



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2020
EMA/645508/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: *Saccharomyces boulardii*

Procedure no.: PSUSA/00009284/202002



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
BIOFLOR® 250mg, capsule	not available	MA239/00102	BIOCODEX	MT
BIOFLOR® 250mg, capsule	not available	MA239/00102	BIOCODEX	MT
BIOFLOR® 250mg, capsule	not available	MA239/00102	BIOCODEX	MT
BIOFLOR® 250mg, powder for oral suspension in sachet	not available	MA239/00101	BIOCODEX	MT
Enterol, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
Enterol, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
Enterol, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
Enterol, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
UL-250, 250 mg, cápsulas	not available	8912428	BIOCODEX	PT
UL-250, 250 mg, cápsulas	not available	8912410	BIOCODEX	PT
ULTRA-LEVURE 250 mg, καψάκιο	not available	155595/13-12-2019	PETSIAS S.A. - INDUSTRIAL AND COMMERCIAL ENTERPRISES	GR
BIOFLOR® 100 mg, powder for oral suspension	not available	20432	BIOCODEX	CY
ENTEROL prášek pro perorální suspenzi	not available	49/168/02-C	BIOCODEX	CZ
Enterol 250 mg milteliai geriamajai suspensijai	not available	LT/1/04/0011/001	BIOCODEX	LT
Enterol 250 mg milteliai geriamajai suspensijai	not available	LT/1/04/0011/003	BIOCODEX	LT
Enterol 250 mg kietosios kapsulės	not available	LT/1/04/0011/002	BIOCODEX	LT
Enterol 250 mg kietosios	not available	LT/1/04/0011/004	BIOCODEX	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
kapsulēs				
Enterol 250 mg kietosios kapsulēs	not available	LT/1/04/0011/005	BIOCODEX	LT
Enterol 250 mg kietosios kapsulēs	not available	LT/1/04/0011/006	BIOCODEX	LT
Enterol 250 mg kietosios kapsulēs	not available	LT/1/04/0011/007	BIOCODEX	LT
Precosa, kapsler, hārde	not available	16958	BIOCODEX	DK
Precosa, kapsler, hārde	not available	16958	BIOCODEX	DK
Precosa, pulver til oral suspension, enkeltdosisbeholder	not available	16957	BIOCODEX	DK
Precosa, pulver til oral suspension, enkeltdosisbeholder	not available	16957	BIOCODEX	DK
Enterol 250 mg belsōleges por	not available	OGYI-T-9660/01	BIOCODEX	HU
Enterol 250 mg belsōleges por	not available	OGYI-T-9660/02	BIOCODEX	HU
Enterol 250 mg belsōleges por	not available	OGYI-T-9660/03	BIOCODEX	HU
Enterol 250 mg kapsuly	not available	49/0464/09-S	BIOCODEX	SK
Enterol 250 mg kapsuly	not available	49/0464/09-S	BIOCODEX	SK
Enterol 250 mg kapsuly	not available	49/0464/09-S	BIOCODEX	SK
Precosa® 250 mg kapsel, hārd	not available	11976	BIOCODEX	FI
Precosa® 250 mg kapsel, hārd	not available	11976	BIOCODEX	FI
Precosa® 250 mg kapsel, hārd	not available	11976	BIOCODEX	FI
Precosa® 250 mg kapsel, hārd	not available	11976	BIOCODEX	FI
Precosa 250 mg kapseli, kova	not available	11976	BIOCODEX	FI
Precosa 250 mg kapseli, kova	not available	11976	BIOCODEX	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
Precosa 250 mg kapseli, kova	not available	11976	BIOCODEX	FI
Precosa 250 mg kapseli, kova	not available	11976	BIOCODEX	FI
Precosa 250 mg jauhe oraalisuspensiota varten, annospussi	not available	11975	BIOCODEX	FI
Precosa 250 mg jauhe oraalisuspensiota varten, annospussi	not available	11975	BIOCODEX	FI
Precosa 250 mg jauhe oraalisuspensiota varten, annospussi	not available	11975	BIOCODEX	FI
Precosa® 250 mg pulver till oral suspension	not available	11975	BIOCODEX	FI
Precosa® 250 mg pulver till oral suspension	not available	11975	BIOCODEX	FI
Precosa® 250 mg pulver till oral suspension	not available	11975	BIOCODEX	FI
BIOFLOR 200, capsules	not available	018642	BIOCODEX	CY
ULTRA-LEVURE 50 mg, gélule	not available	311 001-9	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	368 769-3	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	369 913-0	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	325 988-5	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	369 914-7	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	369 915-3	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	369 917-6	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	552 454-1	BIOCODEX	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
Ultra-Levura 50 mg cápsulas duras	not available	46035	BIOCODEX	ES
ULTRA-LEVURE 100 mg, poudre pour suspension buvable en sachet	not available	343 793-8	BIOCODEX	FR
ULTRA-LEVURE 100 mg, poudre pour suspension buvable en sachet	not available	34009 344 443 0 2	BIOCODEX	FR
ULTRA-LEVURE 100 mg, poudre pour suspension buvable en sachet	not available	343 794-4	BIOCODEX	FR
ULTRA-LEVURE 100 mg, poudre pour suspension buvable en sachet	not available	343 795-0	BIOCODEX	FR
ULTRA-LEVURE 100 mg, poudre pour suspension buvable en sachet	not available	343 796-7	BIOCODEX	FR
Enterol 250 mg kemény kapszula	not available	OGYI-T-9659/01	BIOCODEX	HU
Enterol 250 mg kemény kapszula	not available	OGYI-T-9659/02	BIOCODEX	HU
Enterol 250 mg kemény kapszula	not available	OGYI-T-9659/03	BIOCODEX	HU
Enterol 250 mg kemény kapszula	not available	OGYI-T-9659/04	BIOCODEX	HU
Enterol 250 mg kemény kapszula	not available	OGYI-T-9659/05	BIOCODEX	HU
Enterol 250 mg kemény kapszula	not available	OGYI-T-9659/06	BIOCODEX	HU
ENTEROL 250 mg cietās kapsulas	not available	97-0022	BIOCODEX	LV
ENTEROL 250 mg cietās kapsulas	not available	97-0022	BIOCODEX	LV
ENTEROL 250 mg pulveris iekšķīgi lietojamas suspensijas	not available	97-0021	BIOCODEX	LV

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
pagatavošanai				
ENTEROL 250 mg cietās kapsulas	not available	97-0022	BIOCODEX	LV
ENTEROL 250 mg pulveris iekšķīgi lietojamas suspensijas pagatavošanai	not available	97-0021	BIOCODEX	LV
ENTEROL 250 mg cietās kapsulas	not available	97-0022	BIOCODEX	LV
Ultra-Levura 250 mg granulado para suspensión oral	not available	78258	BIOCODEX	ES
ENTEROL® 250	not available	4069/2003/01	BIOCODEX	RO
ULTRA-LEVURE 100 mg, gélule	not available	34009 300 311 9 3	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 300 312 0 9	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 300 312 1 6	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 300 312 2 3	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 300 312 3 0	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 395 237 9 8	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 395 238 5 9	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 395 239 1 0	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 395 241 6 0	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	34009 395 241 6 0	BIOCODEX	FR
UL-250, 250 mg, pó para suspensão oral	not available	8615203	BIOCODEX	PT
UL-250, 250 mg, pó para	not available	8615211	BIOCODEX	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
suspensão oral				
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg капсули, твърди	not available	II-5839	BIOCODEX	BG
Ентерол 250 mg прах за перорална суспензия	not available	II-5840	BIOCODEX	BG
Ентерол 250 mg прах за перорална суспензия	not available	II-5840	BIOCODEX	BG
Ентерол 250 mg прах за перорална суспензия	not available	II-5840	BIOCODEX	BG
CODEX 5 miliardi capsule rigide	not available	029032012	BIOCODEX	IT
CODEX 5 miliardi capsule rigide	not available	029032024	BIOCODEX	IT
CODEX 5 miliardi polvere per sospensione orale	not available	029032036	BIOCODEX	IT
CODEX 5 miliardi polvere per sospensione orale	not available	029032048	BIOCODEX	IT
CODEX 5 miliardi capsule rigide	not available	029032051	BIOCODEX	IT
CODEX 5 miliardi capsule rigide	not available	029032063	BIOCODEX	IT
CODEX 5 miliardi capsule	not available	029032075	BIOCODEX	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
rigide				
CODEX 5 miliardi capsule rigide	not available	029032087	BIOCODEX	IT
ULTRA-LEVURE 200 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	34009 364 655 3 4	BIOCODEX	FR
ULTRA-LEVURE 200 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	34009 364 657 6 3	BIOCODEX	FR
ULTRA-LEVURE 200 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	34009 364 658 2 4	BIOCODEX	FR
ULTRA-LEVURE 200 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	34009 364 659 9 2	BIOCODEX	FR
ULTRA-LEVURE 200 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	34009 364 672 5 5	BIOCODEX	FR
ULTRA-LEVURE 200 MG, POUDRE POUR SUSPENSION BUVABLE EN SACHET	not available	34009 364 673 1 6	BIOCODEX	FR
ULTRA-LEVURE® 50 MG, καψάκιο σκληρό	not available	155594/13-12-2019	PETSIAS S.A. - INDUSTRIAL AND COMMERCIAL ENTERPRISES	GR
ULTRA-LEVURE 250 mg, κόνις για πόσιμο εναιώρημα σε φακελίσκο	not available	155596/13-12-2019	PETSIAS S.A. - INDUSTRIAL AND COMMERCIAL ENTERPRISES	GR
Ultra-Levura 250 mg cápsulas duras	not available	78272	BIOCODEX	ES
Ultra-Levura 250 mg cápsulas duras	not available	78272	BIOCODEX	ES

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
ENTEROL® 250	not available	4039/2003/01	BIOCODEX	RO
ENTEROL tvrdé tobolky	not available	49/167/02-C	BIOCODEX	CZ
ENTEROL tvrdé tobolky	not available	49/167/02-C	BIOCODEX	CZ
ENTEROL tvrdé tobolky	not available	49/167/02-C	BIOCODEX	CZ
Precosa 250 mg hårda kapslar	not available	12236	BIOCODEX	SE
Precosa 250 mg hårda kapslar	not available	12236	BIOCODEX	SE
Precosa 250 mg pulver till oral suspension, dospåse	not available	12237	BIOCODEX	SE
Precosa 250 mg pulver till oral suspension, dospåse	not available	12237	BIOCODEX	SE
Precosa 250 mg pulver till oral suspension, dospåse	not available	12237	BIOCODEX	SE
Precosa 250 mg hårda kapslar	not available	12236	BIOCODEX	SE
Precosa 250 mg hårda kapslar	not available	12236	BIOCODEX	SE
Enterol 250 mg, poudre pour suspension buvable	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, poudre pour suspension buvable	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, poudre pour suspension buvable	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, poudre pour suspension buvable	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	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
Enterol 250 mg, gélules	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	2011041132	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
ENTEROL, 250 mg kövkapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg	not available	408203	BIOCODEX	EE

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kõvakapslid				
ENTEROL, 250 mg suukaudse suspensiooni pulber	not available	180897	BIOCODEX	EE
ENTEROL, 250 mg suukaudse suspensiooni pulber	not available	180897	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ULTRA-LEVURE 200 mg, gélule	not available	34009 376 072 8 5	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 345 839 5 7	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 376 073 4 6	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 376 074 7 5	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 376 075 7 5	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009-220 965 5 1	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 220 966 1 2	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 220 967 8 0	BIOCODEX	FR
ULTRA-LEVURE 200 mg, gélule	not available	34009 220 968 4 1	BIOCODEX	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
gélule				
PRECOSA, 250 mg kapsel, hard	not available	94-2012	BIOCODEX	NO
PRECOSA, 250 mg kapsel, hard	not available	94-2012	BIOCODEX	NO
PRECOSA, 250 mg pulver i dosepose	not available	94-2013	BIOCODEX	NO
PRECOSA, 250 mg pulver i dosepose	not available	94-2013	BIOCODEX	NO
Enterol, 250 mg, proszek do sporządzania zawiesiny doustnej	not available	7485	BIOCODEX	PL
Enterol, 250 mg, proszek do sporządzania zawiesiny doustnej	not available	7485	BIOCODEX	PL
Enterol 250 mg, gélules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, gélules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE 397896	BIOCODEX BENELUX NV/SA	BE

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capsules				
Enterol 250 mg harde capsules	not available	BE 397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Hartkapseln	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, poudre pour suspension buvable	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, poudre pour suspension buvable	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, poudre pour suspension buvable	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, poudre pour suspension buvable	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	not available	BE 269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Pulver	not available	BE269026	BIOCODEX BENELUX NV/SA	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
zur Herstellung einer Suspension zum Einnehmen				
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, Pulver zur Herstellung einer Suspension zum Einnehmen	not available	BE269026	BIOCODEX BENELUX NV/SA	BE