



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2019
EMA/128842/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: nimesulide (systemic formulations)

Procedure no.: PSUSA/00009236/201806



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
Aulin 200 mg supposte	IT/H/0151/003	025940065	HELSINN BIREX PHARMACEUTICALS LTD.	IT
НИМЕД 100 mg таблетки	IT/H/0150/001	20060230	ANGELINI PHARMA BULGARIA EOOD	BG
Mesulid 100 mg compresse	IT/H/0150/001	025971173	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg compresse	IT/H/0150/001	025971185	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg compresse	IT/H/0150/001	025971197	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg compresse	IT/H/0150/001	025971209	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg compresse	IT/H/0150/001	025971211	HELSINN BIREX PHARMACEUTICALS LTD.	IT
NIMED 100 mg tablety	IT/H/0150/001	29/0098/98-S	HELSINN BIREX PHARMACEUTICALS LTD.	SK
Mesulid® 100mg Δισκία	not available	36240	BOEHRINGER INGELHEIM ELLAS AE	GR
Mesulid 100 mg compresse	IT/H/0150/001	025971021	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg tablettes	IT/H/0150/001	97-0248	HELSINN BIREX PHARMACEUTICALS LTD.	LV
Mesulid 100 mg tabletta	CZ/H/902/01	OGYI-T-6459/01	ANGELINI PHARMA ÖSTERREICH GMBH	HU
MESULID 100 mg tablety	CZ/H/902/01	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG

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AULIN 100 mg comprimate	IT/H/0151/001	6646/2014/05	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg comprimate	IT/H/0151/001	6646/2014/06	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Aulin 100 mg compresse	IT/H/0151/001	025940166	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg compresse	IT/H/0151/001	025940178	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg compresse	IT/H/0151/001	025940180	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg compresse	IT/H/0151/001	025940192	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg compresse	IT/H/0151/001	025940204	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg compresse	IT/H/0151/001	025940026	HELSINN BIREX PHARMACEUTICALS LTD.	IT
AULIN 100 mg tablety	IT/H/0151/001	29/179/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
AULIN 100 mg tablety	IT/H/0151/001	29/0282/97-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
Aulin, 100 mg, tabletki	IT/H/0151/001	4113	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, comprimido	IT/H/0151/001	5809181	ANGELINI FARMACÊUTICA, LDA	PT
AULIN 100 mg comprimate	IT/H/0151/001	6646/2014/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg comprimate	IT/H/0151/001	6646/2014/02	ANGELINI PHARMA ÖSTERREICH GMBH	RO

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AULIN 100 mg comprimate	IT/H/0151/001	6646/2014/03	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg comprimate	IT/H/0151/001	6646/2014/04	ANGELINI PHARMA ÖSTERREICH GMBH	RO
NIMEDEX 400 mg granulato per sospensione orale	not available	029120021	ITALFARMACO S.P.A	IT
NIMEDEX 400 mg granulato per sospensione orale	not available	029120033	ITALFARMACO S.P.A	IT
Nimesil 100 mg granulés geriamajai suspensijai	not available	LT/1/99/0503/003	LABORATORI GUIDOTTI S.P.A.	LT
Nimesil 100 mg granulés geriamajai suspensijai	not available	LT/1/99/0503/001	LABORATORI GUIDOTTI S.P.A.	LT
Nimesil 100 mg granulés geriamajai suspensijai	not available	LT/1/99/0503/002	LABORATORI GUIDOTTI S.P.A.	LT
Xilox 50 mg/g granulátum belsőleges szuszpenzióhoz	not available	OGYI-T-9791/02	LABORATORI GUIDOTTI S.P.A.	HU
Xilox 50 mg/g granulátum belsőleges szuszpenzióhoz	not available	OGYI-T-9791/01	LABORATORI GUIDOTTI S.P.A.	HU
Xilox 50 mg/g granulátum belsőleges szuszpenzióhoz	not available	OGYI-T-9791/03	LABORATORI GUIDOTTI S.P.A.	HU
Аулин 100 мг гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/05	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/06	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940115	HELSINN BIREX PHARMACEUTICALS LTD.	IT

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Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940154	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940127	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940139	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940141	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940053	HELSINN BIREX PHARMACEUTICALS LTD.	IT
AULIN 100 mg granule pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
Aulin, 100 mg, granulát do sporzadzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulado para suspensão oral	IT/H/0151/001	5810882	ANGELINI FARMACÊUTICA, LDA	PT
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/01	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/02	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/03	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/04	ANGELINI PHARMA ÖSTERREICH GMBH	RO
Nimed 100 mg comprimido	not available	4567392	LABORATÓRIOS AZEVEDOS -	PT

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revestido por película			INDÚSTRIA FARMACÊUTICA, S.A.	
Nimed 100 mg comprimido revestido por película	not available	9599258	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Nimed 100 mg comprimido revestido por película	not available	4567491	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
NIMEDEX 400 mg compresse	not available	029120019	ITALFARMACO S.P.A	IT
Mesulid 200 mg supposte	IT/H/0150/003	025971060	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg granulato per sospensione orale	IT/H/0150/002	025971110	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg granulato per sospensione orale	IT/H/0150/002	025971159	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg granulato per sospensione orale	IT/H/0150/002	025971122	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg granulato per sospensione orale	IT/H/0150/002	025971134	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg granulato per sospensione orale	IT/H/0150/002	025971146	HELSINN BIREX PHARMACEUTICALS LTD.	IT
Mesulid 100 mg granulato per sospensione orale	IT/H/0150/002	025971058	HELSINN BIREX PHARMACEUTICALS LTD.	IT
MESULID 100 mg granule pro perorální suspenzi	CZ/H/902/02	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
Mesulid 50 mg/g granulátum	CZ/H/902/02	OGYI-T-6459/02	ANGELINI PHARMA ÖSTERREICH GMBH	HU
Nimed 100 mg granulado	not available	4567095	LABORATÓRIOS AZEVEDOS -	PT

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para solução oral			INDÚSTRIA FARMACÊUTICA, S.A.	
Nimed 100 mg granulado para solução oral	not available	9692137	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
Nimed 100 mg granulado para solução oral	not available	4567194	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
NIMED 100 mg tablety	not available	29/415/99-C	HELSINN BIREX PHARMACEUTICALS LTD.	CZ