



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2023
EMA/509005/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ceftriaxone

Procedure No. PSUSA/00000613/202305



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where the product is authorised
Ceftriaxon Sandoz 0,5 g – Pulver zur Herstellung einer Injektionslösung	NL/H/0423/001	1-25230	SANDOZ GMBH	AT
Rocephine IV 1 g poeder en oplosmiddel voor oplossing voor injectie	IT/H/0697/003	BE129936	N.V. ROCHE S.A.	BE
Rocephine IV 1 g Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	IT/H/0697/003	BE129936	N.V. ROCHE S.A.	BE
Rocephine 2 g poeder voor oplossing voor infusie	IT/H/0697/004	BE129945	N.V. ROCHE S.A.	BE
Rocephine 2 g Pulver zur Herstellung einer Infusionslösung	IT/H/0697/004	BE129945	N.V. ROCHE S.A.	BE
Rocephine IV 1 g poudre et solvant pour solution injectable	IT/H/0697/003	BE129936	N.V. ROCHE S.A.	BE
Rocephine 2 g poudre pour solution pour perfusion	IT/H/0697/004	BE129945	N.V. ROCHE S.A.	BE
Ceftriaxon DALI Pharma 250 mg Pulver zur Herstellung einer Injektionslösung	DE/H/6425/001	2204617.00.00	DALI PHARMA GMBH	DE
Ceftriaxon DALI Pharma 500 mg Pulver zur Herstellung einer Injektionslösung	DE/H/6425/002	2204618.00.00	DALI PHARMA GMBH	DE
Ceftriaxon DALI Pharma 1 g Pulver zur Herstellung einer Injektionslösung	DE/H/6425/003	2204619.00.00	DALI PHARMA GMBH	DE
ROCEPHINE 1 g/10 ml, poudre et solvant pour solution injectable (IV)	IT/H/0697/003	34009 326 748 8 6	ROCHE	FR
Rocephin 1g Powder for solution for injection/infusion.	IT/H/0697/002	PA2307/008/003	ROCHE PRODUCTS (IRELAND) LIMITED	IE

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Rocefin 1 g/10 ml polvere e solvente per soluzione iniettabile per uso endovenoso	IT/H/0697/003	025202096	ROCHE S.P.A.	IT
Rocefin 2 g polvere per soluzione per infusione	IT/H/0697/004	025202108	ROCHE S.P.A.	IT
Rocefin 1 g polvere per soluzione iniettabile/per infusione	IT/H/0697/005	025202122	ROCHE S.P.A.	IT
Rocephine IV 1 g Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	IT/H/0697/003	2007109520	N.V. ROCHE S.A.	LU
Rocephine 2 g Pulver zur Herstellung einer Infusionslösung	IT/H/0697/004	2007109518	N.V. ROCHE S.A.	LU
Rocephine IV 1g poudre et solvant pour solution injectable	IT/H/0697/003	2007109520	N.V. ROCHE S.A.	LU
Rocephine 2 g poudre pour solution pour perfusion	IT/H/0697/004	2007109518	N.V. ROCHE S.A.	LU
Ceftriaxone DALI Pharma 250 mg Powder for Solution for Injection	DE/H/6425/001	MA1435/00401	DALI PHARMA GMBH	MT
Ceftriaxone DALI Pharma 500 mg Powder for Solution for Injection	DE/H/6425/002	MA1435/00402	DALI PHARMA GMBH	MT
Ceftriaxone DALI Pharma 1 g Powder for Solution for Injection	DE/H/6425/003	MA1435/00403	DALI PHARMA GMBH	MT
Ceftriaxone 1g Powder for Solution for Injection or Infusion	not available	PL 48259/0085	NORTHUMBRIA PHARMA LIMITED	XI
Ceftriaxone 2g Powder for Solution for Injection or Infusion	not available	PL 56920/0002	VYOCURE AB	XI
Ceftriaxone 1g Powder for Solution for Injection or Infusion	not available	PL 56920/0001	VYOCURE AB	XI

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Ceftriaxone 2g Powder for Solution for Injection or Infusion	not available	PL 56920/0002	VYOCURE AB	XI
Lopratin 250 mg Powder for Solution for Injection	AT/H/0949/001	PL 04416/0503	SANDOZ LTD	XI
Ceftriaxone 1g Powder for Solution for Injection or Infusion	not available	PL 56920/0001	VYOCURE AB	XI