



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2026
EMADOC-1700519818-2913321
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): mitoxantrone

EURD list No. PSUSA/00002076/202506



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
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 Ebewe 2 mg/ml infuusiokonsentraatti,	DK/H/0439/001	18214	EBEWE PHARMA	FI

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liuosta varten				
Mitoxantron Ebewe 2 mg/ml koncentrat till infusionsvätska, lösning	DK/H/0439/001	19475	EBEWE PHARMA	SE
Mitoxantron Ebewe 2 mg/ml konsentrat til infusjonsvæske	DK/H/0439/001	03-1794	EBEWE PHARMA	NO
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 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 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	not available	2207298	PHARMIS	PT

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mg/ml solução injetável			BIOFARMACÊUTICA, LDA.	
Mitoxantrona Sandoz	DK/H/0439/001	4996583	SANDOZ FARMACÊUTICA LDA.	PT
Mitoxantrona Sandoz	DK/H/0439/001	4996682	SANDOZ FARMACÊUTICA LDA.	PT
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
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,	NL/H/0412/001	34009 550 090 0 9	ACCORD HEALTHCARE FRANCE SAS	FR

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solution à diluer pour perfusion				
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 ACCORD 2 mg/mL, solution à diluer pour perfusion	NL/H/0412/001	34009 550 090 5 4	ACCORD HEALTHCARE FRANCE SAS	FR
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 concentraat voor oplossing voor infusie	DK/H/0439/001	BE269823	SANDOZ N.V.	BE
Mitoxantrone Sandoz 2 mg/ml concentraat voor oplossing voor infusie	DK/H/0439/001	BE269832	SANDOZ N.V.	BE

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Novantron 10 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/002	42913.00.00	VIATRIS HEALTHCARE GMBH	DE
Novantron 10 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/002	42913.00.00	VIATRIS HEALTHCARE GMBH	DE
Novantron 10 mg/5 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/002	42913.00.00	VIATRIS HEALTHCARE GMBH	DE
Novantron 20 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/003	42914.00.00	VIATRIS HEALTHCARE GMBH	DE
Novantron 20 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/003	42914.00.00	VIATRIS HEALTHCARE GMBH	DE
Novantron 20 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/4808/003	42914.00.00	VIATRIS HEALTHCARE GMBH	DE
NOVANTRONE 10 mg/5 ml, solution à diluer pour perfusion	DE/H/4808/002	34009 5632302 9	VIATRIS MEDICAL	FR
Novantrone 2 mg/ml concentrado para solución para perfusión	DE/H/4808/003	57408	MYLAN IRE HEALTHCARE LIMITED	ES
Novantrone 2 mg/ml concentrado para solución para perfusión	DE/H/4808/003	57408	MYLAN IRE HEALTHCARE LIMITED	ES
Novantrone 2 mg/ml concentrado para solución para perfusión	DE/H/4808/003	57408	MYLAN IRE HEALTHCARE LIMITED	ES

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Novantrone 2 mg/ml concentrado para solución para perfusión	DE/H/4808/003	57408	MYLAN IRE HEALTHCARE LIMITED	ES
Novantrone 2 mg/ml concentrado para solución para perfusión	DE/H/4808/003	57408	MYLAN IRE HEALTHCARE LIMITED	ES
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 infusjonsvæske	DE/H/4808/002	7299	VIATRIS AS	NO
Novantrone 2 mg/ml konsentrat til infusjonsvæske	DE/H/4808/002	7299	VIATRIS AS	NO
Novantrone 2 mg/ml konsentrat til infusjonsvæske	DE/H/4808/002	7299	VIATRIS AS	NO
Novantrone 2 mg/ml konsentrat til infusjonsvæske	DE/H/4808/002	7299	VIATRIS AS	NO
Novantrone 2 mg/ml konsentrat til infusjonsvæske	DE/H/4808/002	7299	VIATRIS AS	NO
Novantrone 2 mg/ml konsentrat til infusjonsvæske	DE/H/4808/002	7299	VIATRIS AS	NO
NOVANTRONE 20 mg/10 ml, solution à diluer pour perfusion	DE/H/4808/003	34009 5632294 7	VIATRIS MEDICAL	FR
Onkotrone	not available	3000713.00.00	BAXTER DEUTSCHLAND GMBH	DE
Onkotrone	not available	3000713.00.00	BAXTER DEUTSCHLAND GMBH	DE
Onkotrone	not available	3000713.00.00	BAXTER DEUTSCHLAND GMBH	DE

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Onkotrone	not available	3000713.00.00	BAXTER DEUTSCHLAND GMBH	DE
Onkotrone	not available	3000713.00.00	BAXTER DEUTSCHLAND GMBH	DE
Onkotrone	not available	3000713.00.00	BAXTER DEUTSCHLAND GMBH	DE
Onkotrone	not available	AA1277/04402	BAXTER HOLDING B.V.	MT
Onkotrone	not available	AA1277/04402	BAXTER HOLDING B.V.	MT
Onkotrone	not available	AA1277/04402	BAXTER HOLDING B.V.	MT
Onkotrone	not available	AA1277/04402	BAXTER HOLDING B.V.	MT
Onkotrone	not available	AA1277/04402	BAXTER HOLDING B.V.	MT
Onkotrone	not available	AA1277/04402	BAXTER HOLDING B.V.	MT
ONKOTRONE 2 mg/ ml koncentrāts infūziju šķīduma pagatavošanai	not available	06-0260	BAXTER LATVIA SIA	LV
ONKOTRONE 2 mg/ ml koncentrāts infūziju šķīduma pagatavošanai	not available	06-0260	BAXTER LATVIA SIA	LV
Onkotrone 2 mg/ml koncentrat pentru soluție injectabilă	not available	8636/2016/02	BAXTER HEALTHCARE SRL	RO
Onkotrone 2 mg/ml koncentrat pentru soluție injectabilă	not available	8636/2016/01	BAXTER HEALTHCARE SRL	RO
Onkotrone 2 mg/ml koncentrat pentru soluție injectabilă	not available	8636/2016/03	BAXTER HEALTHCARE SRL	RO
Onkotrone 2 mg/ml koncentrat pentru soluție injectabilă	not available	8636/2016/04	BAXTER HEALTHCARE SRL	RO
ONKOTRONE 2 mg/ml injekčný roztok	not available	44/0019/97-S	BAXTER SLOVAKIA S.R.O.	SK
ONKOTRONE 2 mg/ml injekčný roztok	not available	44/0019/97-S	BAXTER SLOVAKIA S.R.O.	SK
ONKOTRONE 2 mg/ml injekčný roztok	not available	44/0019/97-S	BAXTER SLOVAKIA S.R.O.	SK

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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	UAB "BAXTER LITHUANIA"	LT
Onkotrone 2 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/97/3010/002	UAB "BAXTER LITHUANIA"	LT
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 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 Injection 2 mg/ml concentrate for solution for infusion	not available	PL 00116/0398	BAXTER HEALTHCARE LTD.	XI
Onkotrone Injection 2 mg/ml concentrate for solution for infusion	not available	PL 00116/0398	BAXTER HEALTHCARE LTD.	XI
ONKOTRONE, 2 mg/ml infusioonilahuse kontsentraat	not available	343301	OÜ BAXTER ESTONIA	EE
ONKOTRONE, 2 mg/ml infusioonilahuse kontsentraat	not available	343301	OÜ BAXTER ESTONIA	EE

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ONKOTRONE, 2 mg/ml infusioonilahuse kontsentraat	not available	343301	OÜ BAXTER ESTONIA	EE
ONKOTRONE, 2 mg/ml süstelahus	not available	343301	OÜ BAXTER ESTONIA	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
МИТОКСАНТРОН ЕБЕВЕ 2 МГ/МЛ КОНЦЕНТРАТ ЗА ИНФУЗИОНЕН РАЗТВОР	not available	20050260	EBEWE PHARMA	BG