



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 March 2018
EMA/266096/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): oxytocin

Procedure No.: PSUSA/00002263/201706

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525

Send a question via our website www.ema.europa.eu/contact

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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
Oxitocina Hikma, 10 UI/ml, Concentrado para solução para perfusão	not available	5668330	HIKMA FARMACÉUTICA (PORTUGAL), S.A.	PT
Oxitocina Hikma, 10 UI/ml, Concentrado para solução para perfusão	not available	5668348	HIKMA FARMACÉUTICA (PORTUGAL), S.A.	PT
OXYTOCIN - GAP διάλυμα προς έγχυση.	not available	45180/18-7-2013	GAP S.A.	GR
OXYTOCIN - GAP διάλυμα προς έγχυση.	not available	45181/18-7-2013	GAP S.A.	GR
Oxytocin "Orifarm", koncentrat til injektions-/infusionsvæske, opløsning	FI/H/0924/001	58109	ORIFARM GENERICS A/S	DK
Oxytocin "Orifarm", koncentrat til injektions-/infusionsvæske, opløsning	FI/H/0924/001	58109	ORIFARM GENERICS A/S	DK
Oxytocin "Orifarm", koncentrat til injektions-/infusionsvæske, opløsning	FI/H/0924/001	58109	ORIFARM GENERICS A/S	DK
Oxytocin Orifarm 10 IE, konsentrat til injeksjons-/infusionsvæske, oppløsning	FI/H/0924/002	16-11252	ORIFARM GENERICS A/S	NO
Oxytocin Orifarm 10 IE, konsentrat til injeksjons-/infusionsvæske, oppløsning	FI/H/0924/002	16-11252	ORIFARM GENERICS A/S	NO
Oxytocin Orifarm 10 IE, konsentrat til injeksjons-/infusionsvæske, oppløsning	FI/H/0924/002	16-11252	ORIFARM GENERICS A/S	NO
Oxytocin Orifarm 10 IU injektio-/infuusiokonsentraatti, liuosta varten	FI/H/0924/002	34363	ORIFARM GENERICS A/S	FI
Oxytocin Orifarm 10 IU injektio-/infuusiokonsentraatti, liuosta varten	FI/H/0924/002	34363	ORIFARM GENERICS A/S	FI

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Oxytocin Orifarm 10 IU injektio- /infuusiokonsentraatti, liuosta varten	FI/H/0924/002	34363	ORIFARM GENERICS A/S	FI
Syntocinon 10 a.e./ml stungulyf, lausn.	not available	640369	ALFASIGMA S.P.A.	IS
Syntocinon 10 i.e. koncentrat za raztopino za infundiranje / raztopina za injiciranje	not available	H/92/01479/002	NOVARTIS PHARMA GMBH	SI
Syntocinon 10 I.E./ml Injektionslösung oder Infusionslösung	not available	BE031823	ALFASIGMA S.P.A.	BE
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 40 i.e./ml prsilo za nos, raztopina	not available	H/92/01479/003	NOVARTIS PHARMA GMBH	SI
Syntocinon 40 IE/ml neusspray, oplossing	not available	RVG 03716	ALFASIGMA S.P.A.	NL
Syntocinon 5 i.e. koncentrat za raztopino za infundiranje / raztopina za injiciranje	not available	H/92/01479/001	NOVARTIS PHARMA GMBH	SI
Syntocinon 5 I.E. Lösung zur Injektion	not available	10424	ALFASIGMA S.P.A.	AT
Syntocinon 5 IE/ml, concentraat voor oplossing voor infusie; oplossing voor injectie	not available	RVG 03714	ALFASIGMA S.P.A.	NL
SYNTOCINON 5 U.I./ml Soluzione Iniettabile	not available	014684029	ALFASIGMA S.P.A.	IT

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Syntocinon 6,7 míkroög/skammt nefúði, lausn.	not available	880004	ALFASIGMA S.P.A.	IS
Syntocinon 6,7 mikrogram/dos n ̄, sspray, l ̄ka sning	not available	6557	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	SE
Syntocinon 8,3 mikrog/ml infuusiokonsentraatti, liuosta varten/injektioneste, liuos	not available	8850	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FI
Syntocinon 8,3 mikrogram/ml koncentrat till injektions- och infusionsv ̄, tska, l ̄ka sning	not available	6682	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	SE
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 Spray	not available	11.266	ALFASIGMA S.P.A.	AT
Syntocinon, 40 U.I./ml, solu ̄ ̄ ̄o para pulveriza ̄ ̄ ̄o nasal	not available	8889600	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	PT
Syntocinon, 5 U.I./ml, solu ̄ ̄ ̄o inject ̄. vel	not available	8889709	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	PT
Syntocinon, injektionsvæske, opløsning	not available	02456	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	DK
Syntocinon, næsespray, opløsning	not available	03152	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	DK
Syntocinon® 10 IU/ml Concentrate for solution for infusion	not available	088/03901	NOVARTIS PHARMACEUTICALS UK LIMITED	MT

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	not available	PL 00101/0960	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
SYNTOCINON® 10 IU/mL Concentrate for solution for infusion; Solution for injection	not available	18420	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
Syntocinon® 5 IU/ml Concentrate for solution for infusion	not available	PL 00101/0959	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
SYNTOCINON® 5 U.I. /1 ml, solution injectable en ampoule	not available	34009 310 301 9 5	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
SYNTOCINON® 5 U.I. /1 ml, solution injectable en ampoule	not available	34009 551 491 0 1	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
SYNTOCINON® 5 U.I. /1 ml, solution injectable en ampoule	not available	34009 562 198 8 9	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
SYNTOCINON® 6,7 mikrog/dose nes spray, oppløsning	not available	4115	ALFASIGMA S.P.A.	NO