



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 June 2023
EMA/327388/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydroxycarbamide (except for centrally authorised product)

Procedure no.: PSUSA/00009182/202212



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	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Hydroxycarbamid HEXAL 500 mg Hartkapseln	DE/H/5592/001	71991.00.00	HEXAL AG	DE
LITALIR 500 mg-Kapseln	not available	1-23.227	CHEPLAPHARM ARZNEIMITTEL GMBH	AT
Litalir® 500 mg Hartkapseln	not available	6071862.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
LITALIR 500 mg tvrdé tobolky	not available	44/652/93-C	CHEPLAPHARM ARZNEIMITTEL GMBH	CZ
Hydrea 500 mg kapseli, kova	not available	13345	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Hydrea 500 mg hård kapsel	not available	13345	CHEPLAPHARM ARZNEIMITTEL GMBH	FI
Hydrea 500 mg gélules	not available	2006058591	CHEPLAPHARM ARZNEIMITTEL GMBH	LU
Hydrea 500 mg Hartkapseln	not available	2006058591	CHEPLAPHARM ARZNEIMITTEL GMBH	LU

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
Hydroxycarbamide Pharmacenter 500 mg kemény kapszula	not available	OGYI-T-24061/01	PHARMACENTER EUROPE KFT.	HU
Hydrea 500 mg hårda kapslar	not available	14286	CHEPLAPHARM ARZNEIMITTEL GMBH	SE
Hydroxycarbamid 1A Pharma 1000 mg - Filmdabletten	AT/H/1172/002	141298	1A PHARMA GMBH	AT
Hydroxycarbamid 1A Pharma 100 mg - Filmdabletten	AT/H/1172/001	141297	1A PHARMA GMBH	AT
Hydrea 500 mg Hard Capsules	not available	PA 2239/021/001	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Hydrea 500 mg Hard Capsules	not available	PL45043/0113	NEON HEALTHCARE LIMITED	XI
Litalir 500 mg tvrde kapsule	not available	HR-H-923595891	CHEPLAPHARM ARZNEIMITTEL GMBH	HR
Hydroxycarbamid - 1 A Pharma 500 mg Hartkapseln	DE/H/5593/001	72483.00.00	1 A PHARMA GMBH	DE
Hydrea 500 mg cietās kapsulas	not available	00-0148	CHEPLAPHARM ARZNEIMITTEL GMBH	LV

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
Хидреа 500 mg капсули, твърди	not available	9600254	CHEPLAPHARM ARZNEIMITTEL GMBH	BG
ONCO CARBIDE	not available	021510019	TEOFARMA S.R.L.	IT
HYDREA 500 mg capsule	not available	11474/2019/01	BRISTOL-MYERS SQUIBB KFT.	RO
HYDREA, 500 mg kövakapslid	not available	348901	CHEPLAPHARM ARZNEIMITTEL GMBH	EE
Hydrea 500 mg capsules, hard	not available	BE048851	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Hydrea 500 mg gélules	not available	BE048851	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Hydrea 500 mg Hartkapseln	not available	BE048851	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Hydrea 500 mg capsules, hard	not available	BE048851	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Hydrea 500 mg gélules	not available	BE048851	CHEPLAPHARM ARZNEIMITTEL GMBH	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
Hydrea 500 mg Hartkapseln	not available	BE048851	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Litalir 500 mg trde kapsule	not available	H/94/00929/001	CHEPLAPHARM ARZNEIMITTEL GMBH	SI
Hydrea 500 mg kietosios kapsulės	not available	LT/1/98/0429/001	CHEPLAPHARM ARZNEIMITTEL GMBH	LT
HYDREA 500 mg, gélule	not available	34009 305 126 8 5	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
Litalir 500 mg kemény kapszula	not available	OGYI-T-1878/01	CHEPLAPHARM ARZNEIMITTEL GMBH	HU