



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 July 2023
EMA/480303/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: idarubicin

Procedure no.: PSUSA/00001720/202211

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

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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
Idarubicin Ebewe 1 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0323/001	1-29858	EBEWE PHARMA	AT
Idarubicin Hexal 1 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	AT/H/0392/001	1-30550	HEXAL PHARMA GMBH	AT
Idarubicina Sandoz 1 mg/ml concentrado para solución para perfusión	AT/H/0323/001	75242	SANDOZ FARMACÉUTICA, S.A.	ES
Zavedos 1 mg/ml concentrado para solución para perfusión	not available	86001	PFIZER, S.L.	ES
Zavedos 1 mg/ml concentrado para solución para perfusión	not available	86001	PFIZER, S.L.	ES
Zavedos 1 mg/ml concentrado para solución para perfusión	not available	86001	PFIZER, S.L.	ES
ZAVEDOS 1 mg/ml injekčný roztok	not available	44/0206/18-S	PFIZER EUROPE MA EEIG	SK
Zavedos 1 mg/ml injektioneste, liuos	not available	13283	PFIZER OY	FI
Zavedos 1 mg/ml stungulyf, lausn.	not available	IS/17/079/01	PFIZER APS	IS
ZAVEDOS 10 mg capsule	not available	11180/2018/01	PFIZER EUROPE MA EEIG	RO
ZAVEDOS 10 mg Capsule Rigide	not available	027441043	PFIZER ITALIA S.R.L.	IT
Zavedos 10 mg Capsules	not available	PL 00057/1062	PFIZER LIMITED	XI
Zavedos 10 mg Hard Capsules	not available	PA 822/142/2	PFIZER HEALTHCARE IRELAND	IE
Zavedos 10 mg kapszula	not available	OGYI-T-5125/02	PFIZER KFT.	HU
ZAVEDOS 10 mg polvere	not available	027441029	PFIZER ITALIA S.R.L.	IT

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per soluzione iniettabile per uso endovenoso				
ZAVEDOS 10 mg polvo para concentrado para solución para perfusión	not available	60.071	PFIZER, S.L.	ES
Zavedos 10 mg por oldatos infúzióhoz	not available	OGYI-T-5125/05	PFIZER KFT.	HU
Zavedos 10 mg Powder for Solution for Injection	not available	PL 00057/1060	PFIZER LIMITED	XI
Zavedos 10 mg prašak za otopinu za injekciju	not available	HR-H-362248325	PFIZER CROATIA D.O.O.	HR
ZAVEDOS 10 mg prašek za raztopino za injiciranje	not available	H/93/01698/001	PFIZER LUXEMBOURG SARL	SI
ZAVEDOS 10 mg prášok na injekčný roztok	not available	44/0168/00-S	PFIZER EUROPE MA EEIG	SK
Zavedos 10 mg pulver til injeksjonsvæske, oppløsning	not available	11-8676	PFIZER AS	NO
ZAVEDOS 10 mg pulveris injekciju šķīduma pagatavošanai	not available	04-0055	PFIZER ITALIA S.R.L.	LV
Zavedos 10 mg stungulyfsstofn, lausn.	not available	890179	PFIZER APS	IS
ZAVEDOS 10 mg tvrdé kapsuly	not available	44/0155/99-S	PFIZER EUROPE MA EEIG	SK
Zavedos 10 mg κόνις για ενέσιμο διάλυμα	not available	12801/03-05-1991	PFIZER HELLAS, A.E.	GR
ZAVEDOS 10 mg, gélule	not available	34009 365 751 6 5	PFIZER HOLDING FRANCE	FR
ZAVEDOS 10 mg, poudre pour solution pour perfusion	not available	34009 557 482 3 6	PFIZER HOLDING FRANCE	FR
ZAVEDOS 10 mg, poudre pour solution pour	not available	34009 557 236 2 2	PFIZER HOLDING FRANCE	FR

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perfusion				
ZAVEDOS 10 mg, poudre pour solution pour perfusion	not available	34009 557 235 6 1	PFIZER HOLDING FRANCE	FR
ZAVEDOS 10 mg/10 ml soluzione iniettabile per uso endovenoso	not available	027441070	PFIZER ITALIA S.R.L.	IT
ZAVEDOS 10 mg/10 ml, solution pour perfusion	not available	34009 561 089 0 9	PFIZER HOLDING FRANCE	FR
ZAVEDOS 10 mg/10 ml, solution pour perfusion	not available	34009 562 866 0 7	PFIZER HOLDING FRANCE	FR
Zavedos 10mg Powder for Solution for Injection	not available	PA 822/142/4	PFIZER HEALTHCARE IRELAND	IE
Zavedos 1mg/mL Solution for Injection	not available	PA 822/142/5	PFIZER HEALTHCARE IRELAND	IE
Zavedos 1mg/mL Solution for Injection	not available	PA 822/142/5	PFIZER HEALTHCARE IRELAND	IE
Zavedos 1mg/mL Solution for Injection	not available	PA 822/142/5	PFIZER HEALTHCARE IRELAND	IE
Zavedos 1mg/mL Solution for Injection	not available	PL 00057/1520	PFIZER LIMITED	XI
Zavedos 1mg/mL Solution for Injection	not available	PL 00057/1520	PFIZER LIMITED	XI
Zavedos 1mg/mL Solution for Injection	not available	PL 00057/1520	PFIZER LIMITED	XI
ZAVEDOS 20 mg/20 ml, solution pour perfusion	not available	34009 561 090 9 8	PFIZER HOLDING FRANCE	FR
ZAVEDOS 20 mg/20 ml, solution pour perfusion	not available	34009 562 867 7 5	PFIZER HOLDING FRANCE	FR
ZAVEDOS 25 mg Capsule Rigide	not available	027441056	PFIZER ITALIA S.R.L.	IT
Zavedos 25 mg kapsel, hård	not available	11858	PFIZER AB	SE
Zavedos 25 mg kapszula	not available	OGYI-T-5125/03	PFIZER KFT.	HU

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ZAVEDOS 25 mg tvrdé kapsuly	not available	44/0156/99-S	PFIZER EUROPE MA EEIG	SK
ZAVEDOS 5 mg Capsule Rigide	not available	027441031	PFIZER ITALIA S.R.L.	IT
Zavedos 5 mg Capsules	not available	PL 00057/1064	PFIZER LIMITED	XI
Zavedos 5 mg Hard Capsules	not available	PA 822/142/1	PFIZER HEALTHCARE IRELAND	IE
Zavedos 5 mg kapseli, kova	not available	11345	PFIZER OY	FI
Zavedos 5 mg kapszula	not available	OGYI-T-5125/01	PFIZER KFT.	HU
ZAVEDOS 5 mg milteliai injekciniam tirpalui	not available	LT/1/99/0946/001	PFIZER EUROPE MA EEIG	LT
ZAVEDOS 5 mg polvo para concentrado para solución para perfusión	not available	60.072	PFIZER, S.L.	ES
Zavedos 5 mg por oldatos infúzióhoz	not available	OGYI-T-5125/04	PFIZER KFT.	HU
Zavedos 5 mg Powder for Solution for Injection	not available	PL 00057/1061	PFIZER LIMITED	XI
ZAVEDOS 5 mg prášek pro injekční roztok	not available	44/651/92-C	PFIZER, SPOL. S R.O.	CZ
ZAVEDOS 5 mg prášok na injekčný roztok	not available	44/0167/00-S	PFIZER EUROPE MA EEIG	SK
ZAVEDOS 5 mg pulbere pentru soluție injectabilă	not available	11181/2018/01	PFIZER EUROPE MA EEIG	RO
Zavedos 5 mg pulver til injeksjonsvæske, oppløsning	not available	00-07728	PFIZER AS	NO
ZAVEDOS 5 mg pulveris injekciju šķīduma pagatavošanai	not available	04-0054	PFIZER ITALIA S.R.L.	LV
Zavedos 5 mg stungulyfsstofn, lausn.	not available	890178	PFIZER APS	IS
ZAVEDOS 5 mg tvrdé	not available	44/0154/99-S	PFIZER EUROPE MA EEIG	SK

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kapsuly				
Zavedos 5 mg κόνις για ενέσιμο διάλυμα	not available	12718/03-05-1991	PFIZER HELLAS, A.E.	GR
ZAVEDOS 5 mg, gélule	not available	34009 365 749 1 5	PFIZER HOLDING FRANCE	FR
Zavedos 5 mg, kapsel, hård	not available	11856	PFIZER AB	SE
ZAVEDOS 5 mg, poudre pour solution pour perfusion	not available	34009 557 484 6 5	PFIZER HOLDING FRANCE	FR
ZAVEDOS 5 mg, poudre pour solution pour perfusion	not available	34009 557 237 9 0	PFIZER HOLDING FRANCE	FR
ZAVEDOS 5 mg, poudre pour solution pour perfusion	not available	34009 557 238 5 1	PFIZER HOLDING FRANCE	FR
ZAVEDOS 5 mg/5 ml polvere e solvente per soluzione iniettabile per uso endovenoso	not available	027441017	PFIZER ITALIA S.R.L.	IT
ZAVEDOS 5 mg/5 ml soluzione iniettabile per uso endovenoso	not available	027441068	PFIZER ITALIA S.R.L.	IT
ZAVEDOS 5 mg/5 ml, solution pour perfusion	not available	34009 562 865 4 6	PFIZER HOLDING FRANCE	FR
ZAVEDOS 5 mg/5 ml, solution pour perfusion	not available	34009 561 088 4 8	PFIZER HOLDING FRANCE	FR
Zavedos 5mg Powder for Solution for Injection	not available	PA 822/142/3	PFIZER HEALTHCARE IRELAND	IE
Zavedos CS 10 mg/10 ml solução injetável	not available	3239886	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos CS 10 mg/10 ml solução injetável	not available	3926185	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos CS 20 mg/20 ml solução injetável	not available	3926284	LABORATÓRIOS PFIZER, LDA.	PT

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Zavedos CS 20 mg/20 ml solução injetável	not available	3239985	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos CS 5 mg/5 ml solução injetável	not available	3239787	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos CS 5 mg/5 ml solução injetável	not available	3926086	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos CytoVial 10 mg Solution injectable	not available	BE231235	PFIZER S.A. (BELGIUM)	BE
Zavedos CytoVial 10 mg Solution injectable	not available	2002090034	PFIZER S.A. (BELGIUM)	LU
Zavedos CytoVial 20 mg Solution injectable	not available	BE231244	PFIZER S.A. (BELGIUM)	BE
Zavedos CytoVial 20 mg Solution injectable	not available	2002090035	PFIZER S.A. (BELGIUM)	LU
Zavedos CytoVial 5 mg Solution injectable	not available	BE231226	PFIZER S.A. (BELGIUM)	BE
Zavedos CytoVial 5 mg Solution injectable	not available	2002090033	PFIZER S.A. (BELGIUM)	LU
Zavedos, 1 mg/ml oplossing voor injectie	not available	RVG 119049	PFIZER B.V.	NL
Zavedos, 1 mg/ml oplossing voor injectie	not available	RVG 119049	PFIZER B.V.	NL
Zavedos, 1 mg/ml oplossing voor injectie	not available	RVG 119049	PFIZER B.V.	NL
Zavedos, 1 mg/ml süste-/infusioonilahus	not available	919816	PFIZER EUROPE MA EEIG	EE
Zavedos, 1 mg/ml, roztwór do wstrzykiwań	not available	25102	PFIZER EUROPE MA EEIG	PL
Zavedos, 1 mg/ml, roztwór do wstrzykiwań	not available	25102	PFIZER EUROPE MA EEIG	PL
Zavedos, 10 mg süste-/infusioonilahuse pulber	not available	285099	PFIZER EUROPE MA EEIG	EE
Zavedos, 10 mg, proszek do sporządzania	not available	R/2362	PFIZER EUROPE MA EEIG	PL

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roztworu do wstrzykiwań				
Zavedos, 5 mg süste-/infusioonilahuse pulber	not available	284999	PFIZER EUROPE MA EEIG	EE
Zavedos, 5 mg, proszek do sporządzania roztworu do wstrzykiwań	not available	R/2361	PFIZER EUROPE MA EEIG	PL
Zavedos, injektionsvæske, opløsning	not available	57275	PFIZER APS	DK
Zavedos, pulver til injektionsvæske, opløsning	not available	13549	PFIZER APS	DK
Zavedos, pulver til injektionsvæske, opløsning	not available	13548	PFIZER APS	DK
Zavedos, pulver till injektionsvätska, lösning	not available	11370	PFIZER AB	SE
Zavedos® 10 mg Kapseln	not available	1-21096	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Zavedos® 10 mg Trockenstechampulle	not available	1-19481	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Zavedos® 10 mg/10 ml Injektionslösung Wirkstoff: Idarubicinhydrochlorid	not available	40806.01.00	PFIZER PHARMA GMBH	DE
Zavedos® 20 mg/20 ml Injektionslösung Wirkstoff: Idarubicinhydrochlorid	not available	40806.02.00	PFIZER PHARMA GMBH	DE
Zavedos® 5 mg Kapseln	not available	1-21099	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT

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Zavedos® 5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung Wirkstoff: Idarubicinhydrochlorid	not available	19345.00.00	PFIZER PHARMA GMBH	DE
Zavedos® Oral 10 mg Hartkapseln Wirkstoff: Idarubicinhydrochlorid	not available	19345.01.01	PFIZER PHARMA GMBH	DE
Zavedos® Oral 5 mg Hartkapseln Wirkstoff: Idarubicinhydrochlorid	not available	19345.00.01	PFIZER PHARMA GMBH	DE
ЗАВЕДОС 10 mg прах за инфузионен разтвор	not available	20030569	PFIZER EUROPE MA EEIG	BG
ЗАВЕДОС 10 mg твърди капсули	not available	20030571	PFIZER EUROPE MA EEIG	BG
ЗАВЕДОС 5 mg прах за инфузионен разтвор	not available	20030568	PFIZER EUROPE MA EEIG	BG
ЗАВЕДОС 5 mg твърди капсули	not available	20030570	PFIZER EUROPE MA EEIG	BG