28 January 2021
EMA/150667/2021
Human Medicines Division

List of nationally authorised medicinal products

Active substance: irinotecan (except for liposomal formulations)

Procedure no.: PSUSA/00001783/202005

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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
CAMPTO 20 mg/ml concentrate for solution for infusion	FR/H/0108/002	PA 0822/212/001	PFIZER HEALTHCARE IRELAND	IE
CAMPTO 20 mg/ml concentrate for solution for infusion	FR/H/0108/002	PA 0822/212/001	PFIZER HEALTHCARE IRELAND	IE
CAMPTO 20 mg/ml concentrate for solution for infusion	FR/H/0108/002	PA 0822/212/001	PFIZER HEALTHCARE IRELAND	IE
CAMPTO 20 mg/ml concentrate for solution for infusion	not available	MA505/04703	PFIZER HELLAS, A.E.	MT
CAMPTO 20 mg/ml concentrate for solution for infusion	not available	MA505/04702	PFIZER HELLAS, A.E.	MT
CAMPTO 20 mg/ml concentrate for solution for infusion	not available	MA505/04701	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
CAMPTO 20 mg/ml concentrate for solution for infusion	FR/H/0108/002	PL 00057/0626	PFIZER LIMITED	UK

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
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 koncentrát pro infuzní roztok	not available	44/014/98-C	PFIZER, SPOL. S R.O.	CZ
CAMPTO 20 mg/ml koncentrát pro infuzní roztok	not available	44/014/98-C	PFIZER, SPOL. S R.O.	CZ
CAMPTO 20 mg/ml koncentrát pro infuzní roztok	not available	44/014/98-C	PFIZER, SPOL. S R.O.	CZ
Campto 20 mg/ml koncentrat za otopinu za infuziju	not available	HR-H-391779464	PFIZER CROATIA D.O.O.	HR
Campto 20 mg/ml koncentrat za otopinu za infuziju	not available	HR-H-391779464	PFIZER CROATIA D.O.O.	HR
Campto 20 mg/ml koncentrat za otopinu za infuziju	not available	HR-H-391779464	PFIZER CROATIA D.O.O.	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
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	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, concentrato per soluzione per infusione	FR/H/0108/002	032949051	PFIZER ITALIA S.R.L.	IT
CAMPTO 20 mg/ml, concentrato per soluzione per infusione	FR/H/0108/002	032949063	PFIZER ITALIA S.R.L.	IT
CAMPTO 20 mg/ml, concentrato per soluzione per infusione	FR/H/0108/002	032949048	PFIZER ITALIA S.R.L.	IT
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

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
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	not available	19188	PFIZER HELLAS, A.E.	CY
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

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
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, 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
CAMPTO, 20 mg/ml, koncentrat do sporządzania roztworu do infuzji	not available	7521-7522	PFIZER EUROPE MA EEIG	PL
Irinotecan 1.5 mg/ml solution for infusion.	DE/H/5810/001	PL 31750/0159	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
Irinotecán Aurovitas 20 mg/ml concentrado para solución para perfusión	PT/H/2037/001	69.474	AUROVITAS SPAIN,S.A.U.	ES
Irinotecan SUN 1,5 mg/ml solución para perfusión	DE/H/5810/001	85081	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/09	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO

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
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/08	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/04	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/01	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/05	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/06	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/11	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/12	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/10	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/07	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO

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
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/03	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml soluție perfuzabilă	DE/H/5810/001	13079/2020/02	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Irinotecan SUN 1,5 mg/ml solution pour perfusion	DE/H/5810/001	6 864 55 3	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR