



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 January 2017  
EMA/45363/2017  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: goserelin

Procedure no.: PSUSA/00001562/201605



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
RESELIGO 3,6 mg vefjalyf í áfylltri sprautu	PT/H/1276/001	IS/1/15/120/01	ALVOGEN IPCO S.AR.L	IS
Reseligo 3,6 mg implantátum elóretöltött fecskendőben	PT/H/1276/001	OGYI-T-22933/01	ALVOGEN IPCO S.AR.L	HU
Reseligo 3,6 mg implantátum elóretöltött fecskendőben	PT/H/1276/001	OGYI-T-22933/02	ALVOGEN IPCO S.AR.L	HU
РЕЗЕЛИГО 3,6 mg имплантат в предварително напълнена спринцовка	PT/H/1276/001	II-31472	ALVOGEN IPCO S.AR.L	BG
РЕЗЕЛИГО 3,6 mg имплантат в предварително напълнена спринцовка	PT/H/1276/001	II-31472	ALVOGEN IPCO S.AR.L	BG
Reseligo 3.6 mg implant in seringa preumpluta	PT/H/1276/001	8436/2015/01	ALVOGEN IPCO S.AR.L	RO
Reseligo 3.6 mg implant in seringa preumpluta	PT/H/1276/001	8436/2015/02	ALVOGEN IPCO S.AR.L	RO
Reseligo 3,6 mg implantat u napunjenoj štrcaljki	PT/H/1276/001	HR-H-731754823	ALVOGEN IPCO S.AR.L	HR
Reseligo 3,6 mg implantat u napunjenoj štrcaljki	PT/H/1276/001	HR-H-731754823	ALVOGEN IPCO S.AR.L	HR
Reseligo 3,6 mg implantas užpildytame švirkšte	PT/H/1276/001	LT/1/15/3840/001	ALVOGEN IPCO S.AR.L	LT
Reseligo 3,6 mg implantas užpildytame	PT/H/1276/001	LT/1/15/3840/002	ALVOGEN IPCO S.AR.L	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
švirkšte				
Reseligo, 3,6 mg implantaat, süstlis	PT/H/1276/001	898115	ALVOGEN IPCO S.AR.L	EE
Reseligo, 3,6 mg implantaat, süstlis	PT/H/1276/001	898115	ALVOGEN IPCO S.AR.L	EE
Reseligo 3,6 mg implants pilnšjircē	PT/H/1276/001	15-0332	ALVOGEN IPCO S.AR.L	LV
Reseligo 3,6 mg implants pilnšjircē	PT/H/1276/001	15-0332	ALVOGEN IPCO S.AR.L	LV
Reseligo, 3,6 mg, implant, w ampułko-strzykawce	PT/H/1276/001	22925	ALVOGEN IPCO S.AR.L	PL
Reseligo, 3,6 mg, implant, w ampułko-strzykawce	PT/H/1276/001	22925	ALVOGEN IPCO S.AR.L	PL
Reseligo, 3.6 mg, Implante em seringa pré-cheia	PT/H/1276/001	PT/H/1276/001	ALVOGEN IPCO S.AR.L	PT
Reseligo, 3.6 mg, Implante em seringa pré-cheia	PT/H/1276/001	PT/H/1276/001	ALVOGEN IPCO S.AR.L	PT
Reseligo 3,6 mg implantát v předplněné injekční stříkačce	PT/H/1276/001	56/107/16-C	ALVOGEN IPCO S.AR.L	CZ
Reseligo 3,6 mg implantát v předplněné injekční stříkačce	PT/H/1276/001	56/107/16-C	ALVOGEN IPCO S.AR.L	CZ
Reseligo 3,6 mg implantat v napolnjeni injekcijski brizgi	PT/H/1276/001	H/16/02106/001	ALVOGEN IPCO S.AR.L	SI
Reseligo 3,6 mg implantat v napolnjeni injekcijski brizgi	PT/H/1276/001	H/16/02106/002	ALVOGEN IPCO S.AR.L	SI
Reseligo 3,6 mg implantát naplnený v	PT/H/1276/001	44/0258/16-S	ALVOGEN IPCO S.AR.L	SK

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
injekčnej striekačke				
Reseligo 3,6 mg implantát naplnený v injekčnej striekačke	PT/H/1276/001	44/0258/16-S	ALVOGEN IPCO S.AR.L	SK
RESELIGO 10,8 mg vefjalýf í áfylltri sprautu	PT/H/1277/001	IS/1/15/120/02	ALVOGEN IPCO S.AR.L	IS
Reseligo 10,8 mg implantátum előretöltött fecskendőben	PT/H/1277/001	OGYI-T-22933/03	ALVOGEN IPCO S.AR.L	HU
Reseligo 10,8 mg implantátum előretöltött fecskendőben	PT/H/1277/001	OGYI-T-22933/04	ALVOGEN IPCO S.AR.L	HU
РЕЗЕЛИГО 10,8 mg имплантат в предварително напълнена спринцовка	PT/H/1277/001	II-31471	ALVOGEN IPCO S.AR.L	BG
РЕЗЕЛИГО 10,8 mg имплантат в предварително напълнена спринцовка	PT/H/1277/001	II-31471	ALVOGEN IPCO S.AR.L	BG
Reseligo 10.8 mg implant in seringa preumpluta	PT/H/1277/001	8396/2015/01	ALVOGEN IPCO S.AR.L	RO
Reseligo 10.8 mg implant in seringa preumpluta	PT/H/1277/001	8396/2015/02	ALVOGEN IPCO S.AR.L	RO
Reseligo 10,8 mg implantat u napunjenoj štrcaljki	PT/H/1277/001	HR-H-863040656	ALVOGEN IPCO S.AR.L	HR
Reseligo 10,8 mg	PT/H/1277/001	HR-H-863040656	ALVOGEN IPCO S.AR.L	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
implantat u napunjenoj štrcaljki				
Algonad 10,8 mg implantas užpildytame švirkšte	PT/H/1277/001	LT/1/15/3833/001	ALVOGEN IPCO S.AR.L	LT
Algonad 10,8 mg implantas užpildytame švirkšte	PT/H/1277/001	LT/1/15/3833/002	ALVOGEN IPCO S.AR.L	LT
Reseligo, 10,8 mg implantaat, süstlis	PT/H/1277/001	898015	ALVOGEN IPCO S.AR.L	EE
Reseligo, 10,8 mg implantaat, süstlis	PT/H/1277/001	898015	ALVOGEN IPCO S.AR.L	EE
Reseligo 10,8 mg implants pilnšjircē	PT/H/1277/001	15-0333	ALVOGEN IPCO S.AR.L	LV
Reseligo 10,8 mg implants pilnšjircē	PT/H/1277/001	15-0333	ALVOGEN IPCO S.AR.L	LV
Reseligo, 10,8 mg, implant, w ampułko-strzykawce	PT/H/1277/001	22926	ALVOGEN IPCO S.AR.L	PL
Reseligo, 10,8 mg, implant, w ampułko-strzykawce	PT/H/1277/001	22926	ALVOGEN IPCO S.AR.L	PL
Reseligo, 10.8 mg, Implante em seringa pré-cheia	PT/H/1277/001	PT/H/1277/001	ALVOGEN IPCO S.AR.L	PT
Reseligo, 10.8 mg, Implante em seringa pré-cheia	PT/H/1277/001	PT/H/1277/001	ALVOGEN IPCO S.AR.L	PT
Reseligo 10.8 mg implantát v předplněné injekční stříkačce	PT/H/1277/001	56/108/16-C	ALVOGEN IPCO S.AR.L	CZ
Reseligo 10,8 mg implantát v předplněné injekční stříkačce	PT/H/1277/001	56/108/16-C	ALVOGEN IPCO S.AR.L	CZ
Reseligo 10,8 mg implantat v napolnjeni	PT/H/1277/001	H/16/02107/001	ALVOGEN IPCO S.AR.L	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
injekcijski brizgi				
Reseligo 10,8 mg implantat v napolnjeni injekcijski brizgi	PT/H/1277/001	H/16/02107/002	ALVOGEN IPCO S.AR.L	SI
Reseligo 10,8 mg implantát naplnený v injekčnej striekačke	PT/H/1277/001	44/0266/16-S	ALVOGEN IPCO S.AR.L	SK
Reseligo 10,8 mg implantát naplnený v injekčnej striekačke	PT/H/1277/001	44/0266/16-S	ALVOGEN IPCO S.AR.L	SK
ZOLADEX 3,6 mg implantat	not available	HR-H-247320153	ASTRAZENECA D.O.O.	HR
ZOLADEX LA 10,8 mg implantat	not available	HR-H-936480409	ASTRAZENECA D.O.O.	HR
Zoladex, 3,6 mg, implant podskórny.	not available	R/0823	ASTRAZENECA UK LIMITED	PL
ZOLADEX, 3,6 mg, implant	not available	BE138731	NV ASTRAZENECA SA	BE
ZOLADEX DEPOT 3,6 mg	not available	56/276/92-C	ASTRAZENECA UK LIMITED	CZ
Zoladex depot 3,6 mg	not available	44/0276/92-C/S	ASTRAZENECA UK LIMITED	SK
ZOLADEX, 3,6 mg, implant	not available	BE138731	NV ASTRAZENECA SA	BE
Zoladex® ενέσιμο εμφύτευμα 3.6 mg	not available	13581	ASTRAZENECA UK LIMITED	CY
Zoladex 3,6 mg implantat v napolnjeni injekcijski brizgi	not available	512/B-2998/94	ASTRAZENECA UK LIMITED	SI
Золадекс 3,6 mg имплантат	not available	20020071	ASTRAZENECA UK LIMITED	BG
Zoladex depot 3,6 mg implantátum előretöltött fecskendőben	not available	OGYI-T-1976/01	ASTRAZENECA KFT.	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
ZOLADEX, 3,6 mg implantaat	not available	62494	ASTRAZENECA UK LIMITED	EE
Zoladex® ενέσιμο εμφύτευμα 3.6 mg	not available	39552 / 05-11-2009	ASTRAZENECA S.A	GR
ZOLADEX, 3,6 mg, implant	not available	0173/07109481	NV ASTRAZENECA SA	LU
Zoladex 3.6 mg Implant	not available	PA 970/25/1	ASTRAZENECA UK LIMITED	IE
Zoladex 3.6 mg Implant	not available	044/00901	ASTRAZENECA UK LIMITED	MT
Zoladex 3,6 mg implant	not available	2214/2009/01	ASTRAZENECA UK LIMITED	RO
Zoladex 3,6 mg implante	not available	8679308	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
ZOLADEX 3,6 mg, implant en seringue préremplie pour voie sous cutanée	not available	NL 14490	ASTRAZENECA S.A.S.	FR
Zoladex 3,6 mg implantas	not available	LT /1/94/0813/001	ASTRAZENECA UK LIMITED	LT
ZOLADEX 3,6 mg impianto a rilascio prolungato per uso sottocutaneo	not available	26471019	ASTRAZENECA S.P.A.	IT
ZOLADEX LA, 10,8 mg, implant podskórny.	not available	7832	ASTRAZENECA UK LIMITED	PL
ЗОЛАДЕКС LA 10,8 mg имплантат	not available	9800307	ASTRAZENECA UK LIMITED	BG
Zoladex 3,6 mg implante en jeringa precargada	not available	58.603	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
ZOLADEX LA 10,8 mg implantāts	not available	97-0327	ASTRAZENECA UK LIMITED	LV
Zoladex LA depot 10,8 mg	not available	44/0276/92-C/S	ASTRAZENECA UK LIMITED	SK

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
Zoladex® ενέσιμο εμφύτευμα 10,8 mg	not available	39553 / 04-03-2010	ASTRAZENECA S.A	GR
Zoladex LA 10.8 mg Implant	not available	PA 970/25/2	ASTRAZENECA UK LIMITED	IE
Zoladex LA 10,8 mg implantas	not available	LT/1/94/0813/002	ASTRAZENECA UK LIMITED	LT
Zoladex® 3.6 mg Implant	not available	PL17901/0064	ASTRAZENECA UK LIMITED	UK
Zoladex LA 10.8 mg Implant	not available	044/00902	ASTRAZENECA UK LIMITED	MT
ZOLADEX Long Acting, 10,8 mg, implant	not available	BE179277	NV ASTRAZENECA SA	BE
Zoladex depot 10,8 mg implantátum előretöltött fecskendőben	not available	OGYI-T-1976/02	ASTRAZENECA KFT.	HU
Zoladex® LA 10.8 mg Implant	not available	PL17901/0065	ASTRAZENECA UK LIMITED	UK
ZOLADEX 10,8 mg impianto a rilascio prolungato per uso sottocutaneo.	not available	26471021	ASTRAZENECA S.P.A.	IT
Zoladex LA 10,8 mg implant	not available	1018/2008/01	ASTRAZENECA UK LIMITED	RO
ZOLADEX Long Acting, 10,8 mg, implant	not available	0173/07109482	NV ASTRAZENECA SA	LU
ZOLADEX DEPOT 10,8 mg	not available	56/681/96-C	ASTRAZENECA UK LIMITED	CZ
ZOLADEX Long Acting, 10,8 mg, implantaat	not available	BE179277	NV ASTRAZENECA SA	BE
Zoladex Trimestral 10,8 mg implante en jeringa precargada	not available	61.367	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
ZOLADEX 10,8 mg, implant en seringue préremplie pour voie	not available	NL 21001	ASTRAZENECA S.A.S.	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
sous-cutanée				
Zoladex LA 10,8 mg implante	not available	2845881	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Zoladex® ενέσιμο εμφύτευμα 10.8 mg	not available	18333	ASTRAZENECA UK LIMITED	CY
Zoladex 10,8 mg implantat v napoljnjeni injekcijski brizgi	not available	512/B-154/01	ASTRAZENECA UK LIMITED	SI
Zoladex-3,6, implantatiestaafje 3,6 mg	not available	RVG 12277	ASTRAZENECA BV	NL
Zoladex-10,8, implantatiestaafje 10,8 mg	not available	RVG 18562	ASTRAZENECA BV	NL
Zoladex® 3,6 mg Implantat	not available	19711.00.00	ASTRAZENECA GMBH	DE
Zoladex® 10,8 mg Implantat	not available	34481.00.00	ASTRAZENECA GMBH	DE
Zoladex 10,8 mg implantat, förfylld spruta	not available	12377	ASTRAZENECA AB	SE
Zoladex Depot 3,6 mg - Implantat	not available	1-18860	ASTRAZENECA OSTERREICH GMBH	AT
Zoladex Depot 10,8 mg - Implantat	not available	1-21236	ASTRAZENECA OSTERREICH GMBH	AT
Zoladex	not available	17092	ASTRAZENECA A/S	DK
Zoladex	not available	12614	ASTRAZENECA A/S	DK
Zoladex 10,8 mg implantaatti	not available	11924	ASTRAZENECA OY	FI
Zoladex 3,6 mg implantat, förfylld spruta	not available	10810	ASTRAZENECA AB	SE
Zoladex 3,6 mg	not available	9519	ASTRAZENECA OY	FI

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
implantaatti				
ZOLADEX 3,6 mg implantāts	not available	97-0328	ASTRAZENECA UK LIMITED	LV
Zoladex 10,8 mg implantat	not available	94-2930	ASTRAZENECA UK LIMITED	NO
Zoladex 3,6 mg implantat	not available	7317	ASTRAZENECA UK LIMITED	NO
Zoladex-GYN 3,6 mg Implantat	not available	39268.00.00	ASTRAZENECA GMBH	DE
Zoladex 10,8 mg vefjalyf.	not available	940248	ASTRAZENECA AB	IS
Zoladex 3,6 mg vefjalyf.	not available	870212	ASTRAZENECA AB	IS
Goserrelina AMW 3,6 mg implante, seringa pré-carregada	PT/H/1351/001	5668546	AMW GMBH	PT
Goserrelina AMW LA 10,8 mg implante, seringa pré-carregada	PT/H/1352/001	5668553	AMW GMBH	PT