



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/777741/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): macrogol 4000, macrogol 4000 combinations (systemic use)

Procedure No.: PSUSA/00010392/201605



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
Forlax Junior 4 g, Pulver zur Herstellung einer Lösung zum Einnehmen in einem Beutel	FR/H/0198/002	BE253635	IPSEN N.V.	BE
Forlax 10 g, Pulver zur Herstellung einer Lösung zum Einnehmen in einem Beutel	FR/H/0198/001	BE259305	IPSEN N.V.	BE
PAXABEL 10 g polvere per soluzione orale in bustina	FR/H/0198/001	036003022	IPSEN S.P.A.	IT
PAXABEL 10 g polvere per soluzione orale in bustina	FR/H/0198/001	036003034	IPSEN S.P.A.	IT
PAXABEL 4 g polvere per soluzione orale in bustina	FR/H/0198/002	036003059	IPSEN S.P.A.	IT
PAXABEL 4 g polvere per soluzione orale in bustina	FR/H/0198/002	036003061	IPSEN S.P.A.	IT
PAXABEL 4 g polvere per soluzione orale in bustina	FR/H/0198/002	036003073	IPSEN S.P.A.	IT
FORLAX 4g, poudre pour solution buvable en sachet-dose	FR/H/0198/002	34009 360 521 2 3	IPSEN PHARMA	FR
FORLAX 4g, poudre pour solution buvable en sachet-dose	FR/H/0198/002	34009 360 522 9 1	IPSEN PHARMA	FR
FORLAX 4g, poudre pour solution buvable en sachet-dose	FR/H/0198/002	34009 360 523 5 2	IPSEN PHARMA	FR
FORLAX 10 g, poudre pour solution buvable en sachet	FR/H/0198/001	34009 338 997.8 3	IPSEN PHARMA	FR
FORLAX 10 g, poudre pour solution buvable en sachet	FR/H/0198/001	34009 359 758.2 9	IPSEN PHARMA	FR
FORLAX 10 g, poudre pour solution buvable en sachet	FR/H/0198/001	34009 570 314.3 5	IPSEN PHARMA	FR

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FORLAX JÚNIOR 4 g pó para solução oral em saquetas	FR/H/0198/002	4728085	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
FORLAX JÚNIOR 4 g pó para solução oral em saquetas	FR/H/0198/002	4728184	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
FORLAX JÚNIOR 4 g pó para solução oral em saquetas	FR/H/0198/002	4728283	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
FORLAX 10 g pó para solução oral em saquetas	FR/H/0198/001	4728481	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
FORLAX 10 g pó para solução oral em saquetas	FR/H/0198/001	4728580	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
Dulcolax® M Balance 10 g Pulver zur Herstellung einer Lösung zum Einnehmen	FR/H/0198/001	61944.01.00	IPSEN PHARMA GMBH	DE
Forlax Junior 4 g pulver till oral lösning i dospåse	FR/H/0198/002	21838	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
FORLAX 4 g Prášok na perorálny roztok vo vreckách	FR/H/0198/002	61/0075/05-S	IPSEN PHARMA	SK
Forlax 10 g poudre pour solution buvable en sachet-dose	FR/H/0198/001	BE259305	IPSEN N.V.	BE
Forlax Junior 4 g poeder voor drank in een zakje	FR/H/0198/002	BE253635	IPSEN N.V.	BE
FORLAX 10G PRÁŠOK NA PERORÁLNY ROZTOK VO VRECKÁCH	FR/H/0198/001	61/0076/05-S	IPSEN PHARMA	SK
Forlax Junior 4 g poudre pour solution buvable en sachet-dose	FR/H/0198/002	BE253635	IPSEN N.V.	BE
Forlax 10 g poeder voor drank in een zakje	FR/H/0198/001	BE259305	IPSEN N.V.	BE
Dulcobalance 10 g, powder for oral solution in sachet	FR/H/0198/001	PL 34926/0018	IPSEN LTD	UK
Forlax® 10 g Pulver zur Herstellung einer Lösung zum Einnehmen	FR/H/0198/001	1-24410	IPSEN PHARMA GMBH	AT

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Forlax® 4 g Pulver zur Herstellung einer Lösung zum Einnehmen	FR/H/0198/002	1-24988	IPSEN PHARMA GMBH	AT
TANILAS 10g, σκόνη για πόσιμο διάλυμα σε φακελλίσκο	FR/H/0198/001	9218 – 4-2-2011	IPSEN E.P.E.	GR
TANILAS 4g, σκόνη για πόσιμο διάλυμα σε φακελλίσκο	FR/H/0198/002	9218 – 4-2-2011	IPSEN E.P.E.	GR
FORLAX 4 g, prášek pro perorální roztok v sáčku	FR/H/0198/002	61/147/05-C	IPSEN PHARMA	CZ
FORLAX 10 g, prášek pro perorální roztok v sáčku	FR/H/0198/001	61/148/05-C	IPSEN PHARMA	CZ
FORLAX 4 G SUUKAUDSE LAHUSE PULBER	FR/H/0198/002	424503	IPSEN PHARMA	EE
FORLAX 10 G SUUKAUDSE LAHUSE PULBER	FR/H/0198/001	188498	IPSEN PHARMA	EE
FORLAX 4g, poudre pour solution buvable en sachet-dose	FR/H/0198/002	34009 360 520 6 2	IPSEN PHARMA	FR
FORLAX 10 g, poudre pour solution buvable en sachet	FR/H/0198/001	34009 359 757.6 8	IPSEN PHARMA	FR
Idrolax 10g, powder for oral solution in a sachet	FR/H/0198/001	PA 583/6/1	IPSEN LTD	IE
PAXABEL 4 g polvere per soluzione orale in bustina	FR/H/0198/002	036003046	IPSEN S.P.A.	IT
PAXABEL 10 g polvere per soluzione orale in bustina	FR/H/0198/001	036003010	IPSEN S.P.A.	IT
FORLAX 4 g pulveris iekšķīgi lietojama šķīduma pagatavošanai	FR/H/0198/002	05-0155	IPSEN PHARMA	LV
FORLAX 10 g pulveris iekšķīgi lietojama šķīduma pagatavošanai	FR/H/0198/001	05-0156	IPSEN PHARMA	LV
Forlax Junior 4 g poudre pour solution buvable en sachet-dose	FR/H/0198/002	2004010034	IPSEN N.V.	LU
Forlax 10 g poudre pour solution buvable	FR/H/0198/001	0182/04/05/0029	IPSEN N.V.	LU

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en sachet-dose				
FORLAX JUNIOR 4 g, poeder voor drank in sachet 4 g	FR/H/0198/002	RVG 28913	IPSEN FARMACEUTICA B.V.	NL
FORLAX 10 g, poeder voor drank in sachet 10 g	FR/H/0198/001	RVG 23013	IPSEN FARMACEUTICA B.V.	NL
FORLAX JÚNIOR 4 g pó para solução oral em saquetas	FR/H/0198/002	4727988	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
FORLAX 10 g pó para solução oral em saquetas	FR/H/0198/001	4728382	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
FORLAX 10 g proszek do sporządzania roztworu doustnego	FR/H/0198/001	11783	IPSEN PHARMA	PL
Forlax® 4 g Pulver zur Herstellung einer Lösung zum Einnehmen	FR/H/0198/002	61944.00.00	IPSEN PHARMA GMBH	DE
forlax 4 g milteliai geriamajam tirpalui	FR/H/0198/002	LT/1/05/0632/002	IPSEN PHARMA	LT
forlax 4 g milteliai geriamajam tirpalui	FR/H/0198/002	LT/1/05/0632/003	IPSEN PHARMA	LT
forlax 4 g milteliai geriamajam tirpalui	FR/H/0198/002	LT/1/05/0632/004	IPSEN PHARMA	LT
forlax 4 g milteliai geriamajam tirpalui	FR/H/0198/002	LT/1/05/0632/001	IPSEN PHARMA	LT
SELG polvere per soluzione orale	not available	028877025	ALFA WASSERMANN SPA	IT
SELG polvere per soluzione orale	not available	028877013	ALFA WASSERMANN SPA	IT
forlax 10 g milteliai geriamajam tirpalui	FR/H/0198/001	LT/1/05/0632/006	IPSEN PHARMA	LT
forlax 10 g milteliai geriamajam tirpalui	FR/H/0198/001	LT/1/05/0632/007	IPSEN PHARMA	LT
forlax 10 g milteliai geriamajam tirpalui	FR/H/0198/001	LT/1/05/0632/008	IPSEN PHARMA	LT
forlax 10 g milteliai geriamajam tirpalui	FR/H/0198/001	LT/1/05/0632/005	IPSEN PHARMA	LT
Colofort, Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE 232391	IPSEN N.V.	BE
FORTTRANS, poudre pour solution buvable en sachet	not available	34009 555 793 1 1	IPSEN PHARMA	FR
Fortrans, Associação, Pó para solução oral	not available	4190286	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
Fortrans prášok na perorálny roztok	not available	87/0861/94-S	IPSEN PHARMA	SK

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Colofort poudre pour solution buvable	not available	BE 232391	IPSEN N.V.	BE
Colofort, poeder voor drank	not available	BE 232391	IPSEN N.V.	BE
COLOFORT, poeder voor drank in sachet 74 g	not available	RVG 22626	IPSEN FARMACEUTICA B.V.	NL
Colofort, poudre pour solution buvable	not available	2003040033	IPSEN N.V.	LU
FORTTRANS, prášek pro přípravu perorálního roztoku	not available	61/1281/93-C	IPSEN PHARMA	CZ
FORTTRANS, poudre pour solution buvable en sachet	not available	34009 328 862 2 7	IPSEN PHARMA	FR
FORTTRANS pulber suukaudse loputuslahuse valmistamiseks	not available	218898	IPSEN PHARMA	EE
ФОРТРАНС прах за перорален разтвор	not available	20011270	IPSEN PHARMA	BG
Fortrans pulveris iekšķīgi lietojama šķīduma pagatavošanai	not available	95-0265	IPSEN PHARMA	LV
FORTTRANS, 74 g, proszek do sporządzania roztworu doustnego	not available	R/7084	IPSEN PHARMA	PL
Fortrans, Associação, Pó para solução oral	not available	4190187	IPSEN PORTUGAL PRODUTOS FARMACÊUTICOS, S.A.	PT
Fortrans, pulbere pentru soluție orală	not available	1992/2009/01	IPSEN PHARMA	RO
FORTTRANS, σκόνη για πόσιμο διάλυμα σε φακελλίσκους	not available	2973/4-4-08	IPSEN E.P.E.	GR
ISOCOLAN 29,5 g + 2,843 g + 0,843 g + 0,733 g + 0,371 g polvere per soluzione orale	not available	027593019	GIULIANI SPA	IT
ISOCOLAN 29,5 g + 2,843 g + 0,843 g + 0,733 g + 0,371 g polvere per soluzione orale	not available	027593021	GIULIANI SPA	IT
ISOCOLAN 29,5 g + 2,843 g + 0,843 g + 0,733 g + 0,371 g polvere per soluzione orale	not available	027593033	GIULIANI SPA	IT
ISOCOLAN 29,5 g + 2,843 g + 0,843 g +	not available	027593045	GIULIANI SPA	IT

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0,733 g + 0,371 g polvere per soluzione orale				
ISOCOLAN 14,75 g + 1,422 g + 0,422 g + 0,366 g+ 0,186 g polvere per soluzione orale	not available	027593060	GIULIANI SPA	IT
ISOCOLAN 7,375 g + 0,711 g + 0,211 g + 0,183 g + 0,093 g polvere per soluzione orale	not available	027593072	GIULIANI SPA	IT
fortrans milteliai geriamajam tirpalui	not available	LT/1/93/0110/001	IPSEN PHARMA	LT
Regolint 973,6 mg/g polvere per soluzione orale	not available	038204032	LABORATORI BALDACCİ SPA	IT
Regolint 9,7 g polvere per soluzione orale	not available	038204018	LABORATORI BALDACCİ SPA	IT
Regolint 9,7 g polvere per soluzione orale	not available	038204020	LABORATORI BALDACCİ SPA	IT
MACROGOL BIOGARAN 10 g, poudre pour solution buvable en sachet-dose	not available	34009 379 505 2 7	IPSEN PHARMA	FR
MACROGOL BIOGARAN 10 g, poudre pour solution buvable en sachet-dose	not available	34009 379 506 9 5	IPSEN PHARMA	FR
MACROGOL BIOGARAN 10 g, poudre pour solution buvable en sachet-dose	not available	34009 570 776 7 9	IPSEN PHARMA	FR
MACROGOL 4000 SANDOZ 10 g, poudre pour solution buvable en sachet	not available	34009 391 346 8 0	IPSEN PHARMA	FR
MACROGOL 4000 SANDOZ 10 g, poudre pour solution buvable en sachet	not available	34009 391 347 4 1	IPSEN PHARMA	FR
MACROGOL 4000 SANDOZ 10 g, poudre pour solution buvable en sachet	not available	34009 577 350 5 0	IPSEN PHARMA	FR
FORLAXLIB ADULTE 10 g, poudre pour solution buvable en sachet	not available	34009 278 357 8 0	IPSEN PHARMA	FR
FORLAXLIB ADULTE 10 g, poudre pour solution buvable en sachet	not available	34009 278 356 1 2	IPSEN PHARMA	FR

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FORLAX 10 g por belsőleges oldathoz	not available	OGYI-T-7512/02	IPSEN PHARMA	HU
Forlax 10 g Pulver zur Herstellung einer Lösung zum Einnehmen	not available	41469.00.00	IPSEN PHARMA GMBH	DE
FORLAX 10 g	not available	4344/2004/02	IPSEN PHARMA	RO
FORLAX 10 g	not available	4344/2004/03	IPSEN PHARMA	RO
FORLAX 10 g	not available	4344/2004/04	IPSEN PHARMA	RO
FORLAXLIB ADULTE 10 g, poudre pour solution buvable en sachet	not available	34009 391 348 0 2	IPSEN PHARMA	FR
MACROGOL BIOGARAN 10 g, poudre pour solution buvable en sachet-dose	not available	34009 379 504 6 6	IPSEN PHARMA	FR
MACROGOL 4000 SANDOZ 10 g, poudre pour solution buvable en sachet	not available	34009 391 345 1 2	IPSEN PHARMA	FR
FORLAX 10 g por belsőleges oldathoz	not available	OGYI-T-7512/01	IPSEN PHARMA	HU
FORLAX 10 g	not available	4344/2004/01	IPSEN PHARMA	RO
Forlax 10 g pulver till oral lösning, dospåse	not available	14355	INSTITUT PRODUITS SYNTHÈSE (IPSEN) AB	SE
PERGIDAL 7,3 g polvere per soluzione orale	not available	032920 011	VALEAS S.P.A.	IT
PERGIDAL bambini 3,6 g polvere per soluzione orale	not available	032920 023	VALEAS S.P.A.	IT