



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2016
EMA/648919/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: erdosteine

Procedure no.: PSUSA/00001248/201602



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
ERDOMED 3,5 % prášok na perorálnu suspenziu	not available	52/0233/99-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
ERDOMED 225 mg, proszek do sporządzania zawiesiny doustnej	not available	12739	ANGELINI PHARMA POLSKA SP. Z O.O.	PL
Erdomed 175 mg/5 ml por belsőleges szuszpenzióhoz	not available	OGYI-T-8777/05	ANGELINI PHARMA ÖSTERREICH GMBH	HU
Erdomed 175 mg/5ml pulbere pentru suspensie orală	not available	3063/2010/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Erdomed 225 mg - Granulat	not available	1-25319	ANGELINI PHARMA ÖSTERREICH GMBH	AT
ERDOMED 225 mg prášok na perorálny roztok	not available	52/0233/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
ERDOMED 225 mg granule pentru suspensie orală	not available	3064/2010/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Erdomed 225 mg por belsőleges oldathoz	not available	OGYI-T-8777/04	ANGELINI PHARMA ÖSTERREICH GMBH	HU
Erdomed 225 mg por belsőleges oldathoz	not available	OGYI-T-8777/03	ANGELINI PHARMA ÖSTERREICH GMBH	HU
Erdomed 300 mg - Kapseln	not available	1-25321	ANGELINI PHARMA ÖSTERREICH GMBH	AT
Erdomed 300 mg kemény kapszula	not available	OGYI-T-8777/02	ANGELINI PHARMA ÖSTERREICH GMBH	HU
Erdomed 300 mg kemény kapszula	not available	OGYI-T-8777/01	ANGELINI PHARMA ÖSTERREICH GMBH	HU
ERDOMED 300 mg tvrdé kapsuly	not available	52/0232/99-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
ERDOMED 300 mg, capsule	not available	1120/2008/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
ERDOMED 300 mg, capsule	not available	1120/2008/02	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Erdomed 300 mg, kapsułki	not available	12738	ANGELINI PHARMA POLSKA SP. Z O.O.	PL
Erdomed 35 mg/ml, proszek do sporządzania zawiesiny doustnej	not available	12924	ANGELINI PHARMA POLSKA SP. Z O.O.	PL

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ERDOMED Prášek pro přípravu perorální suspenze	not available	52/046/96-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
ERDOMED Prášek pro přípravu perorálního roztoku	not available	52/047/96-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
ERDOMED Tvrdé tobolky	not available	52/045/96-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
Erdotin	DK/H/0953/001	15802	EDMOND PHARMA S.R.L.	DK
Erdotin 300 mg capsule	DK/H/0953/001	PA 1325/1/1	EDMOND PHARMA S.R.L.	IE
Erdotin 300 mg capsule	DK/H/0953/001	PL 14682/0012	EDMOND PHARMA S.R.L.	UK
Erdotin, kapsler, hárde	DK/H/0953/001	15801	EDMOND PHARMA S.R.L.	DK
Erdotin, pulver til oral suspension	DK/H/0953/001	15803	EDMOND PHARMA S.R.L.	DK
ESTECLIN 175 MG/5 ML GRANULATO PER SOSPENSIONE ORALE	not available	041127046	EDMOND PHARMA S.R.L.	IT
ESTECLIN 225 MG GRANULATO PER SOSPENSIONE ORALE	not available	041127034	EDMOND PHARMA S.R.L.	IT
ESTECLIN 300 MG CAPSULE RIGIDE	not available	041127010	EDMOND PHARMA S.R.L.	IT
ESTECLIN 300 MG COMPRESSE DISPERSIBILI	not available	041127022	EDMOND PHARMA S.R.L.	IT
VECTRINE 300 mg, gélule	not available	34009 336 483 7 4	PHARMA 2000	FR
VECTRINE 300 mg, gélule	not available	34009 336 483 7 4	PHARMA 2000	FR
VECTRINE 300 mg, poudre pour suspension buvable en sachet	not available	34009 337 152 4 3	PHARMA 2000	FR
VECTRINE 300 mg, poudre pour suspension buvable en sachet	not available	34009 337 152 4 3	PHARMA 2000	FR
Ердомед 175 mg/5 ml прах за перорална суспензия	not available	20011042	ANGELINI PHARMA BULGARIA EOOD	BG
Ердомед 225 mg прах за	not available	20011043	ANGELINI PHARMA	BG

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перорален разтвор			BULGARIA EOOD	
Ердомед 300 mg капсули,твърди	not available	20011041	ANGELINI PHARMA BULGARIA EOOD	BG