



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/72827/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ceftriaxone

Procedure no.: PSUSA/00000613/201505



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
Ceftriaxon Sandoz	UK/H/0570/001	1-25205	Sandoz Gmbh	Austria
Ceftriaxone Midas 500mg	DE/H4063/001/DC	91568.00.00	Midas Pharma Gmbh	Germany
Ceftriaxone Midas	DE/H/3802/001/DC	AIC 042675013	Midas Pharma Gmbh	Italy
Lopratin	UK/H/0570/001	PL 04416/0503	Sandoz Ltd	United Kingdom
Rocefin	NL/H/3167/001	025202019	Roche S.P.A.	Italy
Rocefin	NL/H/3167/002	025202058	Roche S.P.A.	Italy
Rocefin	NL/H/3167/004	025202096	Roche S.P.A.	Italy
Rocefin	NL/H/3167/005	025202108	Roche S.P.A.	Italy
Rocefin	PT/H/1251/001	025202033	Roche S.P.A.	Italy
Rocephalin		11726	Roche A/S	Denmark
Rocephalin		11745	Roche A/S	Denmark
Rocephalin		12290	Roche Ab	Sweden
Rocephalin		12291	Roche Ab	Sweden
Rocephalin		822943	Roche A/S	Iceland
Rocephalin		822947	Roche A/S	Iceland
Rocephalin	NL/H/3167/001	9315	Roche Oy	Finland
Rocephalin Cum Lidocain	NL/H/3167/001	9315	Roche Oy	Finland
Rocephin		1733/2009/01-02	Roche Romania Srl	Romania
Rocephin		95-0119	Roche Latvija Sia	Latvia
Rocephin	NL/H/3167/001	OGYI-T-1182/01	Roche (Magyarország) Kft	Hungary
Rocephin	PT/H/1251/001	OGYI-T-1182/02	Roche (Magyarország) Kft	Hungary
Rocephin	NL/H/3167/004	OGYI-T-1182/04	Roche (Magyarország) Kft	Hungary
Rocephin	NL/H/3167/001	4710489	Roche Farmacêutica Química, Lda.	Portugal

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Rocephin	NL/H/3167/001	4710588	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/001	8612564	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/001	RVG 09911	Roche Nederland B.V.	Netherlands
Rocephin	NL/H/3167/002	4710885	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/002	4710984	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/002	8612580	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/002	PA 50/62/8	Roche Products Ltd	Ireland
Rocephin	NL/H/3167/002	RVG 09913	Roche Nederland B.V.	Netherlands
Rocephin	NL/H/3167/003	32904.00.00	Roche Pharma Ag	Germany
Rocephin	NL/H/3167/003	RVG09915	Roche Nederland B.V.	Netherlands
Rocephin	NL/H/3167/004	4711081	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/004	4711180	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/004	8612523	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/005	32906.00.01	Roche Pharma Ag	Germany
Rocephin	NL/H/3167/005	4711289	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/005	4711388	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/005	8613638	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	NL/H/3167/005	RVG 09917	Roche Nederland B.V.	Netherlands

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Rocephin	NL/H3167/004	RVG 09916	Roche Nederland B.V.	Netherlands
Rocephin	PT/H/1251/001	4710687	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	PT/H/1251/001	4710786	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	PT/H/1251/001	8612572	Roche Farmacêutica Química, Lda.	Portugal
Rocephin	UK/H/5791/001	PL 00031/0169	Roche Products Ltd	United Kingdom
Rocephin	UK/H/5791/002	PA 50/62/5	Roche Products Ltd	Ireland
Rocephin	UK/H/5791/002	PL 00031/0171	Roche Products Ltd	United Kingdom
Rocephin	UK/H/5791/003	PL 00031/0172	Roche Products Ltd	United Kingdom
Rocephin I.V.	NL/H/3167/004	32904.01.00	Roche Pharma Ag	Germany
Rocephine	NL/H/3167/002	3400932675258	Roche	France
Rocephine	NL/H/3167/003	3400932674657	Roche	France
Rocephine	NL/H/3167/003	3400955462415	Roche	France
Rocephine	NL/H/3167/004	3400932674886	Roche	France
Rocephine	NL/H/3167/004	3400955462644	Roche	France
Rocephine	NL/H/3167/004	3400955483816	Roche	France
Rocephine	NL/H/3167/02	BE129927	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/02	BE129927	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/02	BE129927	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/04	BE129936	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/04	BE129936	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/04	BE129936	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/05	BE129945	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/05	BE129945	N.V. Roche S.A.	Belgium
Rocephine	NL/H/3167/05	BE129945	N.V. Roche S.A.	Belgium

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Rocephine	PT/H/1251/001	3400932675029	Roche	France
Rocephine	NL/H/3167/005	0178/07109518	N.V. Roche S.A.	Luxembourg
Rocephine	NL/H/3167/004	0178/07109520	N.V. Roche S.A.	Luxembourg
Rocephine	NL/H/3167/002	0178/07109519	N.V. Roche S.A.	Luxembourg
Rocephin	UK/H/5791/003	MA060/01303	Roche Products Ltd	Malta
Rocephin	UK/H/5791/002	MA060/01301	Roche Products Ltd	Malta
Rocephin	UK/H/5791/001	MA060/01302	Roche Products Ltd	Malta
Rocephalin	NL/H/3167/002	12292	Roche Ab	Sweden
Ceftriaxone Midas 2g	DE/H/4063/002/DC	91569.00.00	Midas Pharma Gmbh	Germany
Ceftriaxone Midas 1g	DE/H/3802/001/DC	89521.00.00	Midas Pharma Gmbh	Germany