



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2023
EMA/101604/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): mitoxantrone

Procedure No. PSUSA/00002076/202206



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
Ebexantron 2 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	not available	1-25423	EBEWE PHARMA	AT
Mitoxan 20mg/10mL Concentrate for Solution for Infusion.	not available	33994/14/08-06-15	MEDICAMERC S.A	GR
Mitoxantron "Ebewe", konzentrat til infusionsvæske, opløsning	DK/H/0439/001	30410	EBEWE PHARMA	DK
Mitoxantron 10 mg HEXAL Konzentrat zur Herstellung einer Infusionslösung	not available	50540.00.00	HEXAL AG	DE
Mitoxantron 20 mg HEXAL Konzentrat zur Herstellung einer Infusionslösung	not available	50540.01.00	HEXAL AG	DE
Mitoxantron Accord 2 mg/ml concentraat voor oplossing voor infusie	NL/H/0412/001	RVG 26663	ACCORD HEALTHCARE B.V.	NL
Mitoxantron Accord 2 mg/ml concentraat voor oplossing voor infusie	NL/H/0412/001	RVG 26663	ACCORD HEALTHCARE B.V.	NL
Mitoxantron Accord 2 mg/ml concentraat voor oplossing voor infusie	NL/H/0412/001	RVG 26663	ACCORD HEALTHCARE B.V.	NL
Mitoxantron Accord 2 mg/ml Konzentrat zur Herstellung einer Infusionslösung	NL/H/0412/001	93412.00.00	ACCORD HEALTHCARE B.V.	DE
Mitoxantron Accord 2 mg/ml Konzentrat zur	NL/H/0412/001	93412.00.00	ACCORD HEALTHCARE B.V.	DE

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Herstellung einer Infusionslösung				
Mitoxantron Accord 2 mg/ml Konzentrat zur Herstellung einer Infusionslösung	NL/H/0412/001	93412.00.00	ACCORD HEALTHCARE B.V.	DE
Mitoxantron Ebewe 2 mg/ml infuusiokonsentraatti, liuosta varten	DK/H/0439/001	18214	EBEWE PHARMA	FI
Mitoxantron Ebewe 2 mg/ml koncentrat till infusionsvätska, lösning	DK/H/0439/001	19475	EBEWE PHARMA	SE
Mitoxantron Ebewe 2 mg/ml koncentrat til infusionsvæske	DK/H/0439/001	03-1794	EBEWE PHARMA	NO
Mitoxantron HEXAL MS 10 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	not available	62526.00.00	HEXAL AG	DE
Mitoxantron HEXAL MS 20 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	not available	62527.00.00	HEXAL AG	DE
Mitoxantron Sandoz 2 mg/ml solution à diluer pour perfusion	DK/H/0439/001	2005069016	SANDOZ N.V.	LU
Mitoxantron Sandoz 2 mg/ml, concentraat voor oplossing voor infusie	DK/H/0439/001	RVG 29568	SANDOZ B.V.	NL
Mitoxantron Sandoz, 2 mg/ml, koncentrat do sporządzania roztworu do infuzji	DK/H/0439/001	24649	SANDOZ GMBH	PL
Mitoxantrona Accord 2 mg/ml Concentrado para solução para perfusão	NL/H/0412/001	5732938	ACCORD HEALTHCARE S.L.U.	PT

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Mitoxantrona Accord 2 mg/ml concentrado para solución para perfusión EFG	NL/H/0412/001	79737	ACCORD HEALTHCARE S.L.U.	ES
Mitoxantrona Accord 2 mg/ml concentrado para solución para perfusión EFG	NL/H/0412/001	79737	ACCORD HEALTHCARE S.L.U.	ES
Mitoxantrona Accord 2 mg/ml concentrado para solución para perfusión EFG	NL/H/0412/001	79737	ACCORD HEALTHCARE S.L.U.	ES
Mitoxantrona Jaba 2 mg/ml Solução injetável	not available	3419488	JABA RECORDATI, S.A.	PT
Mitoxantrona Pharmis 2 mg/ml solução injetável	not available	2207397	PHARMIS BIOFARMACÊUTICA, LDA.	PT
Mitoxantrona Pharmis 2 mg/ml solução injetável	not available	3233392	PHARMIS BIOFARMACÊUTICA, LDA.	PT
Mitoxantrona Pharmis 2 mg/ml solução injetável	not available	2207496	PHARMIS BIOFARMACÊUTICA, LDA.	PT
Mitoxantrona Pharmis 2 mg/ml solução injetável	not available	2207298	PHARMIS BIOFARMACÊUTICA, LDA.	PT
Mitoxantrona Sandoz 2 mg/ml concentrado para solución para perfusión	DK/H/0439/001	66166	SANDOZ FARMACÊUTICA, S.A.	ES
Mitoxantrone 2 mg/ml concentrate for solution for infusion	IE/H/0646/001	PA 0822/217/001	PFIZER HEALTHCARE IRELAND	IE
Mitoxantrone 2 mg/ml concentrate for solution for infusion	NL/H/0412/001	PL 20075/0412	ACCORD HEALTHCARE LIMITED	XI
Mitoxantrone 2 mg/ml concentrate for solution for infusion	NL/H/0412/001	PL 20075/0412	ACCORD HEALTHCARE LIMITED	XI
Mitoxantrone 2 mg/ml concentrate for solution for infusion	NL/H/0412/001	PL 20075/0412	ACCORD HEALTHCARE LIMITED	XI

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Mitoxantrone 2mg/ml Sterile Concentrate	not available	PL 14510/0033	EBEWE PHARMA	XI
Mitoxantrone 2mg/ml Sterile Concentrate	not available	PL 14510/0034	EBEWE PHARMA	XI
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 300 259 3 2	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 550 089 9 6	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 550 090 3 0	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 300 259 4 9	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 550 090 0 9	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 550 090 4 7	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 300 259 5 6	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 550 090 1 6	ACCORD HEALTHCARE FRANCE SAS	FR
MITOXANTRONE	NL/H/0412/001	34009 550 090 5 4	ACCORD HEALTHCARE	FR

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ACCORD 2 mg/mL, solution à diluer pour perfusion			FRANCE SAS	
MITOXANTRONE Baxter 2mg/ml Solução Injectável	not available	2706786	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
MITOXANTRONE Baxter 2mg/ml Solução Injectável	not available	2706885	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
MITOXANTRONE Baxter 2mg/ml Solução Injectável	not available	2706984	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
MITOXANTRONE Baxter 2mg/ml Solução Injectável	not available	2707081	BAXTER MÉDICO-FARMACÊUTICA, LDA.	PT
Mitoxantrone Sandoz 2 mg/ml - solution à diluer pour perfusion	DK/H/0439/001	0779205	SANDOZ N.V.	LU
Mitoxantrone Sandoz 2 mg/ml - solution à diluer pour perfusion	DK/H/0439/001	0779219	SANDOZ N.V.	LU
Mitoxantrone Sandoz 2 mg/ml - solution à diluer pour perfusion	DK/H/0439/001	0779222	SANDOZ N.V.	LU
Mitoxantrone Sandoz 2 mg/ml - solution à diluer pour perfusion	DK/H/0439/001	0779236	SANDOZ N.V.	LU
Mitoxantrone Sandoz 2 mg/ml - solution à diluer pour perfusion	DK/H/0439/001	0401108	SANDOZ N.V.	LU
Mitoxantrone Sandoz 2 mg/ml - solution à diluer pour perfusion	DK/H/0439/001	0401092	SANDOZ N.V.	LU
Mitoxantrone Sandoz 2 mg/ml concentraat voor oplossing voor infusie	DK/H/0439/001	BE269823	SANDOZ N.V.	BE
Mitoxantrone Sandoz 2	DK/H/0439/001	BE269832	SANDOZ N.V.	BE

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mg/ml concentraat voor oplossing voor infusie				
Mitoxantrone Sandoz 2 mg/ml, concentrato per soluzione per infusione.	DK/H/0439/001	036111019	SANDOZ S.P.A.	IT
Mitoxantrone Sandoz 2 mg/ml, concentrato per soluzione per infusione.	DK/H/0439/001	036111021	SANDOZ S.P.A.	IT
Mitoxantrone Sandoz 2 mg/ml, concentrato per soluzione per infusione.	DK/H/0439/001	036111033	SANDOZ S.P.A.	IT
Mitoxantrone Sandoz 2 mg/ml, concentrato per soluzione per infusione.	DK/H/0439/001	036111045	SANDOZ S.P.A.	IT
Mitoxantrone Sandoz 2 mg/ml, concentrato per soluzione per infusione.	DK/H/0439/001	036111058	SANDOZ S.P.A.	IT
Mitoxantrone Sandoz 2 mg/ml, concentrato per soluzione per infusione.	DK/H/0439/001	036111060	SANDOZ S.P.A.	IT
Novantron 10 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/002	42913.00.00	MEDA PHARMA GMBH & CO. KG	DE
Novantron 20 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/003	42914.00.00	MEDA PHARMA GMBH & CO. KG	DE
NOVANTRONE 10 mg/5 ml, solution à diluer pour perfusion	DE/H/4808/002	34009 5632302 9	MEDA PHARMA SAS	FR
Novantrone 2 mg/ml concentrado para solución para perfusión	DE/H/4808/003	57408	MYLAN IRE HEALTHCARE LIMITED	ES
Novantrone 2 mg/ml konsentrat til infusionsvæske	DE/H/4808/002	7299	VIATRIS AS	NO

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
Novantrone 20 mg/10 ml πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση	DE/H/4808/003	40109/10/27-05-2011	MEDA PHARMACEUTICALS S.A.	GR
NOVANTRONE 20 mg/10 ml, solution à diluer pour perfusion	DE/H/4808/003	34009 5632294 7	MEDA PHARMA SAS	FR
NOVANTROVE CONCENTRATE SOULTION FOR INFUSION 2MG/ML	DE/H/4808/003	11727	MEDA PHARMACEUTICALS S.A.	CY
Onkotrone	not available	3000713.00.00	BAXTER ONCOLOGY GMBH	DE
ONKOTRONE 10 mg/5 ml koncentrāts infūziju šķīduma pagatavošanai	not available	96-0548	BAXTER ONCOLOGY GMBH	LV
Onkotrone 2 mg/ml concentrat pentru soluție injectabilă	not available	8636/2016/02	BAXTER ONCOLOGY GMBH	RO
Onkotrone 2 mg/ml concentrat pentru soluție injectabilă	not available	8636/2016/01	BAXTER ONCOLOGY GMBH	RO
Onkotrone 2 mg/ml concentrat pentru soluție injectabilă	not available	8636/2016/03	BAXTER ONCOLOGY GMBH	RO
Onkotrone 2 mg/ml concentrat pentru soluție injectabilă	not available	8636/2016/04	BAXTER ONCOLOGY GMBH	RO
ONKOTRONE 2 mg/ml injekčný roztok	not available	44/0019/97-S	BAXTER SLOVAKIA S.R.O.	SK
ONKOTRONE 2 mg/ml koncentrat za raztopino za injiciranje/infundiranje	not available	H/99/01183/001	BAXTER D.O.O.	SI
Onkotrone 2 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/97/3010/001	BAXTER ONCOLOGY GMBH	LT
Onkotrone 2 mg/ml	not available	LT/1/97/3010/002	BAXTER ONCOLOGY GMBH	LT

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koncentratas infuziniam tirpalui				
Onkotrone 2 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-6341/01	BAXTER HUNGARY KFT.	HU
Onkotrone 2 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-6341/02	BAXTER HUNGARY KFT.	HU
ONKOTRONE 20 mg/10 ml koncentráts infúzijū šķiduma pagatavošanai	not available	06-0260	BAXTER ONCOLOGY GMBH	LV
ONKOTRONE 25 mg concentrato per soluzione per infusione	not available	033834033	BAXTER S.P.A.	IT
Onkotrone Injection 2 mg/ml concentrate for solution for infusion	not available	PL 00116/0398	BAXTER HEALTHCARE LTD.	XI
ONKOTRONE, 2 mg/ml süstelahus	not available	343301	BAXTER ONCOLOGY GMBH	EE
ONKOTRONE10 mg concentrato per soluzione per infusione	not available	033834019	BAXTER S.P.A.	IT
ONKOTRONE20 mg concentrato per soluzione per infusione	not available	033834021	BAXTER S.P.A.	IT
ONKOTRONE30 mg concentrato per soluzione per infusione	not available	033834045	BAXTER S.P.A.	IT
Ralenova 2 mg/ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/001	48571.00.00	MEDA PHARMA GMBH & CO. KG	DE
МИТОКСАНТРОН ЕБЕВЕ 2 МГ/МЛ КОНЦЕНТРАТ ЗА ИНФУЗИОНЕН ПАЗТВОР	not available	20050260	EBEWE PHARMA	BG

