



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2021
EMA/78560/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): oxytocin

Procedure No.: PSUSA/00002263/202006

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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
Syntocinon 10 IU/ml Concentrate for Solution for Infusion or Solution for Injection	not available	18420	MYLAN IRE HEALTHCARE LIMITED	CY
SYNTOCINON 5 U.I./ml Soluzione Iniettabile	not available	014684029	ALFASIGMA S.P.A.	IT
Syntocinon, 5 U.I./ml, solu 777]o inject 7. vel.	not available	8889709	ALFASIGMA S.P.A.	PT
Syntocinon 40 U.I./ml solução para pulverização nasal	not available	8889600	ALFASIGMA S.P.A.	PT
Oxytocin "Orifarm", koncentrat til injektions-/infusionsvæske, opløsning	FI/H/0924/001	58109	ORIFARM GENERICS A/S	DK
Oxytocin Orifarm 10 IU injektio-/infuusiokonsentraatti, liuosta varten	FI/H/0924/002	34363	ORIFARM GENERICS A/S	FI
Oxytocin Orifarm 10 IE, konsentrat til injeksjons-/infusjonsvæske, oppløsning	FI/H/0924/002	16-11252	ORIFARM GENERICS A/S	NO
SYNTOCINON 40 i.e./ml pršilo za nos, raztopina	not available	H/92/01479/003	MYLAN IRE HEALTHCARE LIMITED	SI
SYNTOCINON 5 i.e. koncentrat za raztopino za infundiranje / raztopina za injiciranje	not available	H/92/01479/001	MYLAN IRE HEALTHCARE LIMITED	SI
SYNTOCINON 10 i.e. koncentrat za raztopino za infundiranje / raztopina za injiciranje	not available	H/92/01479/002	MYLAN IRE HEALTHCARE LIMITED	SI
SYNTOCINON 5 i.e. koncentrat za raztopino za infundiranje / raztopina za injiciranje	not available	H/92/01479/004	MYLAN IRE HEALTHCARE LIMITED	SI
Syntocinon, næsespray, opløsning	not available	03152	ALFASIGMA S.P.A.	DK
Syntocinon, injektionsvæske, opløsning	not available	02456	ALFASIGMA S.P.A.	DK
Syntocinon 8,3 mikrog/ml infuusiokonsentraatti, liuosta varten/injektioneste, liuos	not available	8850	ALFASIGMA S.P.A.	FI
Syntocinon 5 IE/ml, concentraat voor oplossing voor infusie; oplossing voor	not available	RVG 03714	ALFASIGMA S.P.A.	NL

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injectie				
Syntocinon 40 IE/ml neusspray, oplossing	not available	RVG 03716	ALFASIGMA S.P.A.	NL
Syntocinon® 10 IU/ml Concentrate for solution for infusion	not available	MA 1187/01001	MYLAN IRE HEALTHCARE LIMITED	MT
Syntocinon 10 UI/ml solución inyectable y para perfusion	not available	39.393	ALFASIGMA S.P.A.	ES
SYNTOCINON® 6,7 mikrog/dose nesespray, oppløsning	not available	4115	ALFASIGMA S.P.A.	NO
Oxitocina Hikma, 10 UI/ml, Concentrado para solução para perfusão	not available	5668330	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Oxitocina Hikma, 10 UI/ml, Concentrado para solução para perfusão	not available	5668348	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Syntocinon 10 a.e./ml stungulyf, lausn	not available	640369	ALFASIGMA S.P.A.	IS
Syntocinon 6,7 mÍkróg/skammt nefúði, lausn.	not available	880004	ALFASIGMA S.P.A.	IS
Syntocinon Ampoules 10 IU/ml Solution for Infusion or Injection	not available	PA 2206/003/002	ALFASIGMA S.P.A.	IE
Syntocinon Ampoules 5 IU / ml Solution for Infusion or Injection	not available	PA 2202/003/001	ALFASIGMA S.P.A.	IE
SYNTOCINON® 5 U.I. /1 ml, solution injectable en ampoule	not available	34009 310 301 9 5	ALFASIGMA S.P.A.	FR
SYNTOCINON® 5 U.I. /1 ml, solution injectable en ampoule	not available	34009 551 491 0 1	ALFASIGMA S.P.A.	FR
SYNTOCINON® 5 U.I. /1 ml, solution injectable en ampoule	not available	34009 562 198 8 9	ALFASIGMA S.P.A.	FR
Syntocinon 6,7 mikrogram/dos nässpray, lösning	not available	6557	ALFASIGMA S.P.A.	SE

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Syntocinon 8,3 mikrogram/ml koncentrat till injektions- och infusionsv τ, tska, l τ snig	not available	6682	ALFASIGMA S.P.A.	SE
Syntocinon 5 I.E. Lösung zur Injektion	not available	10.424	ALFASIGMA S.P.A.	AT
Syntocinon 10 I.E./ml oplossing voor injectie of infusie	not available	BE031823	ALFASIGMA S.P.A.	BE
Syntocinon 10 u.i./ml solution injectable ou solution pour perfusion	not available	BE031823	ALFASIGMA S.P.A.	BE
Syntocinon 10 I.E./ml Injektionslösung oder Infusionslösung	not available	BE031823	ALFASIGMA S.P.A.	BE
OXYTOCIN - GAP διάλυμα προς έγχυση.	not available	108574/17-9-2019	GAP S.A.	GR
OXYTOCIN - GAP διάλυμα προς έγχυση.	not available	28362/18/17-7-2019	GAP S.A.	GR
Syntocinon® 5 IU/ml Concentrate for solution for infusion	not available	PL 46302/0062	MYLAN PRODUCTS LIMITED	UK
Syntocinon® 10 IU/ml Concentrate for solution for infusion	not available	PL 46302/0063	MYLAN PRODUCTS LIMITED	UK