopina	IE/H/0140/001	H/05/00868/004	MYLAN IRE HEALTHCARE LIMITED	SI
Lactecon 3,335 g/5 ml, perorálny roztok	IE/H/0140/001	80/0295/05-S	MYLAN IRE HEALTHCARE LIMITED	SK
DUPHALAC 667 g/1000 ml sirup	not available	61/0141/92-S	MYLAN IRE HEALTHCARE LIMITED	SK
Lactulose 3.335 g/5 ml oral solution	not available	PL 17907/0534	BRISTOL LABORATORIES LIMITED	XI
Lactulose Bristol Laboratories 3.335 g/5 ml oral solution	not available	PL 17907/0534	BRISTOL LABORATORIES LIMITED	XI

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
Lactulose Solution BP	not available	PL 04416/0218	SANDOZ LTD	XI
Lactulose 3.3g/5ml Oral Solution	NL/H/2325/001	PL 04416/1310	SANDOZ LTD	XI
Duphalac®	not available	PL 46302/0032	MYLAN PRODUCTS LIMITED	XI
Lactulose 3.335g/5ml oral solution	not available	PL 46302/0032	MYLAN PRODUCTS LIMITED	XI