



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2017
EMA/593214/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): idarubicin

Procedure No.: PSUSA/00001720/201611



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 "Teva", injektionsvæske, opløsning	UK/H/1295/001	42338	TEVA DENMARK A/S	DK
Idarubicin 1 mg/ml Concentrate for Solution for Infusion	AT/H/0323/001	PL 14510/0058	EBEWE PHARMA	UK
Idarubicin Ebewe 1 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0323/001	1-29858	EBEWE PHARMA	AT
Idarubicin Ebewe 1 mg/ml, konzentrat till infusionsvätska, lösning	AT/H/0323/001	42693	EBEWE PHARMA	SE
Idarubicin Hexal 1 mg/ml - Konzentrat zur Herstellung einer Infusionslösung	AT/H/0392/001	1-30550	HEXAL PHARMA GMBH	AT
Idarubicin Hydrochloride 1 mg/ml Solution for Injection	UK/H/1295/001	PL 00289/1080	TEVA UK LIMITED	UK
Idarubicin Sandoz 1 mg/ml concentraat voor oplossing voor infusie	AT/H/0323/001	BE379827	SANDOZ N.V.	BE
Idarubicin Sandoz 1 mg/ml concentraat voor oplossing voor infusie	AT/H/0323/001	BE379836	SANDOZ N.V.	BE
Idarubicin Sandoz 1 mg/ml concentraat voor oplossing voor infusie	AT/H/0323/001	BE379845	SANDOZ N.V.	BE
Idarubicin Sandoz 1mg/ml - Konzentrat zur Herstellung einer Infusionslösung	AT/H/0393/001	1-30551	SANDOZ GMBH	AT
Idarubicin Teva, 1 mg/ml, roztwór do wstrzykiwań	UK/H/1295/001	17340	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL
Idarubicina Sandoz 1 mg/ml concentrado para solución para perfusión	AT/H/0323/001	75242	SANDOZ FARMACÉUTICA, S.A.	ES
Idarubicine HCl Sandoz 1 mg/ml, concentraat voor oplossing voor infusie	AT/H/0323/001	RVG 105232	SANDOZ B.V.	NL
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 530 7 5	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 534 2 6	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 536 5 5	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 537 1 6	SANDOZ	FR

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IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 535 9 4	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 533 6 5	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 539 4 5	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 531 3 6	SANDOZ	FR
IDARUBICINE SANDOZ 1 mg/ml, solution à diluer pour perfusion	AT/H/0323/001	34009 578 538 8 4	SANDOZ	FR
Idarubicin-Ebewe, 1 mg/ml, koncentrat do sporządzania roztworu do infuzji	AT/H/0323/001	18367	EBEWE PHARMA	PL
Zavedos 1 mg/ml injektioneste, liuos	not available	13283	PFIZER OY	FI
ZAVEDOS 10 mg	not available	7987/2006/01	PFIZER EUROPE MA EEIG	RO
ZAVEDOS 10 mg	not available	44/0155/99-S	PFIZER EUROPE MA EEIG	SK
ZAVEDOS 10 mg	not available	44/0168/00-S	PFIZER EUROPE MA EEIG	SK
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	UK
Zavedos 10 mg Gélules	not available	BE175761	PFIZER S.A. (BELGIUM)	BE
Zavedos 10 mg Gélules	not available	2002016450	PFIZER S.A. (BELGIUM)	LU
Zavedos 10 mg Hard Capsules	not available	PA 0822/142/002	PFIZER HEALTHCARE IRELAND	IE
Zavedos 10 mg Harde capsules	not available	BE175761	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 10 mg Hartkapseln	not available	BE175761	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 10 mg Hartkapseln	not available	2002016450	PFIZER S.A. (BELGIUM)	LU
Zavedos 10 mg kapsel, hård	not available	11346	PFIZER OY	FI
Zavedos 10 mg kapsel, hård	not available	11857	PFIZER AB	SE
Zavedos 10 mg kapseli, kova	not available	11346	PFIZER OY	FI
Zavedos 10 mg Kapseln	not available	1-21096	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Zavedos 10 mg kapszula	not available	OGYI-T-5125/02	PFIZER KFT.	HU
ZAVEDOS 10 mg milteliai injekciniam tirpalui	not available	LT/1/99/0946/002	PFIZER EUROPE MA EEIG	LT
Zavedos 10 mg Poeder voor oplossing voor	not available	BE153422	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
injectie				
ZAVEDOS 10 mg polvere per soluzione iniettabile per uso endovenoso	not available	027441029	PFIZER ITALIA S.R.L.	IT
Zavedos 10 mg por oldatos infúzióhoz	not available	OGYI-T-5125/05	PFIZER KFT.	HU
Zavedos 10 mg Poudre pour solution injectable	not available	BE153422	PFIZER S.A. (BELGIUM)	BE
Zavedos 10 mg Poudre pour solution injectable	not available	2002016448	PFIZER S.A. (BELGIUM)	LU
Zavedos 10 mg Powder for Solution for Injection	not available	PL 00057/1060	PFIZER LIMITED	UK
Zavedos 10 mg prašak za otopinu za injekciju	not available	UP/I-530-09/13-02/47	PFIZER CROATIA D.O.O.	HR
ZAVEDOS 10 mg prašek za raztopino za injiciranje	not available	5363-I-536/09	PFIZER LUXEMBOURG SARL	SI
Zavedos 10 mg pulver til injeksjonsvæske, oppløsning	not available	11-8676	PFIZER AS	NO
ZAVEDOS 10 mg Pulver zur Herstellung einer Injektionslösung	not available	BE153422	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 10 mg Pulver zur Herstellung einer Injektionslösung	not available	2002016448	PFIZER S.A. (BELGIUM)	LU
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 (IS)	PFIZER APS	IS
Zavedos 10 mg Trockenstechampulle	not available	1-19481	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
ZAVEDOS 10 mg, gélule	not available	34009 365 751 6 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 10 mg, poudre pour solution pour perfusion	not available	34009 557 482 3 6	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 10 mg, poudre pour solution pour perfusion	not available	34009 557 236 2 2	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 10 mg, poudre pour solution pour perfusion	not available	34009 557 235 6 1	PFIZER HOLDING FRANCE (S.C.A.)	FR

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
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 (S.C.A.)	FR
ZAVEDOS 10 mg/10 ml, solution pour perfusion	not available	34009 562 866 0 7	PFIZER HOLDING FRANCE (S.C.A.)	FR
Zavedos 10mg Powder for Solution for Injection	not available	PA 822/142/4	PFIZER HEALTHCARE IRELAND	IE
ZAVEDOS 20 mg/20 ml, solution pour perfusion	not available	34009 561 090 9 8	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 20 mg/20 ml, solution pour perfusion	not available	34009 562 867 7 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 25 mg	not available	44/0156/99-S	PFIZER EUROPE MA EEIG	SK
ZAVEDOS 25 mg Capsule Rigide	not available	027441056	PFIZER ITALIA S.R.L.	IT
Zavedos 25 mg Gélules	not available	BE175752	PFIZER S.A. (BELGIUM)	BE
Zavedos 25 mg Gélules	not available	2002016451	PFIZER S.A. (BELGIUM)	LU
Zavedos 25 mg Harde capsules	not available	BE175752	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 25 mg Hartkapseln	not available	BE175752	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 25 mg Hartkapseln	not available	2002016451	PFIZER S.A. (BELGIUM)	LU
Zavedos 25 mg kapsel, hård	not available	11858	PFIZER AB	SE
Zavedos 25 mg kapszula	not available	OGYI-T-5125/03	PFIZER KFT.	HU
ZAVEDOS 25 mg, gélule	not available	34009 365 748 5 4	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 5 mg	not available	44/0154/99-S	PFIZER EUROPE MA EEIG	SK
ZAVEDOS 5 mg	not available	44/0167/00-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	UK
Zavedos 5 mg Gélules	not available	BE175743	PFIZER S.A. (BELGIUM)	BE
Zavedos 5 mg Gélules	not available	2002016449	PFIZER S.A. (BELGIUM)	LU
Zavedos 5 mg Hard Capsules	not available	PA 822/142/1	PFIZER HEALTHCARE IRELAND	IE
Zavedos 5 mg Harde capsules	not available	BE175743	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 5 mg Hartkapseln	not available	BE175743	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 5 mg Hartkapseln	not available	2002016449	PFIZER S.A. (BELGIUM)	LU

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
Zavedos 5 mg kapsel, hård	not available	11345	PFIZER OY	FI
Zavedos 5 mg kapseli, kova	not available	11345	PFIZER OY	FI
Zavedos 5 mg Kapseln	not available	1-21099	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
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 Poeder voor oplossing voor injectie	not available	BE153553	PFIZER S.A. (BELGIUM)	BE
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 Poudre pour solution injectable	not available	BE153553	PFIZER S.A. (BELGIUM)	BE
Zavedos 5 mg Poudre pour solution injectable	not available	2002016447	PFIZER S.A. (BELGIUM)	LU
Zavedos 5 mg Powder for Solution for Injection	not available	PL 00057/1061	PFIZER LIMITED	UK
Zavedos 5 mg pulver til injeksjonsvæske, oppløsning	not available	00-07728	PFIZER AS	NO
ZAVEDOS 5 mg Pulver zur Herstellung einer Injektionslösung	not available	BE153553	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS 5 mg Pulver zur Herstellung einer Injektionslösung	not available	2002016447	PFIZER S.A. (BELGIUM)	LU
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 (IS)	PFIZER APS	IS
Zavedos 5 mg Trockenstechampulle	not available	1-19483	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
ZAVEDOS 5 mg, gélule	not available	34009 365 749 1 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
Zavedos 5 mg, kapsel, hård	not available	11856	PFIZER AB	SE

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
ZAVEDOS 5 mg, poudre pour solution pour perfusion	not available	34009 557 484 6 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 5 mg, poudre pour solution pour perfusion	not available	34009 557 237 9 0	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 5 mg, poudre pour solution pour perfusion	not available	34009 557 238 5 1	PFIZER HOLDING FRANCE (S.C.A.)	FR
ZAVEDOS 5 mg, pulbere pentru soluție injectabilă	not available	7110/2006/01	PFIZER EUROPE MA EEIG	RO
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 (S.C.A.)	FR
ZAVEDOS 5 mg/5 ml, solution pour perfusion	not available	34009 561 088 4 8	PFIZER HOLDING FRANCE (S.C.A.)	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
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 Injektionslösung	not available	BE231235	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS CytoVial 10 mg Injektionslösung	not available	2002090034	PFIZER S.A. (BELGIUM)	LU
Zavedos CytoVial 10 mg Oplossing voor injectie	not available	BE231235	PFIZER S.A. (BELGIUM)	BE
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 Injektionslösung	not available	BE231244	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS CytoVial 20 mg Injektionslösung	not available	2002090035	PFIZER S.A. (BELGIUM)	LU
Zavedos CytoVial 20 mg Oplossing voor	not available	BE231244	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
injectie				
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 Injektionslösung	not available	BE231226	PFIZER S.A. (BELGIUM)	BE
ZAVEDOS CytoVial 5 mg Injektionslösung	not available	2002090033	PFIZER S.A. (BELGIUM)	LU
Zavedos CytoVial 5 mg Oplossing voor injectie	not available	BE231226	PFIZER S.A. (BELGIUM)	BE
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 injektiokuiva-aïne, liuosta varten	not available	10691	PFIZER OY	FI
Zavedos injektiokuiva-aïne, liuosta varten	not available	10691	PFIZER OY	FI
Zavedos injektionsvätska, lösning	not available	13283	PFIZER OY	FI
Zavedos Oral 10 mg cápsulas	not available	2303188	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos Oral 10 mg cápsulas	not available	2303287	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos Oral 25 mg cápsulas	not available	2303386	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos Oral 25 mg cápsulas	not available	2303485	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos Oral 5 mg cápsulas	not available	2303089	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos Oral 5 mg cápsulas	not available	2302982	LABORATÓRIOS PFIZER, LDA.	PT
Zavedos pulver till injektionsvätska, lösning	not available	10691	PFIZER OY	FI
Zavedos pulver till injektionsvätska, lösning	not available	10691	PFIZER OY	FI
ZAVEDOS Prášek pro injekční roztok	not available	44/651/92-C	PFIZER, SPOL. S R.O.	CZ
ZAVEDOS Prášek pro injekční roztok	not available	44/651/92-C	PFIZER, SPOL. S R.O.	CZ
Zavedos, 1 mg/ml süste-/infusioonilahus	not available	919816	PFIZER ENTERPRISES SARL	EE
Zavedos, 10 mg süste-/infusioonilahuse pulber	not available	285099	PFIZER ENTERPRISES SARL	EE
Zavedos, 10 mg, proszek do sporządzania roztworu do wstrzykiwań	not available	R/2362	PFIZER EUROPE MA EEIG	PL
Zavedos, 5 mg süste-/infusioonilahuse pulber	not available	284999	PFIZER ENTERPRISES SARL	EE
Zavedos, 5 mg, proszek do sporządzania roztworu do wstrzykiwań	not available	R/2361	PFIZER EUROPE MA EEIG	PL
Zavedos, poeder voor oplossing voor injectie	not available	RVG 14201	PFIZER B.V.	NL

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10 mg				
Zavedos, poeder voor oplossing voor injectie 5 mg	not available	RVG 14201	PFIZER B.V.	NL
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, pulver till injektionsvätska, lösning	not available	11370	PFIZER AB	SE
Zavedos, pulver till injektionsvätska, lösning	not available	11370	PFIZER AB	SE
Zavedos® 10 mg/10 ml Injektionslösung Wirkstoff: Idarubicinhydrochlorid	not available	40806.01.00	PFIZER PHARMA PFE GMBH	DE
Zavedos® 20 mg/20 ml Injektionslösung Wirkstoff: Idarubicinhydrochlorid	not available	40806.02.00	PFIZER PHARMA PFE GMBH	DE
Zavedos® 5 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung Wirkstoff: Idarubicinhydrochlorid	not available	19345.00.00	PFIZER PHARMA PFE GMBH	DE
Zavedos® Oral 10 mg Hartkapseln Wirkstoff: Idarubicinhydrochlorid	not available	19345.01.01	PFIZER PHARMA PFE GMBH	DE
Zavedos® Oral 25 mg Hartkapseln Wirkstoff: Idarubicinhydrochlorid	not available	19345.02.01	PFIZER PHARMA PFE GMBH	DE
Zavedos® Oral 5 mg Hartkapseln Wirkstoff: Idarubicinhydrochlorid	not available	19345.00.01	PFIZER PHARMA PFE GMBH	DE
ZAVEDOS 10 mg polvo para concentrado para solución para perfusión	not available	60.071	PFIZER, S.L.	ES
ZAVEDOS	not available	12801/03.05.91	PFIZER HELLAS, A.E.	GR
ZAVEDOS	not available	12718/03.05.91	PFIZER HELLAS, A.E.	GR
ЗАВЕДОС 10 mg капсули, твърди	not available	20030571	PFIZER ENTERPRISES SARL	BG
ЗАВЕДОС 10 mg прах за инфузионен разтвор	not available	20030569	PFIZER ENTERPRISES SARL	BG
ЗАВЕДОС 5 mg капсули, твърди	not available	20030570	PFIZER ENTERPRISES SARL	BG
ЗАВЕДОС 5 mg прах за инфузионен разтвор	not available	20030568	PFIZER ENTERPRISES SARL	BG

