



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/846866/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexketoprofen / tramadol

Procedure no.: PSUSA/00010468/202201

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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
Skudexa 75 mg/25 mg film-coated tablets	ES/H/0317/001	PL 16239/0041	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	XI
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR

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
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR

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
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg film-coated tablets	ES/H/0317/001	MA204/00701	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Skudexa 75 mg/25 mg filmtabletta	ES/H/0317/001	OGYI-T-22991/09	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmtabletta	ES/H/0317/001	OGYI-T-22991/10	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmtabletta	ES/H/0317/001	OGYI-T-22991/08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmtabletta	ES/H/0317/001	OGYI-T-22991/06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/12	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg film-coated tablets	ES/H/0317/001	PA 865/20/1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE

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Skudexa, 75 mg/25 mg õhukese polümeerikattega tabletid	ES/H/0317/001	905016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Skudexa 75 mg/25 mg filmdragerad tablett	ES/H/0317/001	52445	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SE
Skudexa 75 mg/25 mg filmom obalené tablety	ES/H/0317/001	65/0123/16-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Skudexa 75 mg/25 mg apvalkotās tabletes	ES/H/0317/001	16-0065	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089151	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089124	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089047	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089086	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089199	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089050	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089062	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089100	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089175	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089136	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089163	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089074	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089187	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089112	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089098	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089148	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089213	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089201	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Skudexa 75 mg + 25 mg comprimidos revestidos por película	ES/H/0317/001	5674239	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

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Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg + 25 mg comprimidos revestidos por película	ES/H/0317/001	5674247	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Skudexa 75 mg + 25 mg comprimidos revestidos por película	ES/H/0317/001	5674221	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

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Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plévele dengtos tabletès	ES/H/0317/001	LT/1/16/3912/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa, 75 mg + 25 mg, tabletki powlekane	ES/H/0317/001	23171	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 485 1 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 174 6 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 174 2 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 484 5 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR

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SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 484 7 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 173 9 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 485 0 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 173 3 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 174 5 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 174 4 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 484 9 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 485 4 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 485 5 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR

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SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 484 8 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 173 8 7	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 174 3 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 484 6 7	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 174 0 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 173 4 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 173 7 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 173 6 3	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Skudexa 75 mg/25 mg potahované tablety	ES/H/0317/001	65/081/16-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ

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
Скудекса 75 mg/25 mg филмирани таблетки	ES/H/0317/001	20160172	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BG
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/002	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/007	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/021	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/005	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

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Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/015	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/014	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/001	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/020	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/006	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

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
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/019	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/004	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmomhulde tabletten	ES/H/0317/001	BE497395	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg comprimés pelliculés	ES/H/0317/001	BE497395	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg Filmtabletten	ES/H/0317/001	BE497395	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg filmomhulde tabletten	ES/H/0317/001	BE497413	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg filmomhulde tabletten	ES/H/0317/001	BE497404	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Skudexa 75 mg/25 mg Filmdabletten	ES/H/0317/001	BE497404	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg comprimés pelliculés	ES/H/0317/001	BE497413	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg comprimés pelliculés	ES/H/0317/001	BE497404	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg Filmdabletten	ES/H/0317/001	BE497413	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg filmdragerade tabletter	ES/H/0317/001	33075	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Skudexa 75 mg/25 mg kalvopäällysteinen tabletti	ES/H/0317/001	33075	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Enanplus 75 mg/25 mg comprimidos recubiertos con película.	ES/H/0317/001	80.925	LABORATORIOS MENARINI, S.A.	ES
Skudexa 75 mg/25 mg filmomhulde tabletten	ES/H/0317/001	RVG 116795	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL
Skudexa 75 mg/25 mg Filmdabletten	ES/H/0317/001	137257	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LI

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
Skudexa 75 mg/25 mg Filmdabletten	ES/H/0317/001	137257	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/13	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/18	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/17	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/15	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/16	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmdabletta	ES/H/0317/001	OGYI-T-22991/14	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/032	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

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
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/031	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg comprimés pelliculés	ES/H/0317/001	2016110326	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Skudexa 75 mg/25 mg plėvele dengtos tabletės	ES/H/0317/001	LT/1/16/3912/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plėvele dengtos tabletės	ES/H/0317/001	LT/1/16/3912/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plėvele dengtos tabletės	ES/H/0317/001	LT/1/16/3912/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plėvele dengtos tabletės	ES/H/0317/001	LT/1/16/3912/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plėvele dengtos tabletės	ES/H/0317/001	LT/1/16/3912/009	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg plėvele dengtos tabletės	ES/H/0317/001	LT/1/16/3912/008	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR

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
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-09	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-09	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001	HR-H-561072688-09	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75mg/25mg επικαλυμμένα με λεπτό υμένιο δισκία	ES/H/0317/001	3874	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/033	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/034	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg filmsko obložene tablete	ES/H/0317/001	H/16/02185/035	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

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
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 264 7 1	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 264 9 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 550 264 8 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Skudexa 75mg/25mg επικαλυμμένα με λεπτό υμένιο δισκία	ES/H/0317/001	022464	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089276	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089264	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089237	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089225	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089252	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Lenizak 75 mg/25 mg compresse rivestite con film	ES/H/0317/001	044089249	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 716 9 4	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 716 7 0	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, comprimé pelliculé	ES/H/0317/001	34009 300 716 8 7	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/09	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/17	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO

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
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/10	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/11	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/12	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/13	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/14	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/16	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO

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
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/18	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/25	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/21	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/20	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/24	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/26	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimate filmate	ES/H/0317/001	13786/2021/15	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO

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
Skudexa 75 mg/25 mg comprimato filmato	ES/H/0317/001	13786/2021/27	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimato filmato	ES/H/0317/001	13786/2021/19	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimato filmato	ES/H/0317/001	13786/2021/23	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg comprimato filmato	ES/H/0317/001	13786/2021/22	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Dextradol 75 mg/25 mg compressa rivestita con film	ES/H/0318/001	044090013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compressa rivestita con film	ES/H/0318/001	044090052	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compressa rivestita con film	ES/H/0318/001	044090138	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compressa rivestita con film	ES/H/0318/001	044090088	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compressa rivestita con film	ES/H/0318/001	044090102	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090076	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090025	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090126	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090049	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090153	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090037	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090064	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090140	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090090	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090114	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Takudex 75 mg/25 mg comprimidos recubiertos con película	ES/H/0318/001	80802	GUIDOTTI FARMA, S.L.U.	ES
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090177	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090227	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090278	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090165	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090203	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090191	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090266	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090215	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090189	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090254	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090239	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg compresse rivestite con film	ES/H/0318/001	044090241	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Skudexa 75 mg/25 mg Granulat im Beutel zur Herstellung einer Lösung zum Einnehmen	ES/H/0317/003	138210	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	AT
Skudexa 75 mg/25 mg Granulat im Beutel zur Herstellung einer Lösung zum Einnehmen	ES/H/0317/003	138210	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LI
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granulas iekšķīgi lietojama šķīduma pagatavošanai paciņā	ES/H/0317/003	18-0061	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LV

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Skudexa 75 mg/25 mg granulės geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/010	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003	HR-H-649118396-05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HR
Skudexa 75 mg/25 mg granulės geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/012	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Skudexa 75 mg/25 mg granulés geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/011	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg granulés geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/013	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg granulés geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/016	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg granulés geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/014	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg granulés geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/015	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa 75 mg/25 mg granulés geriamajam tirpalui paketėlyje	ES/H/0317/003	LT/1/16/3912/017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LT
Skudexa, 75 mg/25 mg suukaudse lahuse graanulid kotikeses	ES/H/0317/003	963618	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	EE
Skudexa 75 mg/25 mg granules for oral solution in sachet	ES/H/0317/003	PL 16239/0048	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	XI
Skudexa 75 mg/25 mg granulátum belsőleges oldathoz tasakban	ES/H/0317/003	OGYI-T-22991/19	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Skudexa 75 mg/25 mg granules for oral solution in sachet	ES/H/0317/003	PA 865/020/003	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IE
Skudexa 75 mg/25 mg granulátum belsőleges oldathoz tasakban	ES/H/0317/003	OGYI-T-22991/20	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg granulátum belsőleges oldathoz tasakban	ES/H/0317/003	OGYI-T-22991/22	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg/25 mg granulátum belsőleges oldathoz tasakban	ES/H/0317/003	OGYI-T-22991/21	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	HU
Skudexa 75 mg + 25 mg granulado para solução oral em saqueta	ES/H/0317/003	5747050	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PT
Skudexa 75 mg/25 mg granule pro perorální roztok v sáčku	ES/H/0317/003	65/102/17-C	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CZ
Skudexa 75 mg/25 mg granulát na perorálny roztok vo vrecku	ES/H/0317/003	65/0154/18-S	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SK
Skudexa 75 mg/25 mg Granulat zur Herstellung einer Lösung zum Einnehmen in Beutel	ES/H/0317/003	BE527857	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg granulaat voor drank in sachet	ES/H/0317/003	RVG 120924	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	NL

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
Skudexa 75 mg/25 mg granulaat voor drank in sachet	ES/H/0317/003	BE527857	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg granulés pour solution buvable en sachet	ES/H/0317/003	BE527857	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	BE
Skudexa 75 mg/25 mg granules for oral solution in sachet	ES/H/0317/003	MA204/00703	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	MT
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/029	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/028	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/024	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/027	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/026	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/025	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI

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
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/023	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
Skudexa 75 mg/25 mg zrnca za peroralno raztopino v vrečici	ES/H/0317/003	H/16/02185/022	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	SI
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 550 556 8 6	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 550 556 6 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 550 556 5 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 550 556 7 9	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 301 487 8 5	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 301 487 9 2	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 301 488 0 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
SKUDEXUM 75 mg/25 mg, granulés pour solution buvable en sachet	ES/H/0317/003	34009 301 487 7 8	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FR
Enanplus 75 mg/25 mg granulado para solución oral en sobre.	ES/H/0317/003	83.077	LABORATORIOS MENARINI, S.A.	ES
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/08	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/06	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/07	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/01	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/02	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/03	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/05	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO

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
Skudexa 75 mg/25 mg granule pentru soluție orală în plic	ES/H/0317/003	10870/2018/04	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	RO
Skudexa, 75 mg + 25 mg, granulat do sporządzania roztworu doustnego, w saszetce	ES/H/0317/003	24994	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	PL
Skudexa 75 mg/25 mg granulés pour solution buvable en sachet	ES/H/0317/003	2018110356	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LU
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089353	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089302	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089338	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089288	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089326	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089290	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089314	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Lenizak 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0317/003	044089340	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Skudexa 75 mg/25 mg rakeet oraaliliuosta varten, annospussi	ES/H/0317/003	35089	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Skudexa 75 mg/25 mg granulät till oral lösning i dospåse	ES/H/0317/003	35089	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	FI
Skudexa 75mg/25 mg κοκκία για πόσιμο διάλυμα σε φακελίσκο	ES/H/0317/003	61225	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	GR
Skudexa 75mg/25 mg κοκκία για πόσιμο διάλυμα σε φακελίσκο	ES/H/0317/003	023030	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	CY
Takudex 75 mg/25 mg granulato para solución oral en sobre.	ES/H/0318/003	83.076	GUIDOTTI FARMA, S.L.U.	ES
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090355	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090328	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	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
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090316	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090304	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090280	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090342	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090292	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT
Dextradol 75 mg/25 mg granulato per soluzione orale in bustina	ES/H/0318/003	044090330	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	IT