



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2019
EMA/26458/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acemetacin

Procedure no.: PSUSA/00000026/201805



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
Rantudal 60 mg καψάκια, σκληρά	not available	40006/07/09-05-2008	MEDA PHARMACEUTICALS S.A.	GR
Rantudal retard 90 mg καψάκια ελεγχόμενης αποδέσμευσης, σκληρά	not available	37916/08-06-2010	MEDA PHARMACEUTICALS S.A.	GR
Ziloxicum 60 mg Hartkapseln	not available	90716.00.00	DROSSAPHARM GMBH	DE
Ziloxicum 60 mg Hartkapseln	not available	90717.00.00	DROSSAPHARM GMBH	DE
Ziloxicum 60 mg καψάκια, σκληρά	DE/H/3936/001/DC	3062801	DROSSAPHARM GMBH	GR
Ziloxicum 60 mg capsules, hard	not available	MA716/00301	DROSSAPHARM GMBH	MT
Ziloxicum 60 mg Hartkapseln	not available	2014120447	DROSSAPHARM GMBH	LU
Acemetax 60 mg Hartkapseln	DE/H/3937/001/DC	2014120343	DROSSAPHARM GMBH	LU
Zadex 60 mg kemény kapszula	DE/H/3936/001	OGYI-T-22692/01	GOODWILL PHARMA LTD	HU
Zadex 60 mg kemény kapszula	DE/H/3936/001	OGYI-T-22692/02	GOODWILL PHARMA LTD	HU
Zadex 60 mg kemény kapszula	DE/H/3936/001	OGYI-T-22692/03	GOODWILL PHARMA LTD	HU
Emflex Capsules	not available	PL 11648/0083	MERCK SERONO LTD.	UK
Rantudil® forte 60 mg Hartkapsel	not available	3610.00.00	MEDA MANUFACTURING GMBH	DE
Rantudil® retard 90 mg Hartkapsel retardiert	not available	3610.01.00	MEDA MANUFACTURING GMBH	DE
Rantudil ® forte 60 mg Hartkapsel	not available	1983081001	MEDA MANUFACTURING GMBH	LU
Rantudil® retard 90 mg Hartkapsel retardiert	not available	2010080836	MEDA MANUFACTURING GMBH	LU
Rantudil® forte 60 mg Hard capsule	not available	MA708/00101	MEDA MANUFACTURING GMBH	MT
RHEUTROP- Kapseln	not available	1-17.447	MEDA PHARMA GMBH	AT
RHEUTROP retard- Kapseln	not available	1-18567	MEDA PHARMA GMBH	AT
Rantudil® retard 90 mg Sustained-release	not available	MA708/00102	MEDA MANUFACTURING	MT

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
capsule			GMBH	
Rantudil forte 60 mg kapsule, tvrde	not available	HR-H-016679606	MYLAN HRVATSKA D.O.O.	HR
Rantudil 90 mg retard kemény kapszula	not available	OGYI-T-6085/05	MYLAN EPD KFT.	HU
Rantudil 90 mg retard kemény kapszula	not available	OGYI-T-6085/06	MYLAN EPD KFT.	HU
Rantudil 90 mg retard kemény kapszula	not available	OGYI-T-6085/07	MYLAN EPD KFT.	HU
Rantudil 90 mg retard kemény kapszula	not available	OGYI-T-6085/08	MYLAN EPD KFT.	HU
Rantudil Forte kemény kapszula	not available	OGYI-T-6085/03	MYLAN EPD KFT.	HU
Rantudil Forte kemény kapszula	not available	OGYI-T-6085/02	MYLAN EPD KFT.	HU
Rantudil Forte kemény kapszula	not available	OGYI-T-6085/04	MYLAN EPD KFT.	HU
Rantudil Forte kemény kapszula	not available	OGYI-T-6085/01	MYLAN EPD KFT.	HU
Rantudil Retard, 90 mg, kapsułki o przedłużonym uwalnianiu	not available	4132	MEDA AB	PL
Rantudil Forte, 60 mg, kapsułki twarde	not available	4131	MEDA AB	PL