



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 March 2021
EMA/156149/2021
Human Medicines Division

List of nationally authorised medicinal products

Active substance: ifosfamide

Procedure no.: PSUSA/00001723/202007

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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
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	17803.00.00	BAXTER ONCOLOGY GMBH	DE
Holoxan	not available	39654/16-09-2009	BAXTER HELLAS	GR
Holoxan	not available	39655/16-09-2009	BAXTER HELLAS	GR
Holoxan	not available	39656/16-09-2009	BAXTER HELLAS	GR
HOLOXAN 1 g	not available	6049/2005/01	BAXTER ONCOLOGY GMBH	RO
HOLOXAN 1 g	not available	6049/2005/02	BAXTER ONCOLOGY GMBH	RO
HOLOXAN 1 g polvere per soluzione per infusione	not available	023779061	BAXTER S.P.A.	IT
HOLOXAN 1 g süstelahuse pulber	not available	182497	BAXTER ONCOLOGY GMBH	EE
Holoxan 1 g - Trockensubstanz zur Injektionsbereitung	not available	16.940	BAXTER HEALTHCARE GMBH	AT
Holoxan 1000 mg milteliai infuziniam tirpalui	not available	LT/1/97/2937/002	BAXTER ONCOLOGY GMBH	LT
Holoxan 1000 mg Pó para solução injectável	not available	4408688	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Holoxan 1000 mg Pó para solução injectável	not available	8493866	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Holoxan 1000 mg por oldatos injekcióhoz	not available	OGYI-T-4756/02	BAXTER HUNGARY KFT.	HU
HOLOXAN 1000 mg poudre pour solution injectable	not available	BE117451	BAXTER SA	BE
HOLOXAN 1000 mg prašak za otopinu za injekciju/infuziju	not available	HR-H-792917744	BAXTER D.O.O.	HR
Holoxan 1000 mg pulver til injeksjonsvæske/infusjons	not available	04-2504	BAXTER HOLDING B.V.	NO

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væske, oppløsning				
Holoxan 1000 mg stungulyfsstofn/innrennsli stofn, lausn	not available	970408 (IS)	BAXTER MEDICAL AB	IS
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 369 177 2 9	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 369 178 9 7	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 369 179 5 8	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 369 180 3 0	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 550 286 9 7	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 550 287 1 0	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 550 287 2 7	BAXTER SAS	FR
HOLOXAN 1000 mg, poudre pour solution injectable	not available	34009 550 287 3 4	BAXTER SAS	FR
Holoxan 2 g - Trockensubstanz zur Injektionsbereitung	not available	16.941	BAXTER HEALTHCARE GMBH	AT
HOLOXAN 2 g polvere per soluzione per infusione	not available	023779059	BAXTER S.P.A.	IT
Holoxan 2000 mg Pó para solução injetável	not available	8493841	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Holoxan 2000 mg Pó para	not available	4408787	BAXTER MÉDICO-	PT

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solução injetável			FARMACÉUTICA, LDA.	
Holoxan 2000 mg por oldatos injekcióhoz	not available	OGYI-T-4756/03	BAXTER HUNGARY KFT.	HU
HOLOXAN 2000 mg poudre pour solution injectable	not available	BE128457	BAXTER SA	BE
Holoxan 2000 mg pulver til injeksjonsvæske/infusions væske, oppløsning	not available	04-2505	BAXTER HOLDING B.V.	NO
Holoxan 2000 mg stungulyfsstofn/innrennsli stofn, lausn	not available	970409 (IS)	BAXTER MEDICAL AB	IS
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 558 434 2 9	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 558 435 9 7	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 558 436 5 8	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 558 437 1 9	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 550 287 4 1	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 550 287 5 8	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 550 287 6 5	BAXTER SAS	FR
HOLOXAN 2000 mg, poudre pour usage parentéral	not available	34009 550 287 7 2	BAXTER SAS	FR

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parentéral				
Holoxan 500 mg milteliai infuziniam tirpalui	not available	LT/1/97/2937/001	BAXTER ONCOLOGY GMBH	LT
Holoxan 500 mg Pó para solução injectável	not available	4408589	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Holoxan 500 mg Pó para solução injectável	not available	8493858	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Holoxan 500 mg por oldatos injekcióhoz	not available	OGYI-T-4756/01	BAXTER HUNGARY KFT.	HU
HOLOXAN 500 mg poudre pour solution injectable	not available	BE117485	BAXTER SA	BE
HOLOXAN 500 mg prašak za otopinu za injekciju/infuziju	not available	HR-H-366159114	BAXTER D.O.O.	HR
Holoxan 500 mg pulver til injeksjonsvæske/infusions væske, oppløsning	not available	7315	BAXTER HOLDING B.V.	NO
Holoxan 500 mg stungulyfsstofn/innrennsli sstofn, lausn	not available	970407 (IS)	BAXTER MEDICAL AB	IS
HOLOXAN 500 mg süstelahuse pulber	not available	182397	BAXTER ONCOLOGY GMBH	EE
Holoxan injektio/infuusiokuiva-aine, liuosta varten	not available	10120	BAXTER OY	FI
Holoxan injektio/infuusiokuiva-aine, liuosta varten	not available	10120	BAXTER OY	FI
Holoxan injektio/infuusiokuiva-aine, liuosta varten	not available	10120	BAXTER OY	FI
Holoxan poudre pour préparation injectable 1 g	not available	0131839	BAXTER SA	LU
Holoxan poudre pour préparation injectable 2 g	not available	0131842	BAXTER SA	LU
Holoxan poudre pour	not available	0131856	BAXTER SA	LU

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préparation injectable 500 mg				
Holoxan pulver till injektions-/infusionsvätska, lösning	not available	11097	BAXTER MEDICAL AB	SE
Holoxan pulver till injektions-/infusionsvätska, lösning	not available	11097	BAXTER MEDICAL AB	SE
Holoxan pulver till injektions-/infusionsvätska, lösning	not available	11097	BAXTER MEDICAL AB	SE
Holoxan, 1 g proszek do sporządzania roztworu do wstrzykiwań	not available	R/2411	BAXTER POLSKA SP Z O.O.	PL
Holoxan, 2 g, proszek do sporządzania roztworu do wstrzykiwań	not available	R/2412	BAXTER POLSKA SP Z O.O.	PL
Holoxan, pulver til injektions- og infusionsvæske, opløsning	not available	10917	BAXTER A/S	DK
Holoxan, pulver til injektions- og infusionsvæske, opløsning	not available	10918	BAXTER A/S	DK
Holoxan, pulver til injektions- og infusionsvæske, opløsning	not available	10919	BAXTER A/S	DK
IFO-cell® 2 g Konzentrat zur Herstellung einer Infusionslösung Wirkstoff: Ifosfamid, 200 mg/ml	not available	6244127.00.00	STADAPHARM GMBH	DE
IFO-cell® 5 g Konzentrat zur Herstellung einer Infusionslösung Wirkstoff: Ifosfamid, 200 mg/ml	not available	6244558.00.00	STADAPHARM GMBH	DE
IFO-cell® N 1000 40 mg/ml Infusionslösung	not available	3000452.00.00	STADAPHARM GMBH	DE

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IFO-cell® N 2000 40 mg/ml Infusionslösung	not available	3000454.00.00	STADAPHARM GMBH	DE
IFOSFAMIDE EG 40 mg/ml, solution pour perfusion	not available	NL29337	EG LABO LABORATOIRES EUROGENERICIS	FR
Ifosfamide Injection 1g	not available	PL 00116/0392	BAXTER HEALTHCARE LTD.	UK
Ifosfamide Injection 2g	not available	PL 00116/0393	BAXTER HEALTHCARE LTD.	UK
Mitoxana 1 g Powder for Sterile Concentrate	not available	PA 2299/028/001	BAXTER HOLDING B.V.	IE
Mitoxana 2 g Powder for Sterile Concentrate	not available	PA 2299/028/002	BAXTER HOLDING B.V.	IE
Mitoxana 2 g Powder for Sterile Concentrate	not available	MA 1277/00701	BAXTER HOLDING B.V.	MT
TRONOXAL 1G INYECTABLE	not available	55577	BAXTER, S.L.	ES