



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 January 2018  
EMA/141276/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: irinotecan (except for liposomal formulations)

Procedure no.: PSUSA/00001783/201705



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Campto 20 mg/ml konzentrat za otopinu za infuziju	not available	HR-H-391779464	PFIZER CROATIA D.O.O.	HR
Campto 20 mg/ml konzentrat za otopinu za infuziju	not available	HR-H-391779464	PFIZER CROATIA D.O.O.	HR
Campto 20 mg/ml konzentrat za otopinu za infuziju	not available	HR-H-391779464	PFIZER CROATIA D.O.O.	HR
Campto 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	1-21770	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Campto 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	1-21770	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Campto 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	1-21770	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
CAMPTO 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	BE181291	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	BE181273	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	BE313485	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	2008029708	PFIZER S.A. (BELGIUM)	LU
CAMPTO 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	2008029708	PFIZER S.A. (BELGIUM)	LU
CAMPTO 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	FR/H/0108/002	2008029708	PFIZER S.A. (BELGIUM)	LU

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CAMPTO 20 mg/ml, concentraat voor oplossing voor infusie	FR/H/0108/002	BE181291	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml, concentraat voor oplossing voor infusie	FR/H/0108/002	BE313485	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml, concentraat voor oplossing voor infusie	FR/H/0108/002	BE181273	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml, concentraat voor oplossing voor infusie	FR/H/0108/002	RVG 22820	PFIZER B.V.	NL
CAMPTO 20 mg/ml, concentraat voor oplossing voor infusie	FR/H/0108/002	RVG 22820	PFIZER B.V.	NL
CAMPTO 20 mg/ml, concentraat voor oplossing voor infusie	FR/H/0108/002	RVG 22820	PFIZER B.V.	NL
CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PA 19/53/3	PFIZER LIMITED	IE
CAMPTO 20 mg/ml, concentrate for solution for infusion	not available	505/04703	PFIZER HELLAS, A.E.	MT
CAMPTO 20 mg/ml, concentrate for solution for infusion	not available	505/04702	PFIZER HELLAS, A.E.	MT
CAMPTO 20 mg/ml, concentrate for solution for infusion	not available	505/04701	PFIZER HELLAS, A.E.	MT
CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PL 00057/0627	PFIZER LIMITED	UK
CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PL 00057/0627	PFIZER LIMITED	UK

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CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PL 00057/0626	PFIZER LIMITED	UK
CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PL 00057/0627	PFIZER LIMITED	UK
CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PL 00057/0626	PFIZER LIMITED	UK
CAMPTO 20 mg/ml, concentrate for solution for infusion	FR/H/0108/002	PL 00057/0626	PFIZER LIMITED	UK
CAMPTO 20 mg/ml, concentrato per soluzione per infusione	FR/H/0108/002	032949051/M	PFIZER LIMITED	IT
CAMPTO 20 mg/ml, concentrato per soluzione per infusione	FR/H/0108/002	032949063/M	PFIZER LIMITED	IT
CAMPTO 20 mg/ml, concentrato per soluzione per infusione	FR/H/0108/002	032949048/M	PFIZER LIMITED	IT
Campto 20 mg/ml, innrennslisþykkni, lausn	not available	960194 (IS)	PFIZER APS	IS
Campto 20 mg/ml, innrennslisþykkni, lausn	not available	960194 (IS)	PFIZER APS	IS
Campto 20 mg/ml, innrennslisþykkni, lausn	not available	960194 (IS)	PFIZER APS	IS
CAMPTO 20 mg/ml, solution à diluer pour perfusion	FR/H/0108/002	BE181273	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml, solution à diluer pour perfusion	FR/H/0108/002	BE181291	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml, solution à diluer pour perfusion	FR/H/0108/002	BE313485	PFIZER S.A. (BELGIUM)	BE
CAMPTO 20 mg/ml, solution à diluer pour perfusion	FR/H/0108/002	2008029708	PFIZER S.A. (BELGIUM)	LU

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CAMPTO 20 mg/ml, solution à diluer pour perfusion	FR/H/0108/002	2008029708	PFIZER S.A. (BELGIUM)	LU
CAMPTO 20 mg/ml, solution à diluer pour perfusion	FR/H/0108/002	2008029708	PFIZER S.A. (BELGIUM)	LU
CAMPTO 20 mg/ml, solution à diluer pour perfusion (IV)	FR/H/0108/002	34009 572 692 5 8	PFIZER HOLDING FRANCE	FR
CAMPTO 20 mg/ml, solution à diluer pour perfusion (IV)	FR/H/0108/002	34009 572 690 2 9	PFIZER HOLDING FRANCE	FR
CAMPTO 20 mg/ml, solution à diluer pour perfusion (IV)	FR/H/0108/002	34009 572 691 9 7	PFIZER HOLDING FRANCE	FR
CAMPTO 20 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	not available	19188	PFIZER HELLAS, A.E.	CY
CAMPTO 20 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	FR/H/0108/002	18546/22-02-2016	PFIZER HELLAS, A.E.	GR
CAMPTO 20 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	FR/H/0108/002	18546/22-02-2016	PFIZER HELLAS, A.E.	GR
CAMPTO 20 mg/ml, πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	FR/H/0108/002	18546/22-02-2016	PFIZER HELLAS, A.E.	GR
CAMPTO koncentrát pro infuzní roztok	not available	44/014/98-C	PFIZER, SPOL. S R.O.	CZ
CAMPTO koncentrát pro infuzní roztok	not available	44/014/98-C	PFIZER, SPOL. S R.O.	CZ
CAMPTO koncentrát pro infuzní roztok	not available	44/014/98-C	PFIZER, SPOL. S R.O.	CZ
CAMPTO, 20 mg/ml, koncentrat do sporządzania roztworu do infuzji	not available	7521-7522	PFIZER EUROPE MA EEIG	PL
CAMPTO, 20 mg/ml, koncentrat do sporządzania roztworu do infuzji	not available	7521-7522	PFIZER EUROPE MA EEIG	PL

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CAMPTO, 20 mg/ml, koncentrat do sporządzenia roztworu do infuzji	not available	7521-7522	PFIZER EUROPE MA EEIG	PL
Campto, koncentrat til infusionsvæske, opløsning	FR/H/0108/002	18283	PFIZER APS	DK
Campto, koncentrat til infusionsvæske, opløsning	FR/H/0108/002	18283	PFIZER APS	DK
Campto, koncentrat til infusionsvæske, opløsning	FR/H/0108/002	18283	PFIZER APS	DK
Irinotecán Aurovitas 20 mg/ml concentrado para solución para perfusión	UK/H/1013/001	69.474	AUROVITAS SPAIN,S.A.U.	ES
Irinotecan EG 20 mg/ml concentraat voor oplossing voor infusie	NL/H/1326/001	BE336673	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml concentraat voor oplossing voor infusie	NL/H/1326/001	BE336691	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml concentraat voor oplossing voor infusie	NL/H/1326/001	BE336682	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	NL/H/1326/001	BE336673	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	NL/H/1326/001	BE336682	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	NL/H/1326/001	BE336691	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml solution à diluer pour perfusion	NL/H/1326/001	BE336673	EUROGENERICS N.V./S.A.	BE
Irinotecan EG 20 mg/ml solution à diluer pour perfusion	NL/H/1326/001	BE336691	EUROGENERICS N.V./S.A.	BE

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Irinotecan EG 20 mg/ml solution à diluer pour perfusion	NL/H/1326/001	BE336682	EUROGENERICS N.V./S.A.	BE