



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2021

EMA/217651/2021

Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: epirubicin

Procedure No.: PSUSA/00001234/202006



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 20 mg CytoVial Injektionslösung	not available	2010080850	PFIZER S.A. (BELGIUM)	LU
Farmorubicine 10 mg CytoVial Injektionslösung	not available	2010080849	PFIZER S.A. (BELGIUM)	LU
Farmorubicine 200 mg CytoVial solution injectable	not available	2010080852	PFIZER S.A. (BELGIUM)	LU
Farmorubicine 50 mg CytoVial solution injectable	not available	2010080851	PFIZER S.A. (BELGIUM)	LU
FARMORUBICINA 50 mg Polvere per Soluzione per Infusione	not available	025197043	PFIZER ITALIA S.R.L.	IT
FARMORUBICINA 200 mg/100 ml Soluzione per Infusione per uso Endovenoso	not available	025197082	PFIZER ITALIA S.R.L.	IT
FARMORUBICINA 50 mg/25 ml Soluzione per Infusione	not available	025197070	PFIZER ITALIA S.R.L.	IT
FARMORUBICINA 10 mg/5 ml Soluzione per Infusione	not available	025197068	PFIZER ITALIA S.R.L.	IT
FARMORUBICINA 10 mg/5 ml Polvere e Solvente per Soluzione per Infusione	not available	025197031	PFIZER ITALIA S.R.L.	IT
Farmorubicina 2 mg/ml solución inyectable y para perfusión	not available	60.847	PFIZER, S.L.	ES
Farmorubicin PFS 2 mg/ml otopina za injekciju/ infuziju	not available	HR-H-060784644	PFIZER CROATIA D.O.O.	HR
Farmorubicin PFS 2 mg/ml otopina za injekciju/ infuziju	not available	HR-H-060784644	PFIZER CROATIA D.O.O.	HR
Epirubicin Hydrochloride 2 mg/ml Solution for Injection and Infusion	DK/H/0426/001	PL 04416/1598	SANDOZ LTD	UK
FARMORUBICIN	not available	44399/15.09.2009	PFIZER HELLAS, A.E.	GR

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	not available	44395/15.09.2009	PFIZER HELLAS, A.E.	GR
FARMORUBICIN	not available	44397/15.09.2009	PFIZER HELLAS, A.E.	GR
Farmorubicine 50 mg CytoVial Injektionslösung	not available	BE192446	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 200 mg CytoVial Injektionslösung	not available	BE225373	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 20 mg CytoVial Injektionslösung	not available	BE192455	PFIZER S.A. (BELGIUM)	BE
Farmorubicine 10 mg CytoVial solution injectable	not available	BE192464	PFIZER S.A. (BELGIUM)	BE
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
ФАРМОРУБИЦИН PFS 2 mg/ml инъекционен разтвор	not available	20030657	PFIZER EUROPE MA EEIG	BG
Farmorubicina 50 mg polvo para solución inyectable y para perfusión	not available	57.201	PFIZER, S.L.	ES
FARMORUBICINE 50 mg, poudre pour solution pour perfusion	not available	34009 335 878 8 8	PFIZER HOLDING FRANCE	FR
FARMORUBICINE 10 mg, poudre pour solution pour perfusion	not available	34009 335 877 1 0	PFIZER HOLDING FRANCE	FR
FARMORUBICIN PFS, 2 mg/ml, roztwór do wstrzykiwań i infuzji	not available	7525	PFIZER EUROPE MA EEIG	PL
FARMORUBICIN PFS, 2 mg/ml, roztwór do wstrzykiwań i infuzji	not available	7525	PFIZER EUROPE MA EEIG	PL

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FARMORUBICIN PFS, 2 mg/ml, roztwór do wstrzykiwań i infuzji	not available	7525	PFIZER EUROPE MA EEIG	PL
FARMORUBICIN® 50 mg HL Pulver zur Herstellung einer Injektionslösung	not available	21825.00.00	PFIZER PHARMA PFE GMBH	DE
Farmorubicin® 50 mg Stechampulle	not available	1-20179	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Farmorubicin® 10 mg Stechampulle	not available	1-20181	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Farmorubicin® 200 mg Stechampulle	not available	1-21019	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
FARMORUBICIN PFS 2 mg/ml injekčný roztok	not available	44/0356/00-S	PFIZER EUROPE MA EEIG	SK
Pharmorubicin 2 mg/ml Solution for Injection or Infusion	not available	PL 00057/1023	PFIZER LIMITED	UK
Pharmorubicin 2 mg/ml Solution for Injection or Infusion	not available	PL 00057/1023	PFIZER LIMITED	UK
Pharmorubicin 2 mg/ml Solution for Injection or Infusion	not available	PL 00057/1023	PFIZER LIMITED	UK
Pharmorubicin 2 mg/ml Solution for Injection or Infusion	not available	PL 00057/1023	PFIZER LIMITED	UK
FARMORUBICIN	not available	S01163	PFIZER HELLAS, A.E.	CY
FARMORUBICIN	not available	S01162	PFIZER HELLAS, A.E.	CY