



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 May 2026
EMADOC-1700519818-3153474
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): progesterone

EURD list No. PSUSA/00002540/202509

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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
Lubion	AT/H/1015/002	20-0143	IBSA Farmaceutici Italia S.r.l.	Republic of Latvia
Inprosub	AT/H/1015/002	2013080286	Ibsa Farmaceutici Italia S.r.l.	Grand Duchy of Luxembourg
Gosegyne	PT/H/0980/002		Laboratorios Effik Sociedade Unipessoal Lda.	Portuguese Republic
Utrogestan® Vaginal	SE/H/2023/001	PA 22624/001/001	Besins Healthcare Ireland Limited	Ireland
Gosegyne	PT/H/0980/001		Laboratorios Effik Sociedade Unipessoal Lda.	Portuguese Republic
Crinone			Merck Serono S.p.A.	Italian Republic
Utrogestan		2221405	Faran S.A.	Hellenic Republic
Prolutex	AT/H/1015/003	80882/10-07-2024	IBSA Farmaceutici Italia S.r.l.	Hellenic Republic
Progesterone Exeltis	PT/H/0980/002	OGYI-T-22786/03	EXELTIS Magyarorszag Kft.	Republic of Hungary
Crinone		2009100580	Merck	Grand Duchy of Luxembourg
Lubion	AT/H/1015/003	1126923	IBSA Farmaceutici Italia S.r.l.	Republic of Estonia
Utrogestan		1-22178	Besins Healthcare	Republic of Austria
Лутинус	SE/H/0836/001	20100173	Ferring GmbH	Republic of Bulgaria
Lutinus	SE/H/0836/001	24949	Ferring Laeaeckkeet Oy	Republic of Finland
darstin		55.868	Seid S.A.	Kingdom of Spain
PRONTOGEST			IBSA Farmaceutici Italia S.r.l.	Italian Republic
Utrogestan	SE/H/2242/001	PA 22624/001/002	Besins Healthcare Ireland Limited	Ireland
Famenita	DE/H/2936/002	82478.01.00	Exeltis Germany GmbH	Federal Republic of Germany
Utrogestan		HR-H-979088283	Besins Healthcare	Republic of Croatia
UTROGESTAN		56/056/97-C	Laboratoires Besins International	Czech Republic
Progesterone Besins	SE/H/2242/001	21-0102	Besins Healthcare Ireland Limited	Republic of Latvia
Utrogestan Vaginal		2007119563	Besins Healthcare	Grand Duchy of

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				Luxembourg
UTROGESTAN			Besins Healthcare	Kingdom of Belgium
Progestan		42282.00.00	Besins Healthcare Germany GmbH	Federal Republic of Germany
Progestan	SE/H/2242/001	IS/1/23/061/01	Besins Healthcare Ireland Limited	Republic of Iceland
Progebel	BE/H/0279/002	2019070185	Effik Benelux	Grand Duchy of Luxembourg
Lutinus	SE/H/0836/001		Ferring Magyarorszag Kft.	Republic of Hungary
Progesterone Besins	SE/H/2023/001	19-0041	Besins Healthcare Ireland Limited	Republic of Latvia
Prolutex	AT/H/1015/002	38256	Ibsa Farmaceutici Italia S.r.l.	Republic of Finland
Prolutex	AT/H/1015/002	64799	IBSA Farmaceutici Italia S.r.l.	Kingdom of Denmark
Progedex	AT/H/1015/003	141787	Ibsa Farmaceutici Italia S.r.l.	Republic of Austria
Progebel	BE/H/0279/002	BE461280	Effik Benelux	Kingdom of Belgium
Utrogestan	SE/H/2023/001	18-12518	Besins Healthcare Ireland Limited	Kingdom of Norway
Prolutex	AT/H/1015/002	60938	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Sweden
Prolutex	AT/H/1015/003	22-14707	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Norway
UTROGESTAN		11951/2019/01	Laboratoires Besins International	Romania
Progesterone Besins	SE/H/2242/001		Besins Healthcare Ireland Limited	Republic of Lithuania
Utrogestan	SE/H/2023/001	MA727/00205	Besins Healthcare	Republic of Malta
Lubion	AT/H/1015/003	PA1104/006/001	Ibsa Farmaceutici Italia S.r.l.	Ireland
PROGIRON	AT/H/1015/002	34009 276 440 5 4	IBSA Pharma S.A.S.	French Republic
PRONTOGEST		005239049	IBSA Farmaceutici Italia S.r.l.	Italian Republic
Utrogestan		PA 1054/003/001	Laboratoires Besins	Ireland

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
			International	
Gepretix	PT/H/0979/001	14-0211	Exeltis Baltics UAB	Republic of Latvia
Progesteron Besins	SE/H/2242/001	56/484/22-C	Besins Healthcare Ireland Limited	Czech Republic
Crinone		BE184895	Merck	Kingdom of Belgium
Prolutex	AT/H/1015/002	56/0040/14-S	IBSA Slovakia s.r.o.	Slovak Republic
Progebel	BE/H/0279/002	2019 070 185	Effik Benelux	Grand Duchy of Luxembourg
CRINONE	DE/H/0146/002		Merck Sante	French Republic
Progestogel		1996073863	Besins Healthcare	Grand Duchy of Luxembourg
Gepretix	PT/H/0979/001	LT/1/14/3603/001	Exeltis Baltics UAB	Republic of Lithuania
Lubion	AT/H/1015/003	23-0144	IBSA Farmaceutici Italia S.r.l.	Republic of Latvia
Utrogestan		15510	Besins Healthcare	Kingdom of Denmark
Inprosub	AT/H/1015/002	BE440903	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Belgium
Utrogestan	SE/H/2242/001	023826	Besins Healthcare Ireland Limited	Republic of Cyprus
Seidigestan		64.899	Seid S.A.	Kingdom of Spain
Gepretix	PT/H/0979/002	851014	Exeltis Baltics UAB	Republic of Estonia
Lubion	AT/H/1015/002	20-0143	IBSA Farmaceutici Italia S.r.l.	Republic of Latvia
Prolutex	AT/H/1015/002		IBSA Farmaceutici Italia S.r.l.	Portuguese Republic
Gepretix	PT/H/0979/002	LT/1/14/3603/003	Exeltis Baltics UAB	Republic of Lithuania
Progesterone Besins		PL 42714/0007	Besins Healthcare (UK) Limited	United Kingdom (Northern Ireland)
Prolutex	AT/H/1015/002	OGYI-T-22435/05	IBSA Pharma Kft.	Republic of Hungary
PROGESTOGEL		BE099294	Besins Healthcare	Kingdom of Belgium
Lutinus	SE/H/0836/001	RVG 102442	Ferring B.V.	Kingdom of the Netherlands
Progestan	SE/H/2023/001	IS/1/22/070/01	Besins Healthcare Ireland Limited	Republic of Iceland

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
Utrogestan	SE/H/2242/001	2021060125	Besins Healthcare	Grand Duchy of Luxembourg
Prolutex	AT/H/1015/002	33982/17/23-11-2018	IBSA Farmaceutici Italia S.r.l.	Hellenic Republic
Utrogestan		PL 28397/0004	Besins Healthcare	United Kingdom (Northern Ireland)
UTROGESTAN		023191	Besins Healthcare Ireland Limited	Republic of Cyprus
Gepretix	PT/H/0979/002	LT/1/14/3603/004	Exeltis Baltics UAB	Republic of Lithuania
Utrogestan Vaginal		BE 178954	Besins Healthcare	Kingdom of Belgium
Prolutex	AT/H/1015/002	021775	IBSA Farmaceutici Italia S.r.l.	Republic of Cyprus
Utrogestan		2007070039	Besins Healthcare	Grand Duchy of Luxembourg
Utrogestan	SE/H/2023/001	HR-H-957395225	Besins Healthcare Ireland Limited	Republic of Croatia
Prolutex	AT/H/1015/002	20200256	Ibsa Farmaceutici Italia S.r.l.	Republic of Bulgaria
Prolutex	AT/H/1015/003	RVG 129873	Ibsa Farmaceutici Italia S.r.l.	Kingdom of the Netherlands
Crinone	DE/H/0146/002	22446	Merck Sp. z o.o	Republic of Poland
Folac	PT/H/0979/002		Laboratorios Effik Sociedade Unipessoal Lda.	Portuguese Republic
LUTINUS	SE/H/0836/001	73488.00.00	Ferring GmbH	Federal Republic of Germany
Lutinus	SE/H/0836/001	PA 1009/22/1	Ferring (Ireland) Limited	Ireland
Lubion	AT/H/1015/003	1126923	IBSA Farmaceutici Italia S.r.l.	Republic of Estonia
Progestan	SE/H/2023/001	67624	Besins Healthcare	Kingdom of Denmark
Lutinus	SE/H/0836/001	IS/1/08/082/01	Ferring Lagemidler A/S	Republic of Iceland
Amelgen	IE/H/0695/001	2018010001	Gedeon Richter Plc.	Grand Duchy of Luxembourg
Prolutex	AT/H/1015/002	5569751	IBSA Farmaceutici Italia S.r.l.	Portuguese Republic
PLEYRIS	AT/H/1015/002		IBSA Farmaceutici Italia	Italian Republic

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			S.r.l.	
Lutinus	SE/H/0836/001	26884	Ferring Lakemedel AB	Kingdom of Sweden
Progestanelle	PT/H/0980/002	56/0189/15-S	Exeltis Slovakia s.r.o.	Slovak Republic
CRINONE		41641/07/29-5-2008	Merck Commercial Industrial Pharmaceutical Chemical S.A.	Hellenic Republic
Lutinus	SE/H/0836/001	43218	Ferring Lagemidler A/S	Kingdom of Denmark
Lubion	AT/H/1015/002		Ibsa Farmaceutici Italia S.r.l.	Republic of Lithuania
Utrogestan	SE/H/2023/001	RVG 123999	Besins Healthcare Netherlands B.V.	Kingdom of the Netherlands
Prolutex	AT/H/1015/002	21412	IBSA Farmaceutici Italia S.r.l.	Republic of Poland
Progestogel		2572.00.00	Besins Healthcare Germany GmbH	Federal Republic of Germany
Prolutex	AT/H/1015/002	20200256	Ibsa Farmaceutici Italia S.r.l.	Republic of Bulgaria
Crinone	DE/H/0146/002	15-0067	Merck Serono SIA	Republic of Latvia
Prolutex	AT/H/1015/002	20-13556	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Norway
Folac	PT/H/0979/001		Laboratorios Effik Sociedade Unipessoal Lda.	Portuguese Republic
Esolut		027797024	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A.	Italian Republic
Crinone		PA 2286/1/1	Merck Serono (Ireland) Limited	Ireland
UTROGESTAN		34009 348 401 0 4	Besins Healthcare France	French Republic
Utrogestan	SE/H/2242/001	60954	Besins Healthcare Ireland Limited	Kingdom of Sweden
Progebel	BE/H/0279/001	BE461271	Effik Benelux	Kingdom of Belgium
Utrogestan	SE/H/2023/001	25282	Besins Healthcare Ireland Limited	Republic of Poland
Utrogestan	SE/H/2023/001		Besins Healthcare Ireland Limited	Italian Republic

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Crinone	DE/H/0146/002		Merck Serono SIA	Republic of Lithuania
UTROGESTAN		013736	Besins Healthcare Ireland Limited	Republic of Cyprus
Crinone	DE/H/0146/002		MERCK Proizvodnja in prodaja farmacevtskih in kemijskih proizvodov d.o.o. Ljubljana	Republic of Slovenia
Utrogestan	SE/H/2242/001		Besins Healthcare	Kingdom of Belgium
Crinone		94-2836	Merck AB	Kingdom of Norway
Lugesteron	SE/H/2242/001	36605	Besins Healthcare Ireland Limited	Republic of Finland
Prolutex	AT/H/1015/002	RVG 127083	Ibsa Farmaceutici Italia S.r.l.	Kingdom of the Netherlands
Utrogestan	SE/H/2023/001		Besins Healthcare Ireland Limited	Republic of Slovenia
Lutinus	SE/H/0836/001	4017/21-01-2016	Ferring Hellas M.EPE	Hellenic Republic
Utrogestan		OGYI-T-6628/02	Laboratoires Besins International	Republic of Hungary
Utrogestan		OGYI-T-6628/01	Laboratoires Besins International	Republic of Hungary
Prolutex	AT/H/1015/003	023869	Ibsa Farmaceutici Italia S.r.l.	Republic of Cyprus
Prolutex	AT/H/1015/003	20230229	IBSA Farmaceutici Italia S.r.l.	Republic of Bulgaria
Prolutex	AT/H/1015/003	67669	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Denmark
UTROGESTAN		56/0123/99-S	Laboratoires Besins International	Slovak Republic
Utrogestan	SE/H/2023/001	56/0082/19-S	Besins Healthcare Ireland Limited	Slovak Republic
Утрогестан	SE/H/2023/001	20190096	Besins Healthcare Ireland Limited	Republic of Bulgaria
Crinone		BE184895	Merck	Kingdom of Belgium
Utrogestan	SE/H/2242/001	27934	Besins Healthcare Ireland Limited	Republic of Poland

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Crinone	SE/H/1702/001	13600	Merck AB	Kingdom of Sweden
Progebel	BE/H/0279/001	2019 070 184	Effik Benelux	Grand Duchy of Luxembourg
Progedex	AT/H/1015/002	1-31810	IBSA Farmaceutici Italia S.r.l.	Republic of Austria
Prolutex	AT/H/1015/003		IBSA Farmaceutici Italia S.r.l.	Romania
Утрогестан	SE/H/2242/001	20210194	Besins Healthcare Ireland Limited	Republic of Bulgaria
Prolutex	AT/H/1015/003	023869	Ibsa Farmaceutici Italia S.r.l.	Republic of Cyprus
Lubion	AT/H/1015/003	PL 21039/0082	Ibsa Farmaceutici Italia S.r.l.	United Kingdom (Northern Ireland)
Utrogestan	SE/H/2242/001	050211059	Besins Healthcare Ireland Limited	Italian Republic
Lubion	AT/H/1015/003	23-0144	IBSA Farmaceutici Italia S.r.l.	Republic of Latvia
Prolutex	AT/H/1015/003	7009466.00.00	Ibsa Farmaceutici Italia S.r.l.	Federal Republic of Germany
Utrogestan	SE/H/2023/001	58438	Besins Healthcare Ireland Limited	Kingdom of Sweden
Prolutex	AT/H/1015/003	63300	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Sweden
Progestan	SE/H/2242/001	68770	Besins Healthcare	Kingdom of Denmark
Utrogestan Vaginal		BE 279377	Besins Healthcare	Kingdom of Belgium
Prolutex	AT/H/1015/003	28852	Ibsa Farmaceutici Italia S.r.l.	Republic of Poland
Prolutex	AT/H/1015/003	OGYI-T-22435/08	IBSA Pharma Kft.	Republic of Hungary
Utrogestan	SE/H/2242/001	1036621	Besins Healthcare Ireland Limited	Republic of Estonia
Progesterone Besins	SE/H/2023/001		Besins Healthcare Ireland Limited	Republic of Lithuania
Utrogestan	SE/H/2023/001	985619	Besins Healthcare Ireland Limited	Republic of Estonia
Inprosub	AT/H/1015/003	BE661733	Ibsa Farmaceutici Italia	Kingdom of Belgium

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			S.r.l.	
Crinone	DE/H/0146/002		Merck d.o.o.	Republic of Croatia
Prolutex	AT/H/1015/002	78.108	IBSA Farmaceutici Italia S.r.l.	Kingdom of Spain
PROGESTOGEL			Besins Healthcare France	French Republic
Gepretix	PT/H/0979/002	14-0212	Exeltis Baltics UAB	Republic of Latvia
Пролутекс	AT/H/1015/003	20230229	IBSA Farmaceutici Italia S.r.l.	Republic of Bulgaria
Lubion	AT/H/1015/003		Ibsa Farmaceutici Italia S.r.l.	Republic of Lithuania
LUBION	AT/H/1015/002	1014820	Ibsa Farmaceutici Italia S.r.l.	Republic of Estonia
Arefam	DE/H/2936/002	1-31629	Exeltis Germany GmbH	Republic of Austria
Prometrium		PL 28397/0014	Besins Healthcare	United Kingdom (Northern Ireland)
UTROGESTAN		PL 28397/0003	Besins Healthcare	United Kingdom (Northern Ireland)
UTROGESTAN			Besins Healthcare	Kingdom of Belgium
Lutinus	SE/H/0836/001		Ferring GmbH	Romania
Utrogestan	SE/H/2242/001	MA727/00501	Besins Healthcare	Republic of Malta
Crinone	DE/H/0146/002	869615	Merck Serono SIA	Republic of Estonia
Utrogestan		1-31897	Besins Healthcare	Republic of Austria
Кринон	DE/H/0146/002	20150153	Merck Bulgaria EAD	Republic of Bulgaria
Prolutex	AT/H/1015/002	85288.00.00	IBSA Farmaceutici Italia S.r.l.	Federal Republic of Germany
Utrogestan	SE/H/2242/001	HR-H-677297904	Besins Healthcare Ireland Limited	Republic of Croatia
Utrogestan		2007119562	Besins Healthcare	Grand Duchy of Luxembourg
Inprosub	AT/H/1015/003	2023090190	Ibsa Farmaceutici Italia S.r.l.	Grand Duchy of Luxembourg
Lutinus	SE/H/0836/001	08-5883	Ferring Legemidler AS	Kingdom of Norway
Utrogestan vaginal	SE/H/2242/001		Laboratoires Besins International	Portuguese Republic

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Prolutex	AT/H/1015/003		IBSA Farmaceutici Italia S.r.l.	Portuguese Republic
Utrogestan	SE/H/2023/001	88298	Besins Healthcare Ireland Limited	Kingdom of Spain
Utrogestan	SE/H/2242/001	34009 302 716 8 1	Besins Healthcare France	French Republic
PLEYRIS	AT/H/1015/003		Ibsa Farmaceutici Italia S.r.l.	Italian Republic
Utrogestan	SE/H/2242/001	88928	Besins Healthcare Ireland Limited	Kingdom of Spain
Lutinus	SE/H/0836/001	16573	Ferring GmbH	Republic of Poland
UTROGESTAN	SE/H/2023/001	PL 28397/0005	Besins Healthcare	United Kingdom (Northern Ireland)
Crinone		11961	Merck Oy	Republic of Finland
Crinone		17067	Merck A/S	Kingdom of Denmark
Lutigest	SE/H/0836/001	PL 03194/0103	Ferring Pharmaceuticals Limited	United Kingdom (Northern Ireland)
Crinone	DE/H/0146/002	RVG 114730	Merck B.V.	Kingdom of the Netherlands
Prolutex	AT/H/1015/003	89065	Ibsa Farmaceutici Italia S.r.l.	Kingdom of Spain
Lubion	AT/H/1015/002	PL 21039/0026	Ibsa Farmaceutici Italia S.r.l.	United Kingdom (Northern Ireland)
Utrogestan	SE/H/2023/001		Besins Healthcare Ireland Limited	Republic of Hungary
Progesteron Besins	SE/H/2023/001	56/454/18-C	Besins Healthcare Ireland Limited	Czech Republic
Prolutex	AT/H/1015/003	80882/10-07-2024	IBSA Farmaceutici Italia S.r.l.	Hellenic Republic
Lugesteron		10401	Besins Healthcare Ireland Limited	Republic of Finland
Prolutex	AT/H/1015/003	56/120/22-C	IBSA Slovakia s.r.o.	Czech Republic
Prolutex	AT/H/1015/003	40931	Ibsa Farmaceutici Italia S.r.l.	Republic of Finland
Utrogestan	SE/H/2242/001	20-13563	Besins Healthcare Ireland Limited	Kingdom of Norway

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
Utrogestan	SE/H/2242/001	56/0133/21-S	Besins Healthcare Ireland Limited	Slovak Republic
PROGIRON	AT/H/1015/003		IBSA Pharma S.A.S.	French Republic
Seidigestan		60.814	Seid S.A.	Kingdom of Spain
Prolutex	AT/H/1015/002	56/328/13-C	IBSA Slovakia s.r.o.	Czech Republic
Utrogestan	SE/H/2023/001	5882246	Laboratoires Besins International	Portuguese Republic
Gepretix	PT/H/0979/001	LT/1/14/3603/002	Exeltis Baltics UAB	Republic of Lithuania
UTROGESTAN			Besins Healthcare France	French Republic
Luteina Mikro	PL/H/0951/002	29038	Adamed Pharma S.A.	Republic of Poland
UTROGESTAN			Laboratoires Besins International	Romania
Gepretix	PT/H/0979/001	850814	Exeltis Baltics UAB	Republic of Estonia
Lubion	AT/H/1015/002	20-0143	IBSA Farmaceutici Italia S.r.l.	Republic of Latvia
Utrogestan	SE/H/2242/001	PL 28397/0012	Besins Healthcare	United Kingdom (Northern Ireland)
Crinone	SE/H/1702/001	IS/1/17/044/01	Merck AB	Republic of Iceland
Crinone			Merck Kft.	Republic of Hungary
Crinone		PL 11648/0261	Merck Serono Limited	United Kingdom (Northern Ireland)
Luteina Mikro	PL/H/0951/001	29037	Adamed Pharma S.A.	Republic of Poland
Prolutex	AT/H/1015/003	56/0010/24-S	IBSA Slovakia s.r.o.	Slovak Republic