



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2020
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: busulfan

Procedure no.: PSUSA/00000464/201907

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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
MYLERAN 2 mg-Filmtabletten	not available	10.775	ASPEN PHARMA TRADING LIMITED	AT
MYLERAN 2 mg comprimés pelliculés	not available	BE 058615	ASPEN PHARMA TRADING LIMITED	BE
MYLERAN 2 mg filmomhulde tabletten	not available	BE 058615	ASPEN PHARMA TRADING LIMITED	BE
MYLERAN 2mg Filmtabletten	not available	BE 058615	ASPEN PHARMA TRADING LIMITED	BE
Myleran 2 mg potahované tablety	not available	44/239/89-C	ASPEN PHARMA TRADING LIMITED	CZ
Myleran 2 mg Filmtabletten	not available	6101936.00.00	ASPEN PHARMA TRADING LIMITED	DE
MYLERAN, 2 mg õhukese polümeerikattega tabletid	not available	101095	ASPEN PHARMA TRADING LIMITED	EE
BUSULFANO ASPEN 2 mg comprimidos recubiertos	not available	33.323	ASPEN PHARMA TRADING LIMITED	ES

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
MYLERAN 2 mg, comprimé pelliculé	not available	369 231-7	ASPEN PHARMA TRADING LIMITED	FR
Myleran 2 mg film-coated tablets	not available	PA 1691/008/001	ASPEN PHARMA TRADING LIMITED	IE
Myleran 2 mg filmuhúðaðar töflur.	not available	772142	ASPEN PHARMA TRADING LIMITED	IS
MYLERAN 2 mg Comprimé rivestite con film	not available	024787018	ASPEN PHARMA TRADING LIMITED	IT
Myleran 2 mg plėvele dengtos tabletės	not available	LT/1/94/2445/001	ASPEN PHARMA TRADING LIMITED	LT
MYLERAN 2 mg comprimés pelliculés	not available	26/05/09/8259	ASPEN PHARMA TRADING LIMITED	LU
MYLERAN 2mg Filmtabletten	not available	26/05/09/8259	ASPEN PHARMA TRADING LIMITED	LU
Myleran 2 mg filmomhulde tabletten	not available	RVG 00262	ASPEN PHARMA TRADING LIMITED	NL

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
Myleran, 2 mg, tabletki powlekane	not available	R/2779	ASPEN PHARMA TRADING LIMITED	PL
MYLERAN® 2 mg comprimidos	not available	8144212	ASPEN PHARMA TRADING LIMITED	PT
Myleran, 2 mg, comprimate filmate	not available	546/2008/02	ASPEN PHARMA TRADING LIMITED	RO
Myleran, 2 mg, comprimate filmate	not available	546/2008/01	ASPEN PHARMA TRADING LIMITED	RO
Myleran 2 mg filmdragerade tabletter	not available	5013	ASPEN PHARMA TRADING LIMITED	SE
Myleran 2 mg filmom obalené tablety	not available	44/0239/89-C/S	ASPEN PHARMA TRADING LIMITED	SK
Busulfan 2 mg tablets	not available	PL 39699/ 0042	ASPEN PHARMA TRADING LIMITED	UK