



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2024
EMA/574760/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): aztreonam (parenteral use)

Procedure No. PSUSA/00010178/202308



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
AZACTAM 1 g – Trockenstechampulle	not available	1-18328	BRISTOL-MYERS SQUIBB GESMBH	AT
AZACTAM 2 g – Trockenstechampulle	not available	1-18329	BRISTOL-MYERS SQUIBB GESMBH	AT
Azactam 1 g poudre pour solution injectable	not available	BE132352	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Azactam 2 g poudre pour solution injectable	not available	BE132334	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Azactam 1 g poeder voor oplossing voor injectie	not available	BE132352	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Azactam 2 g poeder voor oplossing voor injectie	not available	BE132334	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Azactam 1 g Pulver zur Herstellung einer Injektionslösung	not available	BE132352	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Azactam 2 g Pulver zur Herstellung einer Injektionslösung	not available	BE132334	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
Azactam 1g polvo para solución inyectable	not available	57.781	BRISTOL-MYERS SQUIBB SA	ES
AZACTAM® pulver till injektions-/infusionsvätska, lösning.	not available	10819	BRISTOL-MYERS SQUIBB AB	FI
AZACTAMâ pulver till injektions-/infusionsvätska, lösning.	not available	10819	BRISTOL-MYERS SQUIBB AB	FI
AZACTAM® injektio- ja infuusiokuiva-aine, liuosta varten.	not available	10819	BRISTOL-MYERS SQUIBB AB	FI
AZACTAM® injektio- ja infuusiokuiva-aine, liuosta varten.	not available	10819	BRISTOL-MYERS SQUIBB AB	FI
AZACTAM 1 g, poudre et	not available	34009 329 710 1 5	AMDIPHARM LIMITED	FR

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solution pour usage parentéral				
AZACTAM 1 g, poudre et solution pour usage parentéral	not available	34009 369 208 5 9	AMDIPHARM LIMITED	FR
Azactam 1 g Powder for Solution for Injection or Infusion	not available	PA 2/52/2	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	IE
Azactam 2 g Powder for Solution for Injection or Infusion	not available	PA 2/52/3	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	IE
Azactam 2 g poudre pour solution injectable	not available	2009070452-0009894	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
Azactam 1 g poudre pour solution injectable	not available	2009070451-0009880	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
Azactam 1 g Pulver zur Herstellung einer Injektionslösung	not available	2009070451-0009880	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
Azactam 2 g Pulver zur Herstellung einer Injektionslösung	not available	2009070452-0009894	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
AZACTAM 2 g pulver til injeksjons-/infusjonsvæske, oppløsning	not available	06-4041	BRISTOL-MYERS SQUIBB AB	NO
Azactam 1000 mg pó para solução injetável	not available	5752902	BRISTOL-MYERS SQUIBB FARMACÉUTICA PORTUGUESA, SA	PT
Azactam 1000 mg pó para solução injetável	not available	5752878	BRISTOL-MYERS SQUIBB FARMACÉUTICA PORTUGUESA, SA	PT
Azactam 1000 mg pulbere pentru soluție injectabilă	not available	5/2023/01	BRISTOL-MYERS SQUIBB ROMANIA S.R.L.	RO
Azactam 1000 mg pulbere pentru soluție injectabilă	not available	5/2023/02	BRISTOL-MYERS SQUIBB ROMANIA S.R.L.	RO
Azactam, pulver till	not available	10284	BRISTOL-MYERS SQUIBB AB	SE

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injektions- /infusionsvätska, lösning				
Azactam, pulver till injektions- /infusionsvätska, lösning	not available	10284	BRISTOL-MYERS SQUIBB AB	SE
Azactam 1 g Powder for Solution for Injection or Infusion	not available	PL 12038/0002	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	XI
Azactam 2 g Powder for Solution for Injection or Infusion	not available	PL 12038/0003	BRISTOL-MYERS SQUIBB PHARMACEUTICALS UNLIMITED COMPANY	XI