



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 September 2017
EMA/639207/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: *saccharomyces boulardii*

Procedure no.: PSUSA/00009284/201702



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 200, capsules	not available	018642	BIOCODEX	CY
BIOFLOR® 100 mg, powder for oral suspension	not available	20432	BIOCODEX	CY
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
Codex 5 miliardi capsule rigide	not available	029032075	ZAMBON ITALIA S.R.L.	IT
Codex 5 miliardi capsule rigide	not available	029032087	ZAMBON ITALIA S.R.L.	IT
Codex 5 miliardi capsule rigide	not available	029032012	ZAMBON ITALIA S.R.L.	IT
Codex 5 miliardi capsule rigide	not available	029032024	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
Codex 5 miliardi capsule rigide	not available	029032051	ZAMBON ITALIA S.R.L.	IT
Codex 5 miliardi capsule rigide	not available	029032063	ZAMBON ITALIA S.R.L.	IT
CODEX 5 miliardi polvere per sospensione orale	not available	029032036	ZAMBON ITALIA S.R.L.	IT
CODEX 5 miliardi polvere per sospensione orale	not available	029032048	ZAMBON ITALIA S.R.L.	IT
ENTEROL prášek pro perorální suspenzi	not available	49/168/02-C	BIOCODEX	CZ
ENTEROL tvrdé tobolky	not available	49/167/02-C	BIOCODEX	CZ
Enterol 250 mg belsőleges por	not available	OGYI-T-9660/01	BIOCODEX	HU
Enterol 250 mg belsőleges por	not available	OGYI-T-9660/02	BIOCODEX	HU
Enterol 250 mg belsőleges por	not available	OGYI-T-9660/03	BIOCODEX	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
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 harde capsules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE269035	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg harde capsules	not available	BE397896	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
Enterol 250 mg harde capsules	not available	BE397896	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg kietosios kapsulės	not available	LT/1/04/0011/002	BIOCODEX	LT
Enterol 250 mg kietosios kapsulės	not available	LT/1/04/011/004	BIOCODEX	LT
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 poeder voor orale suspensie	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg poeder voor orale suspensie	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
ENTEROL 250 mg pulveris iekšķīgi lietojamas suspensijas pagatavošanai	not available	97-0021	BIOCODEX	LV
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

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, 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
Enterol 250 mg, Hartkapseln	not available	BE269035	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
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, Hartkapseln	not available	2011041131	BIOCODEX BENELUX NV/SA	LU
Enterol 250 mg, Hartkapseln	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, 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, poudre pour suspension buvable	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, poudre pour suspension buvable	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
Enterol 250 mg, poudre pour suspension buvable	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
Enterol 250 mg, poudre pour suspension buvable	not available	BE269026	BIOCODEX BENELUX NV/SA	BE
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, 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

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, 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	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, 250 mg , proszek do sporządzania zawiesiny doustnej	not available	7485	BIOCODEX	PL
Enterol 250, 250 mg , proszek do sporządzania zawiesiny doustnej	not available	7485	BIOCODEX	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
Enterol 250, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
Enterol 250, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
Enterol 250, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
Enterol 250, 250 mg, kapsułki	not available	7484	BIOCODEX	PL
ENTEROL tvrdé tobolky	not available	49/167/02-C	BIOCODEX	CZ
ENTEROL tvrdé tobolky	not available	49/167/02-C	BIOCODEX	CZ
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg kõvakapslid	not available	408203	BIOCODEX	EE
ENTEROL, 250 mg suukaudse suspensiooni pulber	not available	180897	BIOCODEX	EE

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	4069/2003/01	BIOCODEX	RO
ENTEROL® 250	not available	4039/2003/01	BIOCODEX	RO
Precosa 250 mg hårda kapslar	not available	12236	BIOCODEX	SE
Precosa 250 mg hårda kapslar	not available	12236	BIOCODEX	SE
PRECOSA 250 mg kapsel, hard	not available	94-2012	BIOCODEX	NO
Precosa 250 mg kapseli, kova	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
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 pulver till oral suspension, dospåse	not available	12237	BIOCODEX	SE
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
Precosa, kapsler, hårde	not available	16958	BIOCODEX	DK
Precosa, kapsler, hårde	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
Precosa® 250 mg jauhe oraalisuspensiota varten, annospussi	not available	11975	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 jauhe oraalisuspensiota varten, annospussi	not available	11975	BIOCODEX	FI
Precosa® 250 mg jauhe oraalisuspensiota varten, annospussi	not available	11975	BIOCODEX	FI
Precosa® 250 mg kapsel, hård	not available	11976	BIOCODEX	FI
Precosa® 250 mg kapsel, hård	not available	11976	BIOCODEX	FI
Precosa® 250 mg kapsel, hård	not available	11976	BIOCODEX	FI
Precosa® 250 mg kapsel, hård	not available	11976	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

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
UL-250, 250 mg, cápsulas	not available	8912428	BIOCODEX	PT
UL-250, 250 mg, cápsulas	not available	8912410	BIOCODEX	PT
UL-250, 250 mg, pó para suspensão oral	not available	8615203	BIOCODEX	PT
UL-250, 250 mg, pó para suspensão oral	not available	8615211	BIOCODEX	PT
Ultra-Levura 250 mg cápsulas duras	not available	78272	BIOCODEX	ES
Ultra-Levura 250 mg cápsulas duras	not available	78272	BIOCODEX	ES
Ultra-Levura 250 mg granulado para suspensión oral	not available	78258	BIOCODEX	ES
Ultra-Levura 50 mg cápsulas duras	not available	46.035	BIOCODEX	ES
ULTRA-LEVURE	not available	33135/20-4-2016	PETSIAVAS S.A. - INDUSTRIAL AND COMMERCIAL ENTERPRISES	GR

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-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	395 237-9	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	395 238-5	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	395 239-1	BIOCODEX	FR
ULTRA-LEVURE 100 mg, gélule	not available	395 241-6	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-LEVURE 100 mg, gélule	not available	395 242-2	BIOCODEX	FR
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	344 443.0	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
ULTRA-LEVURE 200 mg, poudre pour suspension buvable en sachet	not available	364 655-3	BIOCODEX	FR
ULTRA-LEVURE 200 mg, poudre pour suspension buvable en sachet	not available	364 657-6	BIOCODEX	FR
ULTRA-LEVURE 200 mg, poudre pour suspension buvable en sachet	not available	364 658-2	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-LEVURE 200 mg, poudre pour suspension buvable en sachet	not available	364 659-9	BIOCODEX	FR
ULTRA-LEVURE 200 mg, poudre pour suspension buvable en sachet	not available	364 672-5	BIOCODEX	FR
ULTRA-LEVURE 200 mg, poudre pour suspension buvable en sachet	not available	364 673-1	BIOCODEX	FR
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

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-LEVURE 50 mg, gélule	not available	369 917-6	BIOCODEX	FR
ULTRA-LEVURE 50 mg, gélule	not available	552 454-1	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	376 072.8	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	345 839.5	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	376 073.4	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	376 074.0	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	376 075.7	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	220 956-5	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	220 966-1	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-LEVURE® 200 mg, gélule	not available	220 967-8	BIOCODEX	FR
ULTRA-LEVURE® 200 mg, gélule	not available	220 968-4	BIOCODEX	FR
ULTRA-LEVURE® 250 mg, καψάκιο	not available	91361/15	PETSIAVAS S.A. - INDUSTRIAL AND COMMERCIAL ENTERPRISES	GR
ULTRA-LEVURE® 250 mg, κόνις για πόσιμο εναιώρημα σε φακελίσκο	not available	91361/15	PETSIAVAS S.A. - INDUSTRIAL AND COMMERCIAL ENTERPRISES	GR
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