



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 March 2018
EMA/191568/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): epirubicin

Procedure No.: PSUSA/00001234/201706



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
Epiham, injektions- og infusionsvæske, opløsning	not available	40330	HAMELN RDS GMBH	DK
Epirubicine HCl Pharmachemie 2 mg/ml, oplossing voor injectie of intraveneuze infusie	NL/H/1250/001	RVG 101490	PHARMACHEMIE B.V	NL
Epi Teva 2 mg/ml Injektionslösung oder Infusionslösung	NL/H/1250/001	71687.00.00	TEVA GMBH	DE
Epirubicin hydrochloride 10 mg Powder for Solution for Injection	-	PL 40378/0153	TORRENT PHARMA LTD.	UK
Epirubicin hydrochloride 50 mg Powder for Solution for Injection	-	PL 40378/0154	TORRENT PHARMA LTD.	UK
Epirubicin "Meda" 2mg/ml solution for injection	DK/H/0426/001	PL 14510/0041	EBEWE PHARMA	UK
Epirubicin 100 mg HEXAL® Injektionslösung	not available	50674.00.00	HEXAL AG	DE
Formorubicin PFS 2 mg/ml otopina za injekciju ili infuziju	not available	UP/I-530-09/12-02/389	PFIZER CROATIA D.O.O.	HR
Formorubicine 50 mg CytoVial Injektionslösung	not available	BE192446	PFIZER S.A. (BELGIUM)	BE
Formorubicine 20 mg Ready To Use Injektionslösung	not available	BE160185	PFIZER S.A. (BELGIUM)	BE
Formorubicine 10 mg Pulver zur Herstellung einer Injektionslösung	not available	BE130347	PFIZER S.A. (BELGIUM)	BE
Formorubicine 50 mg Ready To Use Injektionslösung	not available	BE160194	PFIZER S.A. (BELGIUM)	BE
Formorubicine 150 mg Pulver zur Herstellung einer Injektionslösung	not available	BE158566	PFIZER S.A. (BELGIUM)	BE
Formorubicine 200 mg CytoVial Injektionslösung	not available	BE225373	PFIZER S.A. (BELGIUM)	BE
Formorubicine 20 mg CytoVial Injektionslösung	not available	BE192455	PFIZER S.A. (BELGIUM)	BE
Formorubicine 10 mg CytoVial Injektionslösung	not available	BE192464	PFIZER S.A. (BELGIUM)	BE
Formorubicine 50 mg Pulver zur Herstellung einer Injektionslösung	not available	BE130331	PFIZER S.A. (BELGIUM)	BE
Formorubicine 10 mg Ready To Use Injektionslösung	not available	BE160176	PFIZER S.A. (BELGIUM)	BE
Formorubicine 50 mg Ready To Use oplossing voor injectie	not available	BE160194	PFIZER S.A. (BELGIUM)	BE
Formorubicine 10 mg Ready To Use oplossing	not available	BE160176	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
voor injectie				
Formorubicine 20 mg Ready To Use Injektionslösung	not available	2010080854	PFIZER S.A. (BELGIUM)	LU
Formorubicine 50 mg CytoVial Injektionslösung	not available	2010080851	PFIZER S.A. (BELGIUM)	LU
Formorubicine 10 mg Ready To Use Injektionslösung	not available	2010080853	PFIZER S.A. (BELGIUM)	LU
Formorubicine 50 mg Ready To Use Injektionslösung	not available	2010080855	PFIZER S.A. (BELGIUM)	LU
Formorubicine 200 mg CytoVial Injektionslösung	not available	2010080852	PFIZER S.A. (BELGIUM)	LU
Formorubicine 10 mg Pulver zur Herstellung einer Injektionslösung	not available	2010080846	PFIZER S.A. (BELGIUM)	LU
Formorubicine 20 mg CytoVial Injektionslösung	not available	2010080850	PFIZER S.A. (BELGIUM)	LU
Formorubicine 10 mg CytoVial Injektionslösung	not available	2010080849	PFIZER S.A. (BELGIUM)	LU
Formorubicine 150 mg Pulver zur Herstellung einer Injektionslösung	not available	2010080848	PFIZER S.A. (BELGIUM)	LU
Formorubicine 50 mg Pulver zur Herstellung einer Injektionslösung	not available	2010080847	PFIZER S.A. (BELGIUM)	LU
Formorubicine 10 mg Ready To Use solution injectable	not available	BE160176	PFIZER S.A. (BELGIUM)	BE
Formorubicine 50 mg Ready To Use solution injectable	not available	BE160194	PFIZER S.A. (BELGIUM)	BE
Formorubicina 2 mg/ml solución inyectable y para perfusión	not available	60.847	PFIZER, S.L.	ES
Formorubicina 2 mg/ml solución inyectable y para perfusión	not available	60.847	PFIZER, S.L.	ES
ФАРМОРУБИЦИН PFS 2 mg/ml инъекционен разтвор	not available	II-4264/19.02.2009	PFIZER ENTERPRISES SARL	BG
Formorubicin® 50 mg Stechampulle	not available	1-20179	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
FARMORUBICINA 50 mg Polvere per Soluzione per Infusione	not available	025197043	PFIZER LIMITED	IT
Formorubicin® 10 mg Stechampulle	not available	1-20181	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT

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
Farmorubicin® 200 mg Stechampulle	not available	1-21019	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Farmorubicine 10 mg poudre pour solution injectable	not available	BE130347	PFIZER S.A. (BELGIUM)	BE
Farmorubicin PFS 2 mg/ml otopina za injekciju ili infuziju	not available	UP/I-530-09/12-02/389	PFIZER CROATIA D.O.O.	HR
FARMORUBICIN PFS, 2 mg/ml (10 mg/5 ml), roztwór do wstrzykiwań i infuzji	not available	7525	PFIZER EUROPE MA EEIG	PL
FARMORUBICIN PFS, 2 mg/ml (200 mg/100 ml), roztwór do wstrzykiwań i infuzji	not available	7525	PFIZER EUROPE MA EEIG	PL
FARMORUBICINA 200 mg/100 ml Soluzione per Infusione per uso Endovenoso	not available	025197082	PFIZER LIMITED	IT
Farmorubicina 10 mg polvo y disolvente para solución inyectable y para perfusión	not available	57.200	PFIZER, S.L.	ES
Farmorubicine 20 mg Ready To Use solution injectable	not available	BE160185	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 150 mg poudre pour solution injectable	not available	BE158566	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 200 mg CytoVial solution injectable	not available	BE225373	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 20 mg CytoVial solution injectable	not available	BE192455	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 10 mg CytoVial solution injectable	not available	BE192464	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 50 mg poudre pour solution injectable	not available	BE130331	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 50 mg CytoVial solution injectable	not available	BE192446	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 200 mg CytoVial solution injectable	not available	2010080852	PFIZER S.A. (BELGIUM)	LU
Farmorubicine 50 mg poudre pour solution injectable	not available	2010080847	PFIZER S.A. (BELGIUM)	LU
Farmorubicin, pulver til injektionsvæske, opløsning	not available	11829	PFIZER APS	DK

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
FARMORUBICINE 50 mg, poudre pour solution pour perfusion	not available	34009 335 878 8 8	PFIZER HOLDING FRANCE (S.C.A.)	FR
Farriorubicine 10 mg CytoVial solution injectable	not available	2010080849	PFIZER S.A. (BELGIUM)	LU
FARMORUBICIN 50 mg jauhe injektioiliuosta/liuosta varten, virtsarakkoon	not available	9318	PFIZER OY	FI
Farriorubicine 150 mg poudre pour solution injectable	not available	2010080848	PFIZER S.A. (BELGIUM)	LU
Farriorubicin, pulver til injektionsvæske, opløsning	not available	12583	PFIZER APS	DK
Farriorubicine 50 mg CytoVial solution injectable	not available	2010080851	PFIZER S.A. (BELGIUM)	LU
Farriorubicine 20 mg CytoVial solution injectable	not available	2010080850	PFIZER S.A. (BELGIUM)	LU
FARMORUBICINE 150 mg, poudre pour solution injectable	not available	34009 557 473 4 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
Farriorubicine 10 mg poudre pour solution injectable	not available	2010080846	PFIZER S.A. (BELGIUM)	LU
Farriorubicin, pulver til injektionsvæske, opløsning	not available	11828	PFIZER APS	DK
FARMORUBICINA 50 mg/25 ml Soluzione per Infusione	not available	025197070	PFIZER LIMITED	IT
Farriorubicine 20 mg Ready To Use solution injectable	not available	2010080854	PFIZER S.A. (BELGIUM)	LU
FARMORUBICIN® 50 mg HL Pulver zur Herstellung einer Injektionslösung	not available	21825.00.00	PFIZER PHARMA PFE GMBH	DE
Pharriorubicin 2 mg/ml Solution for Injection	not available	PL 00057/1023	PFIZER LIMITED	UK
Pharriorubicin 2 mg/ml Solution for Injection	not available	PL 00057/1023	PFIZER LIMITED	UK
Pharriorubicin 2 mg/ml Solution for Injection	not available	PL 00057/1023	PFIZER LIMITED	UK
Pharriorubicin 2 mg/ml Solution for Injection	not available	PL 00057/1023	PFIZER LIMITED	UK
FARMORUBICINE 10 mg/5 ml, solution pour perfusion	not available	34009 561 501 9 9	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICINE 20 mg/10 ml, solution pour perfusion	not available	34009 561 502 5 0	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
FARMORUBICINE 200 mg/100 ml, solution pour perfusion	not available	34009 561 498 8 9	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICINE 10 mg/5 ml, solution pour perfusion	not available	34009 556 804 7 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICINE 50 mg/25 ml, solution pour perfusion	not available	34009 556 802 4 6	PFIZER HOLDING FRANCE (S.C.A.)	FR
Farmorubicin, injektionsvæske, opløsning	not available	13521	PFIZER APS	DK
FARMORUBICIN PFS, 2 mg/ml (10 mg/5 ml), roztwór do wstrzykiwań i infuzji	not available	7524	PFIZER EUROPE MA EEIG	PL
FARMORUBICIN PFS, 2 mg/ml (50 mg/25 ml), roztwór do wstrzykiwań i infuzji	not available	7525	PFIZER EUROPE MA EEIG	PL
FARMORUBICINE 50 mg/25 ml, solution pour perfusion	not available	34009 561 503 1 1	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICINE 10 mg, poudre pour solution pour perfusion	not available	34009 335 877 1 0	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICINE 200 mg/100 ml, solution pour perfusion	not available	34009 559 020 7 2	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICINE 20 mg/10 ml, solution pour perfusion	not available	34009 556 803 0 7	PFIZER HOLDING FRANCE (S.C.A.)	FR
FARMORUBICIN	not available	44399/15.09.2009	PFIZER HELLAS, A.E.	GR
FARMORUBICINA 10 mg/5 ml Soluzione per Infusione	not available	025197068	PFIZER LIMITED	IT
FARMORUBICIN	not available	44401/15.09.2009	PFIZER HELLAS, A.E.	GR
FARMORUBICIN	not available	44395/15.09.2009	PFIZER HELLAS, A.E.	GR
FARMORUBICIN	not available	44397/15.09.2009	PFIZER HELLAS, A.E.	GR
FARMORUBICINA 10 mg/5 ml Polvere e Solvente per Soluzione per Infusione	not available	025197031	PFIZER LIMITED	IT
Farmorubicine 10 mg Ready To Use solution injectable	not available	2010080853	PFIZER S.A. (BELGIUM)	LU
Farmorubicin 2 mg/ml stungulyf, lausn	not available	890024	PFIZER APS	IS
Farmorubicina 50 mg polvo para solución inyectable y para perfusión	not available	57.201	PFIZER, S.L.	ES
Farmorubicine 50 mg Ready To Use solution	not available	2010080855	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
injectable				
FARMORUBICIN PFS 2 mg/ml injekčný roztok	not available	44/0356/00-S	PFIZER EUROPE MA EEIG	SK
Formorubicine 20 mg CytoVial oplossing voor injectie	not available	BE192455	PFIZER S.A. (BELGIUM)	BE
Formorubicine 10 mg poeder voor oplossing voor injectie	not available	BE130347	PFIZER S.A. (BELGIUM)	BE
Formorubicine 20 mg Ready To Use oplossing voor injectie	not available	BE160185	PFIZER S.A. (BELGIUM)	BE
Formorubicine 50 mg CytoVial oplossing voor injectie	not available	BE192446	PFIZER S.A. (BELGIUM)	BE
Formorubicine 50 mg poeder voor oplossing voor injectie	not available	BE130331	PFIZER S.A. (BELGIUM)	BE
Formorubicine 200 mg CytoVial oplossing voor injectie	not available	BE225373	PFIZER S.A. (BELGIUM)	BE
Formorubicine 10 mg CytoVial oplossing voor injectie	not available	BE192464	PFIZER S.A. (BELGIUM)	BE
Formorubicine 150 mg poeder voor oplossing voor injectie	not available	BE158566	PFIZER S.A. (BELGIUM)	BE