24 February 2022
EMA/194907/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: nimesulide (systemic formulations)

Procedure no.: PSUSA/00009236/202106

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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
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 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 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
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
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK

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AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/001	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/001	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/001	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/001	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg granulát	IT/H/0151/002	29/0311/03-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
Aulin 100 mg granulato per sospensione orale	IT/H/0151/002	025940115	HELSINN BIREX PHARMACEUTICALS LTD.	IT
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 pentru suspensie orală	IT/H/0151/002	6647/2014/04	ANGELINI PHARMA ÖSTERREICH GMBH	RO
AULIN 100 mg granule pentru suspensie orală	IT/H/0151/002	6647/2014/05	ANGELINI PHARMA ÖSTERREICH GMBH	RO

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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	6647/2014/06	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 pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 granule pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 granule pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 granule pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 granule pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 granule pro perorální suspenzi	IT/H/0151/002	29/180/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 tablety	IT/H/0151/001	29/179/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ

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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	29/179/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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	29/179/97-C	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	CZ
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 tablety	IT/H/0151/001	29/0282/97-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg tablety	IT/H/0151/001	29/0282/97-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg tablety	IT/H/0151/001	29/0282/97-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg tablety	IT/H/0151/001	29/0282/97-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
AULIN 100 mg tablety	IT/H/0151/001	29/0282/97-S	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	SK
Aulin, 100 mg, comprimido	IT/H/0151/001	5809181	ANGELINI FARMACÊUTICA, LDA	PT
Aulin, 100 mg, granulado para suspensão oral	IT/H/0151/002	5810882	ANGELINI FARMACÊUTICA, LDA	PT
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulat do sporządzania	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL

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zawiesiny doustnej				
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, granulat do sporządzania zawiesiny doustnej	IT/H/0151/002	4114	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, tabletki	IT/H/0151/001	4113	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, tabletki	IT/H/0151/001	4113	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Aulin, 100 mg, tabletki	IT/H/0151/001	4113	ANGELINI PHARMA ČESKÁ REPUBLIKA S.R.O.	PL
Аулин 100 mg гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg гранули за перорална суспензия	IT/H/0151/002	9700287	ANGELINI PHARMA BULGARIA EOOD	BG

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Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG
Аулин 100 mg таблетки	IT/H/0151/001	9600168	ANGELINI PHARMA BULGARIA EOOD	BG
Donulide, 100 mg, comprimido	IT/H/0150/001	8736504	ANGELINI FARMACÊUTICA, LDA	PT
Donulide, 100 mg, granulado para suspensão oral	IT/H/0150/002	5687702	ANGELINI PHARMA PORTUGAL, UNIPESSOAL LDA	PT
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ

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suspenzi				
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/0902/002	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg granule pro perorální suspenzi	CZ/H/902/02	29/124/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
Mesulid 100 mg tabletta	CZ/H/902/01	OGYI-T-6459/01	ANGELINI PHARMA ÖSTERREICH GMBH	HU
MESULID 100 mg tablety	CZ/H/0902/001	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg tablety	CZ/H/0902/001	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg tablety	CZ/H/0902/001	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg tablety	CZ/H/0902/001	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg tablety	CZ/H/0902/001	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
MESULID 100 mg tablety	CZ/H/902/01	29/125/01-C	ANGELINI PHARMA ÖSTERREICH GMBH	CZ
Mesulid 50 mg/g	CZ/H/0902/002	OGYI-T-6459/02	ANGELINI PHARMA	HU

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granulátum			ÖSTERREICH GMBH	
Mesulid®100mg Διασκία	IT/H/150/001-003	36240	VIANEX S.A.	GR
Nimed 100 mg comprimido revestido por película	not available	4567392	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
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
Nimed 100 mg granulado para solução oral	not available	4567095	LABORATÓRIOS AZEVEDOS - INDÚSTRIA FARMACÊUTICA, S.A.	PT
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
NIMEDEX 400 mg compresse	not available	029120019	ITALFARMACO S.P.A	IT
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 granulės geriamajai suspensijai	not available	LT/1/99/0503/003	LABORATORI GUIDOTTI S.P.A.	LT
Nimesil 100 mg granulės geriamajai suspensijai	not available	LT/1/99/0503/001	LABORATORI GUIDOTTI S.P.A.	LT
Nimesil 100 mg granulės geriamajai suspensijai	not available	LT/1/99/0503/002	LABORATORI GUIDOTTI S.P.A.	LT

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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