



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2017
EMA/429979/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydroxycarbamide (except for centrally authorised product)

Procedure no.: PSUSA/00009182/201612



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
LITALIR 500 mg-Kapseln	not available	1-23.227	BRISTOL-MYERS SQUIBB GESMBH	AT
Litalir 500 mg trde kapsule	not available	H/94/00929/001	BRISTOL-MYERS SQUIBB SPOL. S R.O.	SI
Litalir 500 mg kemény kapszula	not available	OGYI-T-1878/01	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	HU
HYDREA 500 mg, gélule	not available	305 126-8	BRISTOL-MYERS SQUIBB	FR
HYDREA 500 mg capsule	not available	5178/2005/01	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	RO
Hydrea 500 mg capsules, hard	not available	BE048851	BRISTOL-MYERS SQUIBB BELGIUM NV	BE
Hydroxycarbamide 500 mg capsules, hard	UK/H/1732/001	PL 10880/0129	HEXAL AG	UK
Hydroxycarbamide 500 mg capsules, hard	UK/H/1731/001	PL 10880/0128	HEXAL AG	UK
Hydroxycarbamide 500 mg capsules, hard	UK/H/1733/001	PL 04416/0947	SANDOZ LTD	UK
Hydroxycarbamid HEXAL 500 mg	UK/H/1731/001	71991.00.00	HEXAL AG	DE
Hydroxycarbamid - 1 A Pharma 500 mg Hartkapseln	UK/H/1732/001	72483.00.00	1 A PHARMA GMBH	DE
Hydrea 500 mg cietās kapsulas	not available	00-0148	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	LV
HYDREA, 500 mg kõvakapslid	not available	348901	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI	EE

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
			KFT.	
ONCO CARBIDE	not available	021510019	TEOFARMA S.R.L.	IT
Хидреа 500 mg капсули, твърди	not available	9600254	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	BG
Litalir® 500 mg Hartkapseln	not available	6071862.00.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
Hydrea 500 mg kietosios kapsulės	not available	LT/1/98/0429/001	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	LT
Litalir 500 mg kapsule	not available	UP/I-530-09/11-02/107	BRISTOL-MYERS SQUIBB SPOL. S R.O.	HR
Hydrea 500 mg gélules	not available	2006058591-0054810	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
Hydrea 500 mg capsules, hard	not available	BE048851	BRISTOL-MYERS SQUIBB BELGIUM NV	BE
Hydrea 500 mg hårda kapslar	not available	14286	BRISTOL-MYERS SQUIBB AB	SE
Hydrea 500 mg hårda kapslar Hydroxikarbamid	not available	13345	BRISTOL-MYERS SQUIBB AB	FI
Hydrea 500 mg kapseli, kova	not available	13345	BRISTOL-MYERS SQUIBB AB	FI
Hydrea 500 mg Hard Capsules	not available	PA 0002/027/001	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	IE
Hydrea 500 mg Hard Capsules	not available	PL 0034/5044R	E.R. SQUIBB & SONS LIMITED	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
LITALIR 500 mg Tvrdé tobolky	not available	44/652/ 93 – C	BRISTOL-MYERS SQUIBB SPOL. S R.O.	CZ
HYDREA 500 mg cápsulas duras	not available	61.633	BRISTOL-MYERS SQUIBB SA	ES