



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 April 2022  
EMA/559241/2022  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: dexketoprofen and tramadol

Procedure no.: EMEA/H/N/PSR/S/0035

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Enanplus Film-coated tablets	ES/H/0317/001/DC	80.925	Laboratorios Menarini S.A.	Spain
Enanplus Granules for oral solution in sachet	ES/H/0317/003/DC	83.077	Laboratorios Menarini S.A.	Spain
Takudex Film-coated tablets	ES/H/0318/001/DC	80.802	Guidotti Farma, S.L.	Spain
Takudex Granules for oral solution in sachet	ES/H/0318/003/DC	83.076	Guidotti Farma, S.L.	Spain
Skudexa Film-coated tablets	ES/H/0317/001/DC	137257	Menarini International Operations Luxembourg S. A.	Austria
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	138210	Menarini International Operations Luxembourg S. A.	Austria
Skudexa Film-coated tablets	ES/H/0317/001/DC	BE497395, BE497404, BE497413	Menarini International Operations Luxembourg S. A.	Belgium
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	BE527857	Menarini International Operations Luxembourg S. A.	Belgium
Skudexa Film-coated tablets	ES/H/0317/001/DC	20160172	Menarini International Operations Luxembourg S. A.	Bulgaria
Skudexa 75 mg/25 mg filmom obložene tablete	ES/H/0317/001/DC	HR-H-561072688	Menarini International Operations Luxembourg S. A.	Croatia
Skudexa 75 mg/25 mg granule za oralnu otopinu u vrećici	ES/H/0317/003/DC	HR-H-649118396	Menarini International Operations Luxembourg S. A.	Croatia
Skudexa Film-coated tablets	ES/H/0317/001/DC	022464	Menarini International Operations Luxembourg S. A.	Cyprus

Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	023030	Menarini International Operations Luxembourg S. A.	Cyprus
Skudexa Film-coated tablets	ES/H/0317/001/DC	65/081/16-C	Menarini International Operations Luxembourg S. A.	Czech Republic
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	65/102/17-C	Menarini International Operations Luxembourg S. A.	Czech Republic
Skudexa Film-coated tablets	ES/H/0317/001/DC	905016	Menarini International Operations Luxembourg S. A.	Estonia
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	963618	Menarini International Operations Luxembourg S. A.	Estonia
Skudexa Film-coated tablets	ES/H/0317/001/DC	33075	Menarini International Operations Luxembourg S. A.	Finland
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	35089	Menarini International Operations Luxembourg S. A.	Finland
Skudexum Film-coated tablets	ES/H/0317/001/DC	34009 300 485 11, 34009 300 485 42, 34009 300 485 59, 34009 550 174 31, 34009 550 174 48, 34009 550 174 55, 34009 550 174 62, 34009 300 484 81, 34009 300 484 98, 34009 300 485 04, 34009 550 173 87, 34009 550 173 94, 34009 550 174 00, 34009 550 174 24, 34009 300 484 50, 34009 300 484 67, 34009 300 484 74, 34009 550 173 32, 34009 550 173 49, 34009 550 173 63, 34009 550 173 70, 34009 300 716 7 0, 34009 550 264 7 1, 34009 300 716 8 7, 34009 550 264 8 8, 34009 300 716 9 4, 34009 550 264 9 5.	Menarini International Operations Luxembourg S. A.	France

Skudexum Granules for oral solution in sachet	ES/H/0317/003/DC	34009 301 487 9 2, 34009 550 556 7 9, 34009 301 488 0 8, 34009 301 487 7 8, 34009 550 556 5 5, 34009 301 487 8 5, 34009 550 556 6 2, 34009 550 556 8 6,	Menarini International Operations Luxembourg S. A.	France
Skudexa Film-coated tablets	ES/H/0317/001/DC	3874	Menarini International Operations Luxembourg S. A.	Greece
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	61225	Menarini International Operations Luxembourg S. A.	Greece
Skudexa Film-coated tablets	ES/H/0317/001/DC	OGYI-T-22991/01-04, 13, 16 OGYI-T-22991/05-08, 14, 17 OGYI-T-22991/09-12, 15, 18	Menarini International Operations Luxembourg S. A.	Hungary
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	OGYI-T-22991/19-22	Menarini International Operations Luxembourg S. A.	Hungary
Skudexa Film-coated tablets	ES/H/0317/001/DC	PA 865/20/001	Menarini International Operations Luxembourg S. A.	Ireland
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	PA 865/020/003	Menarini International Operations Luxembourg S. A.	Ireland
Lenizak Film-coated tablets	ES/H/0317/001/DC	044089011, 044089023 044089035, 044089047 044089050, 044089062 044089074, 044089086 044089098, 044089100 044089112, 044089124 044089136, 044089148 044089151, 044809163 044089175, 044089187 044089199, 044089201 044089213, 044089225 044089237, 044089249 044089252, 044089264 044089276	Menarini International Operations Luxembourg S. A.	Italy

Lenizak Granules for oral solution in sachet	ES/H/0317/003/DC	044089288, 044089290, 044089302, 044089314, 044089326, 044089338, 044089340, 044089353	Menarini International Operations Luxembourg S. A.	Italy
Dextradol Film-coated tablets	ES/H/0318/001/DC	044090013, 044090025, 044090037, 044090049, 044090052, 044090064, 044090076, 044090088, 044090090, 044090102, 044090114, 044090126, 044090138, 044090140, 044090153, 044090165, 044090177, 044090191, 044090203, 044090215, 044090227, 044090239, 044090241, 044090254, 044090266, 044090278, 044090189	Menarini International Operations Luxembourg S. A.	Italy
Dextradol Granules for oral solution in sachet	ES/H/0318/003/DC	044090280, 044090292, 044090304, 044090316, 044090328, 044090330, 044090342, 044090355	Menarini International Operations Luxembourg S. A.	Italy
Skudexa Film-coated tablets	ES/H/0317/001/DC	16-0065	Menarini International Operations Luxembourg S. A.	Latvia
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	18-0061	Menarini International Operations Luxembourg S. A.	Latvia
Skudexa Film-coated tablets	ES/H/0317/001/DC	137257	Menarini International Operations Luxembourg S. A.	Liechtenstein
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	138210	Menarini International Operations Luxembourg S. A.	Liechtenstein
Skudexa Film-coated tablets	ES/H/0317/001/DC	LT/1/16/3912/001-009	Menarini International Operations Luxembourg S. A.	Lithuania

Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	LT/1/16/3912/010-017	Menarini International Operations Luxembourg S. A.	Lithuania
Skudexa Film-coated tablets	ES/H/0317/001/DC	2016110326	Menarini International Operations Luxembourg S. A.	Luxembourg
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	2018110356	Menarini International Operations Luxembourg S. A.	Luxembourg
Skudexa Film-coated tablets	ES/H/0317/001/DC	MA204/00701	Menarini International Operations Luxembourg S. A.	Malta
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	MA204/00703	Menarini International Operations Luxembourg S. A.	Malta
Skudexa Film-coated tablets	ES/H/0317/001/DC	RVG116795	Menarini International Operations Luxembourg S. A.	Netherlands
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	RVG 120924	Menarini International Operations Luxembourg S. A.	Netherlands
Skudexa Film-coated tablets	ES/H/0317/001/DC	23171	Menarini International Operations Luxembourg S. A.	Poland
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	24994	Menarini International Operations Luxembourg S. A.	Poland
Skudexa Film-coated tablets	ES/H/0317/001/DC	5674239, 5674221, 5674247	Menarini International Operations Luxembourg S. A.	Portugal
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	5747050	Menarini International Operations Luxembourg S. A.	Portugal
Skudexa Film-coated tablets	ES/H/0317/001/DC	13786/2021/01-27	Menarini International Operations Luxembourg S. A.	Romania

Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	10870/2018/01-08	Menarini International Operations Luxembourg S. A.	Romania
Skudexa 75 mg/25 mg filmom obalené tablety	ES/H/0317/001/DC	65/0123/16-S	Menarini International Operations Luxembourg S. A.	Slovakia
Skudexa 75 mg/25 mg granulát na perorálny roztok vo vrecku	ES/H/0317/003/DC	65/0154/18-S	Menarini International Operations Luxembourg S. A.	Slovakia
Skudexa Film-coated tablets	ES/H/0317/001/DC	H/16/02185/001 - 021 H/16/02185/030 - 035	Menarini International Operations Luxembourg S. A.	Slovenia
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	H/16/02185/022 - 029	Menarini International Operations Luxembourg S. A.	Slovenia
Skudexa Film-coated tablets	ES/H/0317/001/DC	52445	Menarini International Operations Luxembourg S. A.	Sweden
Skudexa Film-coated tablets	ES/H/0317/001/DC	PL 16239/0041	Menarini International Operations Luxembourg S. A.	United Kingdom (Northern Ireland)
Skudexa Granules for oral solution in sachet	ES/H/0317/003/DC	PL 16239/0048	Menarini International Operations Luxembourg S. A.	United Kingdom (Northern Ireland)