



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2019
EMA/226016/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ceftriaxone

Procedure no.: PSUSA/00000613/201805

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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
Ceftriaxone 1g Powder for Solution for Injection or Infusion	not available	PL28395/0109	PHARMADREAMS LTD	UK
Ceftriaxone 2g Powder for Solution for Injection or Infusion	not available	PL28395/0110	PHARMADREAMS LTD	UK
Lopratin 250 mg Powder for Solution for Injection	UK/H/0570/001	PL 04416/0503	SANDOZ LTD	UK
Rocephin 250 mg Powder for solution for injection	UK/H/5791/001	PL 00031/0169	ROCHE PRODUCTS LTD	UK
Rocephin 1 g Powder for solution for injection or infusion	UK/H/5791/002	PL 00031/0171	ROCHE PRODUCTS LTD	UK
Rocephin 1g Powder for solution for injection or infusion	UK/H/5791/002	PA 50/62/5	ROCHE PRODUCTS LTD	IE
Rocephin 2 g Powder for solution for injection or infusion.	UK/H/5791/003	PL 00031/0172	ROCHE PRODUCTS LTD	UK
Rocefin 500 mg/2 ml polvere e solvente per soluzione iniettabile per uso intramuscolare	PT/H/1251/001	025202033	ROCHE S.P.A.	IT
Rocephin IM 500 mg Powder and Solvent for Solution for Injection	UK/H/6518/003	PL 00031/0842	ROCHE PRODUCTS LTD	UK

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
ROCEPHINE 500 mg/2 ml, poudre et solvant pour solution injectable (IM)	PT/H/1251/001	3400932675029	ROCHE	FR
Rocephine IM 1 g poeder en oplosmiddel voor oplossing voor injectie	UK/H/6518/02	BE129927	N.V. ROCHE S.A.	BE
Rocephine 1 g Pulver und Lösungsmittel zur Herstellung einer IM Injektionslösung	UK/H/5791/002	BE129927	N.V. ROCHE S.A.	BE
Rocephine IV 1 g poeder en oplosmiddel voor oplossing voor injectie	UK/H/5791/004	BE129936	N.V. ROCHE S.A.	BE
Rocephine 1 g Pulver und Lösungsmittel zur Herstellung einer IV Injektionslösung	UK/H/5791/002	BE129936	N.V. ROCHE S.A.	BE
Rocephine 2 g poeder voor oplossing voor infusie	UK/H/5791/002	BE129945	N.V. ROCHE S.A.	BE
Rocephine 2 g Pulver zur Herstellung einer Infusionslösung	UK/H/5791/002	BE129945	N.V. ROCHE S.A.	BE
Rocephalin CUM LIDOCAIN 1 g pulver och vätska till im-injektionsvätska, lösning	NL/H/3167/001	9315	ROCHE OY	FI

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
Rocephine IM 1 g Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	UK/H/5791/002	0178/07109519	N.V. ROCHE S.A.	LU
Rocephine IV 1 g Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	UK/H/5791/002	0178/07109520	N.V. ROCHE S.A.	LU
Rocephine 2 g Pulver zur Herstellung einer Infusionslösung	NL/H/3167/05	0178/07109518	N.V. ROCHE S.A.	LU
Rocephalin CUM LIDOCAIN 1 g injektiokuiva-aine ja liuotin, liuosta varten	NL/H/3167/001	9315	ROCHE OY	FI
Rocefin 1 g/3,5 ml - polvere e solvente per soluzione iniettabile per uso intramuscolare	NL/H/3167/002	025202058	ROCHE S.P.A.	IT
Rocefin 1 g/10 ml polvere e solvente per soluzione iniettabile per uso endovenoso	NL/H/3167/004	025202096	ROCHE S.P.A.	IT
Rocefin 2 g polvere per soluzione per infusione	NL/H/3167/005	025202108	ROCHE S.P.A.	IT
Rocefin 250 mg/2 ml polvere e solvente per soluzione iniettabile per	NL/H/3167/001	025202019	ROCHE S.P.A.	IT

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uso intramuscolare				
Rocephalin 2 g, pulver til infusionsvæske, opløsning	UK/H/5791/003	11726	ROCHE A/S	DK
Rocephalin 2 g innrennslisstofn, lausn	NL/H/3167/005	822943	ROCHE A/S	IS
Rocephalin 1 g, pulver og solvens til injektionsvæske, opløsning	UK/H/5791/002	11745	ROCHE A/S	DK
Rocephalin 1 g stungulyfsstofn og leysir, lausn	NL/H/3167/004	822947	ROCHE A/S	IS
Rocephin IV 1 g powder and solvent for solution for injection	UK/H/6518/004	PL 00031/0839	ROCHE PRODUCTS LTD	UK
Rocephin 1 g powder and solvent for solution for injection	UK/H/6518/004	PL 00031/0841	ROCHE PRODUCTS LTD	UK
Rocephin 2 g powder for solution for infusion	UK/H/6518/005	PL 00031/0837	ROCHE PRODUCTS LTD	UK
Rocephin IM 250 mg powder and solvent for solution for injection	UK/H/6518/004	PL 00031/0840	ROCHE PRODUCTS LTD	UK

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
Rocephin IV 500 mg powder and solvent for solution for injection	UK/H/6518/002	PL 00031/0838	ROCHE PRODUCTS LTD	UK
ROCEPHINE 1 g/3,5 ml, poudre et solvant pour solution injectable (IM)	NL/H/3167/002	3400932675258	ROCHE	FR
ROCEPHINE 1 g/10 ml, poudre et solvant pour solution injectable (IV)	NL/H/3167/004	3400932674886	ROCHE	FR
ROCEPHINE 500 mg/5 ml, poudre et solvant pour solution injectable (IV)	NL/H/3167/003	3400932674657	ROCHE	FR
Rocephine IV 1 g poudre et solvant pour solution injectable	UK/H/5791/004	0178/07109520	N.V. ROCHE S.A.	LU
Rocephine IV 1 g poudre et solvant pour solution injectable	UK/H/5791/004	BE129936	N.V. ROCHE S.A.	BE
Rocephine 2 g poudre pour solution pour perfusion	NL/H/3167/05	0178/07109518	N.V. ROCHE S.A.	LU
Rocephine IM 1 g poudre et solvant pour solution injectable	UK/H/5791/002	BE129927	N.V. ROCHE S.A.	BE
Rocephine 2 g poudre pour solution pour perfusion	UK/H/5791/002	BE129945	N.V. ROCHE S.A.	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
Rocephine IM 1 g poudre et solvant pour solution injectable	UK/H/5791/002	0178/07109519	N.V. ROCHE S.A.	LU
Rocephin 1g Powder and solvent for IM injection only	NL/H/3167/002	PA 50/62/8	ROCHE PRODUCTS LTD	IE
Ceftriaxon Sandoz 0,5 g – Pulver zur Herstellung einer Injektionslösung	NL/H/0423/001	1-25230	SANDOZ GMBH	AT
Ceftriaxone Sandoz 1 g poeder voor oplossing voor injectie/infusie	NL/H/0423/002	BE261186	SANDOZ N.V.	BE
Ceftriaxone Sandoz 2 g poeder voor oplossing voor injectie/infusie	NL/H/0423/003	BE261195	SANDOZ N.V.	BE
Ceftriaxone Sandoz 2 g poeder voor oplossing voor injectie/infusie	NL/H/0423/003	BE261204	SANDOZ N.V.	BE