



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 July 2018
EMA/584534/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydroxycarbamide (except for centrally authorised product)

Procedure no.: PSUSA/00009182/201712



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
HYDREA 500 mg cápsulas duras	not available	61.633	BRISTOL-MYERS SQUIBB SA	ES
HYDREA 500 mg capsule	not available	5178/2005/01	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	RO
Hydrea 500 mg cietās kapsulas	not available	00-0148	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	LV
Hydrea 500 mg gélules	not available	BE048851	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Hydrea 500 mg gélules	not available	2006058591-0054810	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
Hydrea 500 mg Hard Capsules	not available	PA 0002/027/001	BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED	IE
Hydrea 500 mg hårda kapslar	not available	13345	BRISTOL-MYERS SQUIBB AB	FI
Hydrea 500 mg hårda kapslar	not available	14286	BRISTOL-MYERS SQUIBB AB	SE
Hydrea 500 mg kapseli, kova	not available	13345	BRISTOL-MYERS SQUIBB AB	FI
Hydrea 500 mg kietosios kapsulės	not available	LT/1/98/0429/001	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	LT
HYDREA 500 mg, gélule	not available	305 126-8	BRISTOL-MYERS SQUIBB	FR
HYDREA, 500 mg kõvakapslid	not available	348901	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	EE
Hydroxycarbamid - 1 A Pharma 500 mg Hartkapseln	UK/H/1732/001	72483.00.00	1 A PHARMA GMBH	DE
Hydroxycarbamid HEXAL 500 mg	UK/H/1731/001	71991.00.00	HEXAL AG	DE
Hydroxycarbamide 500 mg capsules, hard	UK/H/1732/001	PL 10880/0129	HEXAL AG	UK
Hydroxycarbamide 500 mg capsules, hard	UK/H/1733/001	PL 04416/0947	SANDOZ 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
Hydroxyurea 500 mg capsules, hard	UK/H/1731/001	PL 10880/0128	HEXAL AG	UK
Litalir 500 mg kemény kapszula	not available	OGYI-T-1878/01	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	HU
Litalir 500 mg trde kapsule	not available	H/94/00929/001	BRISTOL-MYERS SQUIBB SPOL. S R.O.	SI
Litalir 500 mg tvrde kapsule	not available	HR-H-923595891	BRISTOL-MYERS SQUIBB SPOL. S R.O.	HR
LITALIR 500 mg Tvrde tobolky	not available	44/652/ 93 – C	BRISTOL-MYERS SQUIBB SPOL. S R.O.	CZ
LITALIR 500 mg-Kapseln	not available	1-23.227	BRISTOL-MYERS SQUIBB GESMBH	AT
Litalir® 500 mg Hartkapseln	not available	6071862.00.00	BRISTOL-MYERS SQUIBB GMBH & CO. KGAA	DE
ONCO CARBIDE	not available	021510019	TEOFARMA S.R.L.	IT
Хидреа 500 мг капсули, твърди	not available	9600254	BRISTOL-MYERS SQUIBB GYOGYSZERKERESKEDELMI KFT.	BG