



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 July 2016
EMA/184638/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexketoprofen

Procedure no.: PSUSA/00000997/201510

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Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dexketoprofeno Menarini 25 mg cápsulas duras	not available	78.706	LABORATORIOS FERMON, S.L.U.	ES
Enantyum 25 mg cápsulas duras	not available	78.705	LABORATORIOS MENARINI, S.A.	ES
Дексофен саше 25 mg гранули за перорален разтвор	not available	20140186	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
Enantyum 25 mg filmomhulde tabletten	ES/H/0100/002	BE196707	LABORATORIOS MENARINI, S.A.	BE
Enantyum 12,5 mg filmomhulde tabletten	ES/H/0100/001	BE196682	LABORATORIOS MENARINI, S.A.	BE
Ketesse 12,5 mg filmomhulde tabletten	ES/H/0101/001	BE196621	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 25 mg filmomhulde tabletten	ES/H/0101/002	BE196691	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Enantyum 25 mg granulaat voor drank	ES/H/0100/005	BE395516	LABORATORIOS MENARINI, S.A.	BE
Enantyum 12,5 mg granulaat voor drank	ES/H/0100/004	BE395507	LABORATORIOS MENARINI, S.A.	BE
Ketesse 12,5 mg Granulat zur Herstellung einer Lösung zum Einnehmen	ES/H/0101/004	BE392052	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Ketesse 50 mg/2 ml oplossing voor injectie of concentraat voor oplossing voor infusie	ES/H/0101/003	BE254405	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Enantyum 50 mg/2 ml oplossing voor injectie of concentraat voor oplossing voor infusie	ES/H/0100/003	BE254335	LABORATORIOS MENARINI, S.A.	BE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 25 mg granulaat voor drank	ES/H/0101/005	BE392061	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
KERAL 25 mg film-coated tablets	ES/H/0101/002	MA204/00107	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
KERAL 12.5 mg film-coated tablets	ES/H/0101/001	MA204/00106	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Ketesse 25 mg filmdragerade tabletter	ES/H/0101/002	13047	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Ketesse 50 mg/2 ml injektionsvätska, lösning eller koncentrat till infusionsvätska, lösning	ES/H/0101/003	17583	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 25 mg granulät för oral lösning	ES/H/0101/005	29033	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
MENADEx 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/07/00838/018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/014	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
MENADEx 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/014	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/024	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/015	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/015	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 12,5 mg granulés pour solution buvable	ES/H/0101/004	2011080035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Ketesse 25 mg granulés pour solution buvable	ES/H/0101/005	2011080036	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Enantyum 25 mg granulés pour solution buvable	ES/H/0100/005	2011090014	LABORATORIOS MENARINI, S.A.	LU
Enantyum 12,5 mg granulés pour solution buvable	ES/H/0100/004	2011090013	LABORATORIOS MENARINI, S.A.	LU
MENADEX 12,5 mg filmsko obložene tablete	ES/H/0101/001	H/03/00992/021	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/033	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
MENADEx 25 mg filmsko obložene tablete	ES/H/0101/002	H/03/00992/028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 12,5 mg filmsko obložene tablete	ES/H/0101/001	H/03/00992/022	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 25 mg filmsko obložene tablete	ES/H/0101/002	H/03/00992/029	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 12,5 mg filmsko obložene tablete	ES/H/0101/001	H/03/00992/023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
MENADEX 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/036	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 50 mg/2ml, solución inyectable o concentrado para solución para perfusión	ES/H/0101/003	64.888	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
KETESSE 50 mg/2ml Solution for injection or concentrate for solution for infusion	ES/H/0101/003	1-24938	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
NOSATEL® Ενέσιμο διάλυμα ή πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση 50mg/2ml	ES/H/0101/003	20155	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dexoket injekce Injekční roztok/koncentrát pro infuzní roztok	ES/H/0101/003	07/185/06-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Ketesse	ES/H/0101/003	34105	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
DOLMEN, 50 mg/2ml süstelahus või infusioonilahuse kontsentraat	ES/H/0101/003	510306	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
NOSATEL® Ενέσιμο διάλυμα ή πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση 50mg/2ml	ES/H/0101/003	26002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
KETESSE 50 mg/2 ml, solution injectable ou solution à diluer pour perfusion	ES/H/0101/003	34009 564 3352 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 50 mg/2 ml, solution injectable ou solution à diluer pour perfusion	ES/H/0101/003	34009 361 8864 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Ketodex forte 50 mg/2 ml oldatos injekció vagy koncentrátum oldatos infúzióhoz	ES/H/0101/003	OGYI-T-8884/13	BERLIN-CHEMIE AG	HU
Ketodex forte 50 mg/2 ml oldatos injekció vagy koncentrátum oldatos infúzióhoz	ES/H/0101/003	OGYI-T-8884/10	BERLIN-CHEMIE AG	HU
Ketodex forte 50 mg/2 ml oldatos injekció vagy koncentrátum oldatos infúzióhoz	ES/H/0101/003	OGYI-T-8884/11	BERLIN-CHEMIE AG	HU
Ketodex forte 50 mg/2 ml oldatos injekció vagy koncentrátum oldatos infúzióhoz	ES/H/0101/003	OGYI-T-8884/12	BERLIN-CHEMIE AG	HU
Kettesse 50 mg/2 ml stungulyf, lausn eða innrennslispykkni, lausn	ES/H/0101/003/E/001	IS/1/06/001/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635095	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KERAL 50 mg/2ml Solution for injection or concentrate for solution for infusion	ES/H/0101/003	PA 865/2/3	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635069	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635107	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635057	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635071	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635044	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dolmen 50 mg/2 ml šķīdums injekcijām vai koncentrāts infūziju šķīduma pagatavošanai	ES/H/0101/003	06-0082	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0101/003	033635083	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/019	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/014	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/015	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Kettesse 50 mg/2 ml solution injectable ou solution à diluer pour perfusion	ES/H/0101/003	0951/09030246	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Dolmen 50 mg/2ml injekcinis tirpalas/koncentratas infuziniam tirpalui	ES/H/0101/003	LT/1/06/0539/016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Stadium 50 mg/2 ml oplossing voor injectie of concentraat voor oplossing voor infusie	ES/H/0101/003	RVG 28295	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
KETESSE 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0101/003	4249082	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 50 mg/2 ml, injeksjonsvæske, oppløsning eller konsentrat til infusjonsvæske, oppløsning	ES/H/0101/003	05-3705	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
KETESSE 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0101/003	4249389	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
KERAL 50 mg/2ml Solution for injection or concentrate for solution for infusion	ES/H/0101/003	MA204/00103	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Dexak 50 50 mg/2ml roztwór do wstrzykiwań lub koncentrat do sporządzenia roztworu do infuzji	ES/H/0101/003	12356	BERLIN-CHEMIE AG	PL
KETESSE 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0101/003	4249488	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0101/003	4249280	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
KETESSE 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0101/003	4249181	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
KETESSE 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0101/003	4248985	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
MENADEx 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEx 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/032	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 50 mg/2 ml, injektionsvätska, lösning eller koncentrat till infusionsvätska, lösning	ES/H/0101/003	18714	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
MENADEX 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0101/003	H/03/00992/031	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Dexadol 50 mg/2 ml sol inj injekčný roztok alebo infúzny koncentrát	ES/H/0101/003	07/0450/06-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
ENANTYUM 50 mg/2ml Solution for injection or concentrate for solution for infusion	ES/H/0100/003	1-24937	LABORATORIOS MENARINI, S.A.	AT
VIAXAL® Ενέσιμο διάλυμα ή πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση 50mg/2ml	ES/H/0100/003	26001	LABORATORIOS MENARINI, S.A.	GR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE, 50 mg/2ml süstelahus või infusioonilahuse kontsentraat	ES/H/0100/003	509806	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Enantyum 50 mg/2 ml stungulyf, lausn eða innrennslispykkni, lausn	ES/H/0100/003/E/001	IS/1/06/002/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
ENANTYUM 50 mg/2ml Solution for injection or concentrate for solution for infusion	ES/H/0100/003	PA 901/1/3	LABORATORIOS MENARINI, S.A.	IE
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656051	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656099	LABORATORIOS MENARINI, S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656087	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656063	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656075	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656048	LABORATORIOS MENARINI, S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 50 mg/2ml – Soluzione per iniezione o concentrato per soluzione per infusione	ES/H/0100/003	033656101	LABORATORIOS MENARINI, S.A.	IT
Ketesse 50 mg/2 ml šķīdums injekcijām vai koncentrāts infūziju šķīduma pagatavošanai	ES/H/0100/003	06-0085	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Enantyum 50 mg/2 ml oplossing voor injectie of concentraat voor oplossing voor infusie	ES/H/0100/003	RVG 28294	LABORATORIOS MENARINI, S.A.	NL
ENANTYUM 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0100/003	4248688	LABORATORIOS MENARINI, S.A.	PT
ENANTYUM 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0100/003	4248886	LABORATORIOS MENARINI, S.A.	PT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 50 mg/2 ml solution injectable ou solution à diluer pour perfusion	ES/H/0100/003	1405/09030241	LABORATORIOS MENARINI, S.A.	LU
ENANTYUM 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0100/003	4248589	LABORATORIOS MENARINI, S.A.	PT
ENANTYUM 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0100/003	4248381	LABORATORIOS MENARINI, S.A.	PT
Ketesse 50 mg/2 ml sol inj injekčný roztok alebo infúzny koncentrát	ES/H/0100/003	07/0451/06-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
ENANTYUM 50 mg/2ml Solution for injection or concentrate for solution for infusion	ES/H/0100/003	PL 16239/0026	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
ENANTYUM 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0100/003	4248787	LABORATORIOS MENARINI, S.A.	PT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 50 mg/2 ml raztopina za injiciranje ali koncentrat za raztopino za infundiranje	ES/H/0100/003	5363-I-1681/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
ENANTYUM 50 mg/2 ml, solução injectável ou concentrado para solução para perfusão	ES/H/0100/003	4248480	LABORATORIOS MENARINI, S.A.	PT
Enantyum 50 mg/2 ml, injektionsvätska, lösning eller koncentrat till infusionsvätska, lösning	ES/H/0100/003	18713	LABORATORIOS MENARINI, S.A.	SE
ENANTYUM 50 mg/2ml, solución inyectable o concentrado para solución para perfusión	ES/H/0100/003	64.887	LABORATORIOS MENARINI, S.A.	ES
ENANTYUM 25 mg, granulado para solución oral	ES/H/0100/005	66.819	LABORATORIOS MENARINI, S.A.	ES

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 12,5 mg, granulado para solución oral	ES/H/0101/004	66.825	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
ENANTYUM 12,5 mg, comprimidos recubiertos	ES/H/0100/001	60.927	LABORATORIOS MENARINI, S.A.	ES
ENANTYUM 25 mg, comprimidos recubiertos	ES/H/0100/002	60.928	LABORATORIOS MENARINI, S.A.	ES
ENANTYUM 12,5 mg, granulado para solución oral	ES/H/0100/004	66.818	LABORATORIOS MENARINI, S.A.	ES
KETESSE 12,5 mg, comprimidos recubiertos	ES/H/0101/001	60.929	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
KETESSE 25 mg, comprimidos recubiertos	ES/H/0101/002	60.930	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 25 mg, granulado para solución oral	ES/H/0101/005	66.820	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Enantyum® 12,5 mg Filmtabletten	ES/H/0100/001	1-22479	LABORATORIOS MENARINI, S.A.	AT
ENANTYUM 12,5 mg, comprimé pelliculé	ES/H/0100/001	34009 346 173 0 0	LABORATORIOS MENARINI, S.A.	FR
Enantyum	ES/H/0100/001	19139	LABORATORIOS MENARINI, S.A.	DK
ENANTYUM 12,5 mg, comprimé pelliculé	ES/H/0100/001	34009 346 172 4 9	LABORATORIOS MENARINI, S.A.	FR
KETESSE, 12,5 mg õhukese polümeerikattega tabletid	ES/H/0100/001	510006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
VIAXAL® Επικαλυμμένο με λεπτό υμένιο δισκίο 12,5mg	ES/H/0100/001	6335	LABORATORIOS MENARINI, S.A.	GR
Enantyum 12,5 mg filmuhúðaðar töflur	ES/H/0100/001/E/001	IS/1/06/002/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
ENANTYUM 12.5 mg film-coated tablets	ES/H/0100/001	PA 901/1/1	LABORATORIOS MENARINI, S.A.	IE
ENANTYUM 12,5 mg compresse rivestite con film	ES/H/0100/001	033656012	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 12,5 mg compresse rivestite con film	ES/H/0100/001	033656024	LABORATORIOS MENARINI, S.A.	IT
Enantyum 12,5 mg comprimés pelliculés	ES/H/0100/001	1405/09030239	LABORATORIOS MENARINI, S.A.	LU

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 12,5 mg filmomhulde tabletten	ES/H/0100/001	RVG 22079	LABORATORIOS MENARINI, S.A.	NL
ENANTYUM 12,5 mg, comprimidos revestidos por película	ES/H/0100/001	2633584	LABORATORIOS MENARINI, S.A.	PT
ENANTYUM 12,5 mg, comprimidos revestidos por película	ES/H/0100/001	2633485	LABORATORIOS MENARINI, S.A.	PT
Ketesse 12,5 mg tbl	ES/H/0100/001	07/0411/06-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
ENANTYUM 12.5 mg film-coated tablets	ES/H/0100/001	PL 16239/0024	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
Enantyum 12,5 mg filmdragerade tablettor	ES/H/0100/001	13886	LABORATORIOS MENARINI, S.A.	SE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 12,5 mg filmsko obložene tablete	ES/H/0100/001	5363-I-85/08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Enantyum® 25 mg Filmtabletten	ES/H/0100/002	1-22480	LABORATORIOS MENARINI, S.A.	AT
Kettesse 25 tablety Potahované tablety	ES/H/0100/002	07/163/06-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
KETESSE, 25 mg õhukese polümeerikattega tabletid	ES/H/0100/002	509906	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
ENANTYUM 25 mg, comprimé pelliculé	ES/H/0100/002	34009 346 174 7 8	LABORATORIOS MENARINI, S.A.	FR
Enantyum	ES/H/0100/002	19140	LABORATORIOS MENARINI, S.A.	DK

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 25 mg compresse rivestite con film	ES/H/0100/002	033656036	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg film-coated tablets	ES/H/0100/002	PA 901/1/2	LABORATORIOS MENARINI, S.A.	IE
VIAXAL® Επικαλυμμένο με λεπτό υμένιο δισκίο 25mg	ES/H/0100/002	6336	LABORATORIOS MENARINI, S.A.	GR
Kettesse 25 mg plėvele dengtos tabletės	ES/H/0100/002	LT/1/06/0696/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Kettesse 25 mg apvalkotās tabletes	ES/H/0100/002	06-0084	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Kettesse 25 mg plėvele dengtos tabletės	ES/H/0100/002	LT/1/06/0696/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 25 mg plèvele dengtos tabletės	ES/H/0100/002	LT/1/06/0696/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Enantyum 25 mg comprimés pelliculés	ES/H/0100/002	1405/09030240	LABORATORIOS MENARINI, S.A.	LU
Kettesse 25 tabletki powlekane 25 mg	ES/H/0100/002	12354	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Kettesse 25 mg plèvele dengtos tabletės	ES/H/0100/002	LT/1/06/0696/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Kettesse 25 mg plèvele dengtos tabletės	ES/H/0100/002	LT/1/06/0696/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Kettesse 25 mg plèvele dengtos tabletės	ES/H/0100/002	LT/1/06/0696/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Orodek 25 mg tableter, filmdrasjerte	ES/H/0100/002	05-3695	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
Enantyum 25 mg filmomhulde tabletten	ES/H/0100/002	RVG 22080	LABORATORIOS MENARINI, S.A.	NL
ENANTYUM 25 mg, comprimidos revestidos por película	ES/H/0100/002	2956985	LABORATORIOS MENARINI, S.A.	PT
Enantyum 25 mg filmdragerade tableter	ES/H/0100/002	13887	LABORATORIOS MENARINI, S.A.	SE
ENANTYUM 25 mg film-coated tablets	ES/H/0100/002	PL 16239/0025	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
KETESSE 25 mg filmsko obložene tablete	ES/H/0100/002	5363-I-86/08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 25 mg tbl	ES/H/0100/002	07/0412/06-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
ENANTYUM 25 mg, comprimidos revestidos por película	ES/H/0100/002	2633683	LABORATORIOS MENARINI, S.A.	PT
Ketesse® 12,5 mg Filmtabletten	ES/H/0101/001	1-22481	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
NOSATEL Επικαλυμμένο με λεπτό υμένιο δισκίο 12,5mg	ES/H/0101/001	20153	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
DOLMEN, 12,5 mg õhukese polümeerikattega tabletid	ES/H/0101/001	510106	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Ketesse	ES/H/0101/001	19135	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 12,5 mg, comprimé pelliculé	ES/H/0101/001	34009 346 175 3 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
KETESSE 12,5 mg, comprimé pelliculé	ES/H/0101/001	34009 346 177 6 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Sympal® 12,5 mg Filmtabletten	ES/H/0101/001	41690.00.00	BERLIN-CHEMIE AG	DE
Ketodex 12,5 mg filmtabletta	ES/H/0101/001	OGYI-T-8884/06	BERLIN-CHEMIE AG	HU
Kettesse 12,5 mg filmhúðaðar töflur	ES/H/0101/001/E/001	IS/1/06/001/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
NOSATEL® Επικαλυμμένο με λεπτό υμένιο δισκίο 12,5mg	ES/H/0101/001	6338	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketodex 12,5 mg filmtabletta	ES/H/0101/001	OGYI-T-8884/09	BERLIN-CHEMIE AG	HU
KERAL 12.5 mg film-coated tablets	ES/H/0101/001	PA 865/2/1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Ketodex 12,5 mg filmtabletta	ES/H/0101/001	OGYI-T-8884/08	BERLIN-CHEMIE AG	HU
KETESSE 12,5 mg compresse rivestite con film	ES/H/0101/001	033635018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Ketodex 12,5 mg filmtabletta	ES/H/0101/001	OGYI-T-8884/07	BERLIN-CHEMIE AG	HU
KETESSE 12,5 mg compresse rivestite con film	ES/H/0101/001	033635020	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KERAL 12.5 mg film-coated tablets	ES/H/0101/001	MA204/00102	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Ketesse12,5 mg comprimés pelliculés	ES/H/0101/001	0951/09030244	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
MENADEx 12,5 mg filmsko obložene tablete	ES/H/0101/001	H/03/00992/018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Dexak 12,5, tabletki powlekane 12,5 mg	ES/H/0101/001	12420	BERLIN-CHEMIE AG	PL
KETESSE 12,5 mg, comprimidos revestidos por película	ES/H/0101/001	2633782	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Dexadol 12,5 mg tbl	ES/H/0101/001	07/0413/06-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 12,5 mg tableter, filmdrasjerte	ES/H/0101/001	05-3703	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
MENADEX 12,5 mg filmsko obložene tablete	ES/H/0101/001	H/03/00992/020	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
MENADEX 12,5 mg filmsko obložene tablete	ES/H/0101/001	H/03/00992/019	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 12,5 mg, comprimidos revestidos por película	ES/H/0101/001	2633881	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Kettesse 12,5 mg filmdragerade tableter	ES/H/0101/001	13883	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Kettesse® 25 mg Filmtabletten	ES/H/0101/002	1-22482	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
NOSATEL Επικαλυμμένο με λεπτό υμένιο δισκίο 25mg	ES/H/0101/002	20154	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Dexoket 25 tablety Potahované tablety	ES/H/0101/002	07/184/06-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Sympal® 25 mg Filmtabletten	ES/H/0101/002	41690.01.00	BERLIN-CHEMIE AG	DE
NOSATEL® Επικαλυμμένο με λεπτό υμένιο δισκίο 25mg	ES/H/0101/002	6337	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Ketodex 25 mg filmtabletta	ES/H/0101/002	OGYI-T-8884/02	BERLIN-CHEMIE AG	HU
Ketodex 25 mg filmtabletta	ES/H/0101/002	OGYI-T-8884/01	BERLIN-CHEMIE AG	HU

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 25 mg, comprimé pelliculé	ES/H/0101/002	34009 346 178 2 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Ketodex 25 mg filmtabletta	ES/H/0101/002	OGYI-T-8884/04	BERLIN-CHEMIE AG	HU
Ketodex 25 mg filmtabletta	ES/H/0101/002	OGYI-T-8884/05	BERLIN-CHEMIE AG	HU
Kettesse 25 mg filmuhúðaðar töflur	ES/H/0101/002/E/001	IS/1/06/001/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
Ketodex 25 mg filmtabletta	ES/H/0101/002	OGYI-T-8884/03	BERLIN-CHEMIE AG	HU
KERAL 25 mg film-coated tablets	ES/H/0101/002	PA 865/2/2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse	ES/H/0101/002	19136	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
Ketesse 25 mg comprimés pelliculés	ES/H/0101/002	0951/09030245	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Dolmen 25 mg plėvele dengtos tabletės	ES/H/0101/002	LT/1/06/0539/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
KETESSE 25 mg compresse rivestite con film	ES/H/0101/002	033635032	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dolmen 25 mg plėvele dengtos tabletės	ES/H/0101/002	LT/1/06/0539/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg apvalkotās tabletes	ES/H/0101/002	06-0081, (16-0031)	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dolmen 25 mg plèvele dengtos tabletės	ES/H/0101/002	LT/1/06/0539/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
KERAL 25 mg film-coated tablets	ES/H/0101/002	MA204/00101	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Dolmen 25 mg plèvele dengtos tabletės	ES/H/0101/002	LT/1/06/0539/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg plèvele dengtos tabletės	ES/H/0101/002	LT/1/06/0539/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg plèvele dengtos tabletės	ES/H/0101/002	LT/1/06/0539/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse 25 mg tableter, filmdrasjerte	ES/H/0101/002	05-3704	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dexak, tabletki powlekane 25 mg	ES/H/0101/002	12419	BERLIN-CHEMIE AG	PL
Stadium 25 mg filmomhulde tabletten	ES/H/0101/002	RVG 22082	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Dexadol 25 mg tbl	ES/H/0101/002	07/0414/06-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
MENADEX 25 mg filmsko obložene tablete	ES/H/0101/002	H/03/00992/024	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KETESSE 25 mg, comprimidos revestidos por película	ES/H/0101/002	2633980	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
KETESSE 25 mg, comprimidos revestidos por película	ES/H/0101/002	2956084	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
MENADEx 25 mg filmsko obložene tablete	ES/H/0101/002	H/03/00992/026	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
DOLMEN, 25 mg õhukese polümeerikattega tabletid	ES/H/0101/002	510206	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
MENADEx 25 mg filmsko obložene tablete	ES/H/0101/002	H/03/00992/027	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
KERAL 25 mg film-coated tablets	ES/H/0101/002	PL 16239/0007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
Kettesse 25 mg filmdragerade tabletter	ES/H/0101/002	13884	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Stadium 12,5 mg filmomhulde tabletten	ES/H/0101/001	RVG 22081	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 12.5 mg granules for oral solution	ES/H/0100/004	1-30346	LABORATORIOS MENARINI, S.A.	AT
Kettesse 12,5 mg suukaudse lahuse graanulid	ES/H/0100/004	746711	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Enantyum 12,5 mg granulátum belsőleges oldathoz	ES/H/0100/004	OGYI-T-20115/15	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Enantyum	ES/H/0100/004	47434	LABORATORIOS MENARINI, S.A.	DK
Enantyum 12,5 mg granulátum belsőleges oldathoz	ES/H/0100/004	OGYI-T-20115/14	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
ENANTYUM 12,5 mg mixtúrukrjni, lausn	ES/H/0100/004	IS/1/11/049/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 12.5 mg granules for oral solution	ES/H/0100/004	PA 901/1/4	LABORATORIOS MENARINI, S.A.	IE
Enantyum 12,5 mg granulaat voor drank	ES/H/0100/004	RVG 108129	LABORATORIOS MENARINI, S.A.	NL
Dexadol 12,5 mg gro por granulát na perorálny roztok	ES/H/0100/004	07/0297/11-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Enantyum 12,5 mg granulado para solução oral	ES/H/0100/004	5398102	LABORATORIOS MENARINI, S.A.	PT
KETESSE 12,5 mg zrnca za peroralno raztopino	ES/H/0100/004	H/07/00838/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
ENANTYUM 25 mg granules for oral solution	ES/H/0100/005	1-30347	LABORATORIOS MENARINI, S.A.	AT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum	ES/H/0100/005	47435	LABORATORIOS MENARINI, S.A.	DK
Dexoket 25 mg granule pro perorální roztok	ES/H/0100/005	07/591/11-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Kettesse 25 mg suukaudse lahuse graanulid	ES/H/0100/005	746611	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
ENANTYUM 25 mg mixtúrukrnyi, lausn	ES/H/0100/005	IS/1/11/049/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
Enantyum 25 mg granules for oral solution	ES/H/0100/005	PA 901/1/5	LABORATORIOS MENARINI, S.A.	IE
Enantyum 25 mg granulátum belsőleges oldathoz	ES/H/0100/005	OGYI-T-20115/17	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 12.5 mg granules for oral solution	ES/H/0100/004	PL 16239/0035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
Enantyum 25 mg granulátum belsólleges oldathoz	ES/H/0100/005	OGYI-T-20115/18	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Enantyum 25 mg granulátum belsólleges oldathoz	ES/H/0100/005	OGYI-T-20115/16	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Kettesse 25 mg granulas iekšķīgi lietojama šķīduma pagatavošanai	ES/H/0100/005	11-0261	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Kettesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Kettesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/036	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/033	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/032	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/031	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse 25 mg granulés geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 25 mg granulės geriamajam tirpalui	ES/H/0100/005	LT/1/06/0696/029	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Ketesse SL 25 mg granulát do sporządzenia roztworu doustnego	ES/H/0100/005	18394	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Enantyum 25 mg granulaat voor drank	ES/H/0100/005	RVG 108131	LABORATORIOS MENARINI, S.A.	NL
Enantyum 25 mg granulado para solução oral	ES/H/0100/005	5398110	LABORATORIOS MENARINI, S.A.	PT
Dexadol 25 mg gro por granulát na perorálny roztok	ES/H/0100/005	07/0298/11-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
KETESSE 12.5 mg granules for oral solution	ES/H/0101/004	1-30351	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 25 mg granules for oral solution	ES/H/0100/005	PL 16239/0036	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
KETESSE 25 mg zrnca za peroralno raztopino	ES/H/0100/005	H/07/00838/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Dolmen 12,5 mg suukaudse lahuse graanulid	ES/H/0101/004	746811	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Kettesse	ES/H/0101/004	47432	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
Ketodex 12,5 mg granulátum belsőleges oldathoz	ES/H/0101/004	OGYI-T-8884/14	BERLIN-CHEMIE AG	HU
Keral 12.5 mg granules for oral solution	ES/H/0101/004	PA 865/2/4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 12,5 mg mixtúrukyrni, lausn	ES/H/0101/004	IS/1/11/050/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
Ketodex 12,5 mg granulátum belsőleges oldathoz	ES/H/0101/004	OGYI-T-8884/15	BERLIN-CHEMIE AG	HU
Dexak SL 12, 5 mg granulát do sporządzania roztworu doustnego	ES/H/0101/004	18369	BERLIN-CHEMIE AG	PL
Keral 12.5 mg granules for oral solution	ES/H/0101/004	MA204/00104	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Stadium 12,5 mg granulaat voor drank	ES/H/0101/004	RVG 108125	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Kettesse 12,5 mg gro por granulát na perorálny roztok	ES/H/0101/004	07/0292/11-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
MENADEx 12,5 mg zrnca za peroralno raztopino	ES/H/0101/004	H/03/00992/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Kettese 12,5 mg granulado para solução oral	ES/H/0101/004	5397807	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
KETESSE 25 mg granules for oral solution	ES/H/0101/005	1-30352	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Kettese	ES/H/0101/005	47433	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	DK
Dolmen 25 mg suukaudse lahuse graanulid	ES/H/0101/005	746511	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Kettese 25 mg granule pro perorální roztok	ES/H/0101/005	07/593/11-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Keral 25 mg granules for oral solution	ES/H/0101/005	PA 865/2/5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Sympal® 25 mg Granulat zur Herstellung einer Lösung zum Einnehmen in Beuteln	ES/H/0101/005	41690.01.02	BERLIN-CHEMIE AG	DE
Ketodex 25 mg granulátum belsőleges oldathoz	ES/H/0101/005	OGYI-T-8884/17	BERLIN-CHEMIE AG	HU
Ketodex 25 mg granulátum belsőleges oldathoz	ES/H/0101/005	OGYI-T-8884/16	BERLIN-CHEMIE AG	HU
KETESSE 25 mg mixtúrukyrni, lausn	ES/H/0101/005	IS/1/11/050/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
Ketodex 25 mg granulátum belsőleges oldathoz	ES/H/0101/005	OGYI-T-8884/18	BERLIN-CHEMIE AG	HU

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dolmen 25 mg granulas iekšķīgi lietojama šķīduma pagatavošanai	ES/H/0101/005	11-0259, (16-0032)	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Dolmen 25 mg granulēs geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg granulēs geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg granulēs geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/031	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg granulēs geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg granulēs geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/033	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dolmen 25 mg granulés geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/029	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg granulés geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/032	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Dolmen 25 mg granulés geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/036	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Stadium 25 mg granulaat voor drank	ES/H/0101/005	RVG 108128	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Keral 25 mg granules for oral solution	ES/H/0101/005	MA204/00105	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Dolmen 25 mg granulés geriamajam tirpalui	ES/H/0101/005	LT/1/06/0539/034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Dexak SL 25 mg granulat do sporządzania roztworu doustnego	ES/H/0101/005	18370	BERLIN-CHEMIE AG	PL
MENADEx 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Keral 25 mg granules for oral solution	ES/H/0101/005	PL 16239/0037	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	UK
Ketesse 25 mg granulado para solução oral	ES/H/0101/005	5398078	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
MENADEx 25 mg zrnca za peroralno raztopino	ES/H/0101/005	H/03/00992/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Ketesse 25 mg gro por granulát na perorálny roztok	ES/H/0101/005	07/0293/11-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Sympal® injekt 50 mg Injektionslösung 50 mg/2 ml, Injektionslösung oder Konzentrat zur Herstellung einer Infusionslösung	ES/H/0101/003	41690.00.01	BERLIN-CHEMIE AG	DE
Дексофен® инжект 50 mg/2 ml инжекционен разтвор	not available	20050451	BERLIN-CHEMIE AG	BG
Дексофен® 25 mg филмирани таблетки	not available	20010826	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
DESKETO 25 mg compresse rivestite con film	not available	034041032	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
TADOR INJECT 50 mg/2 ml soluție injectabilă / concentrat pentru soluție perfuzabilă	not available	6653/2006/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Tador 25 mg comprimate filmate	not available	1044/2008/02	BERLIN-CHEMIE AG	RO
TADOR INJECT 50 mg/2 ml soluție injectabilă / concentrat pentru soluție perfuzabilă	not available	6653/2006/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Dexketoprofeno Menarini 12,5 mg granulado para solución oral	not available	66.824	LABORATORIOS FERMON, S.L.U.	ES
QUIRALAM 12,5 mg, comprimidos recubiertos	not available	60.931	RETRAIN, S.A.U.	ES
DEKTOPROFENO MENARINI 50 mg/2ml solución inyectable o concentrado para solución para perfusión	not available	64.890	LABORATORIOS FERMON, S.L.U.	ES

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041083	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041071	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041069	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041044	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041057	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041095	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 50 mg/2ml - Soluzione per iniezione o concentrato per soluzione per infusione	not available	034041107	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
QUIRALAM 50 mg/2ml, solución inyectable o concentrado para solución para perfusión	not available	64.889	RETRAIN, S.A.U.	ES

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
QUIRALAM 25 mg, granulado para solución oral	not available	66.821	RETRAIN, S.A.U.	ES
Dexketoprofeno Menarini 25 mg granulado para solución oral	not available	66.823	LABORATORIOS FERMON, S.L.U.	ES
Tador 25 mg comprimato filmate	not available	1044/2008/03	BERLIN-CHEMIE AG	RO
Tador 25 mg comprimato filmate	not available	1044/2008/01	BERLIN-CHEMIE AG	RO
QUIRALAM 25 mg, comprimidos recubiertos	not available	60.932	RETRAIN, S.A.U.	ES

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETOPROFENO MENARINI 25 mg, comprimidos recubiertos	not available	63.155	LABORATORIOS FERMON, S.L.U.	ES
QUIRALAM 12,5 mg, granulado para solución oral	not available	66.822	RETRAIN, S.A.U.	ES
DESKETO 12,5 mg compresse rivestite con film	not available	034041020	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 12,5 mg compresse rivestite con film	not available	034041018	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
QUIRALAM 25 mg, Solución Oral	not available	70.883	RETRAIN, S.A.U.	ES
Enantyum 25 mg solución oral	not available	70.879	LABORATORIOS MENARINI, S.A.	ES
Ketesse 25 mg solución oral	not available	70.882	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	ES
Dexketoprofeno Menarini 25 mg solución oral	not available	70.885	LABORATORIOS FERMON, S.L.U.	ES
DESKETO 12,5 mg granulato per soluzione orale	not available	034041133	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETO 12,5 mg granulato per soluzione orale	not available	034041119	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041210	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 12,5 mg granulato per soluzione orale	not available	034041145	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 12,5 mg granulato per soluzione orale	not available	034041158	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETO 12,5 mg granulato per soluzione orale	not available	034041121	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 12,5 mg granulato per soluzione orale	not available	034041184	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 12,5 mg granulato per soluzione orale	not available	034041172	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 12,5 mg granulato per soluzione orale	not available	034041160	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETO 25 mg granulato per soluzione orale	not available	034041273	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041259	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041196	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041261	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
DESKETO 25 mg granulato per soluzione orale	not available	034041222	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041208	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041246	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
DESKETO 25 mg granulato per soluzione orale	not available	034041234	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656190	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656202	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656277	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656214	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656265	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656253	LABORATORIOS MENARINI, S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635119	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635133	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635121	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656238	LABORATORIOS MENARINI, S.A.	IT
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635158	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635172	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635160	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635184	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635208	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635196	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Kettesse 12,5 mg granulato per soluzione orale	ES/H/0101/004	033635145	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635210	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656226	LABORATORIOS MENARINI, S.A.	IT
ENANTYUM 25 mg granulato per soluzione orale	ES/H/0100/005	033656240	LABORATORIOS MENARINI, S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635273	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635222	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635246	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635234	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656113	LABORATORIOS MENARINI, S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635261	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656137	LABORATORIOS MENARINI, S.A.	IT
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656125	LABORATORIOS MENARINI, S.A.	IT
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656188	LABORATORIOS MENARINI, S.A.	IT
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656152	LABORATORIOS MENARINI, S.A.	IT

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656149	LABORATORIOS MENARINI, S.A.	IT
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656176	LABORATORIOS MENARINI, S.A.	IT
KETESSE 25 mg granulato per soluzione orale	ES/H/0101/005	033635259	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Enantyum 12,5 mg granulato per soluzione orale	ES/H/0100/004	033656164	LABORATORIOS MENARINI, S.A.	IT
VIAXAL® 12,5mg κοκκία για πόσιμο διάλυμα	ES/H/0100/004	35762	LABORATORIOS MENARINI, S.A.	GR
Kettesse 12,5 mg, granulés pour solution buvable en sachet	ES/H/0101/004	34009 418 257 0 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ketesse 25 mg, granulés pour solution buvable en sachet	ES/H/0101/005	34009 418 307 8 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Ketesse 12,5 mg, granulés pour solution buvable en sachet	ES/H/0101/004	34009 418 258 7 3	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Enantyum 25 mg, granulés pour solution buvable en sachet	ES/H/0100/005	34009 418 312 1 8	LABORATORIOS MENARINI, S.A.	FR
Enantyum 25 mg, granulés pour solution buvable en sachet	ES/H/0100/005	34009 418 313 8 6	LABORATORIOS MENARINI, S.A.	FR
NOSATEL® 12,5mg κοκκία για πόσιμο διάλυμα	ES/H/0101/004	35760	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Enantyum 12,5 mg, granulés pour solution buvable en sachet	ES/H/0100/004	34009 418 310 9 6	LABORATORIOS MENARINI, S.A.	FR

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
VIAXAL® 25mg κοκκία για πόσιμο διάλυμα	ES/H/0100/005	35763	LABORATORIOS MENARINI, S.A.	GR
Enantyum 12,5 mg, granulés pour solution buvable en sachet	ES/H/0100/004	34009 418 311 5 7	LABORATORIOS MENARINI, S.A.	FR
Ketesse 25 mg, granulés pour solution buvable en sachet	ES/H/0101/005	34009 418 306 1 7	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
NOSATEL® 25mg κοκκία για πόσιμο διάλυμα	ES/H/0101/005	35761	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Enantyum 25 mg filmuhúðaðar töflur	ES/H/0100/002/E/001	IS/1/06/002/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IS
ENANTYUM 12.5 mg granules for oral solution	ES/H/0100/004	44860	LABORATORIOS MENARINI, S.A.	SE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
KETESSE 25 mg granules for oral solution	ES/H/0101/005	44863	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
KETESSE® 12.5 mg granules for oral solution	ES/H/0101/004	10-7816	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
ORODEK® 12.5 mg granules for oral solution	ES/H/0100/004	10-7815	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
KETESSE® 25 mg granules for oral solution	ES/H/0101/005	10-7817	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
ORODEK® 25 mg granules for oral solution	ES/H/0100/005	10-7819	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NO
KETESSE 12.5 mg granules for oral solution	ES/H/0101/004	44862	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE

Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ENANTYUM 25 mg granules for oral solution	ES/H/0100/005	44861	LABORATORIOS MENARINI, S.A.	SE
Dexomen 25 mg filmom obložene tablete	not available	UP/I-530-09/11-01/411	BERLIN-CHEMIE MENARINI HRVATSKA D.O.O.	HR
Dexomen 25 mg filmom obložene tablete	not available	UP/I-530-09/12-01/136	BERLIN-CHEMIE MENARINI HRVATSKA D.O.O.	HR
Dexomen 50 mg/2 ml otopina za injekciju ili koncentrat za otopinu za infuziju	not available	UP/I-530-09/12-01/548	BERLIN-CHEMIE MENARINI HRVATSKA D.O.O.	HR