



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 2017
EMA/302920/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): biperiden

Procedure No.: PSUSA/00000415/201608



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
AKINETON L.P. 4 mg, comprimé enrobé à libération prolongée	not available	3149889-6	DESMA PHARMA	FR
Akineton® 2 mg tablete	not available	UP/I-530-09/10-02/282	DESMA D.O.O.	HR
Akineton 5 mg/ml otopina za injekciju	not available	UP/I-530-09/10-02/283	DESMA D.O.O.	HR
Akineton	not available	8920710	DESMA LABORATORIO FARMACÉUTICO SL	PT
Akineton 2 mg comprimate	not available	4133/2011/01	DESMA GMBH (ART 57)	RO
Akineton 2 mg comprimate	not available	4133/2011/02	DESMA GMBH (ART 57)	RO
Akineton® 2 mg Tabletten	not available	6899182.00.00	DESMA GMBH (ART 57)	DE
Akineton® 2 mg - Tabletten	AT/H/0521/001	8.853	DESMA GMBH (ART 57)	AT
Akineton 2 mg tablets	not available	20020915	DESMA GMBH (ART 57)	BG
AKINETON 2 mg, tabletki	not available	R/1932	DESMA GMBH (ART 57)	PL
Akineton 2 mg comprimate	not available	4133/2011/01-02	DESMA GMBH (ART 57)	RO
Akineton 2 mg tablete	not available	5363-I-681/07	DESMA GMBH (ART 57)	SI
Akineton 2 mg compresse	not available	028330013	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Akineton 4 mg compresse a rilascio prolungato	not available	028330037	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
AKINETON FIALE 5 mg/ml fiale soluzione iniettabile	not available	016479040	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Akinetón 2 mg comprimidos	not available	26.692	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	ES
Akineton Inyectable	not available	28994	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	ES
Akinetón 2 mg comprimidos	not available	26.692	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	ES
Akineton Retard 4 mg comprimidos de liberacion prolongada	not available	51224	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	ES
Akineton Retard 4 mg comprimidos de liberacion prolongada	not available	51224	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	ES
AKINETON 2 mg comprimés	not available	BE083133	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	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
AKINETON 2 mg comprimés	not available	BE083133	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	BE
AKINETON 2 mg comprimés	not available	BE083133	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	BE
Akineton Tablets 2 mg	not available	PA1253/001/001	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IE
Akineton Retard Prolonged Release Tablets 4 mg	not available	PA1253/002/001	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IE
Akineton 2 mg Tabletter	not available	3866	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	NO
AKINETON 2 mg tabletti	not available	5413	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	FI
Akineton 2 mg, tablety	not available	27/1343/93-C	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	CZ
Akineton 2 mg, tablety	not available	27/1343/93-C	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	CZ
Akineton 2 mg Tabletta	not available	OGYI-T-330/01	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	HU
Akineton 5 mg/ml oldatos injekció	not available	OGYI-T-4260/01	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	HU
Akineton 2 mg töflur	not available	660766	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IS
Akineton 5 mg/ml stungulyf, lausn	not available	741796	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IS
Akineton, tabletten 2 mg	not available	RVG 02196	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	NL
Akineton, injectie 5 mg/ml	not available	RVG 02197	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	NL
Akineton, tabletten 2 mg	not available	RVG 02196	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	NL
Akineton	not available	27/0126/94-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton	not available	27/0127/94-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK

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
Akineton SR 4 mg	not available	27/0079/01-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton SR 4 mg	not available	27/0079/01-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton SR 4 mg	not available	27/0079/01-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton, tabletter	not available	02318	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	DK
Akineton 2 mg tabletter	not available	6035	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SE
Akineton, injektionsvæske, opløsning	not available	02491	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	DK
Akineton 5 mg/ml injektionsvätska, lösning	not available	6034	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SE
Akineton® 4 mg Retardtabletten	not available	6899153.00.00	DESMA GMBH (ART 57)	DE
Akineton® 4 mg - Retardtabletten	AT/H/0521/002	15.197	DESMA GMBH (ART 57)	AT
Акинетон SR 4 mg таблетки с удължено освобождаване	not available	9800106	DESMA GMBH (ART 57)	BG
AKINETON SR 4 mg 4 mg, tabletki o przedłużonym uwalnianiu	not available	8842	DESMA GMBH (ART 57)	PL
AKINETON SR 4 mg 4 mg, tabletki o przedłużonym uwalnianiu	not available	8842	DESMA GMBH (ART 57)	PL
Akineton® 4 mg Retardtabletten	not available	6899153.00.00	DESMA GMBH (ART 57)	DE
Akineton® 4 mg - Retardtabletten	AT/H/0521/002	15.197	DESMA GMBH (ART 57)	AT
Акинетон SR 4 mg таблетки с удължено освобождаване	not available	9800106	DESMA GMBH (ART 57)	BG
AKINETON SR 4 mg 4 mg, tabletki o przedłużonym uwalnianiu	not available	8842	DESMA GMBH (ART 57)	PL
AKINETON SR 4 mg 4 mg, tabletki o przedłużonym uwalnianiu	not available	8842	DESMA GMBH (ART 57)	PL

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
Akineton® 4 mg Retardtabletten	not available	6899153.00.00	DESMA GMBH (ART 57)	DE
Akineton® 4 mg - Retardtabletten	AT/H/0521/002	15.197	DESMA GMBH (ART 57)	AT
Акинетон SR 4 mg таблетки с удължено освобождаване	not available	9800106	DESMA GMBH (ART 57)	BG
AKINETON SR 4 mg 4 mg, tabletki o przedluzonym uwalnianiu	not available	8842	DESMA GMBH (ART 57)	PL
AKINETON SR 4 mg 4 mg, tabletki o przedluzonym uwalnianiu	not available	8842	DESMA GMBH (ART 57)	PL
Akineton® 5 mg/ml Injektionslösung	not available	6899182.00.01	DESMA GMBH (ART 57)	DE
Akineton® 5 mg - Injektionslösung	AT/H/0521/003	10.234	DESMA GMBH (ART 57)	AT
Akineton 5 mg/ml solution for injection	not available	20020916	DESMA GMBH (ART 57)	BG
AKINETON 5 mg/ml, roztwór do wstrzykiwań	not available	3716	DESMA GMBH (ART 57)	PL
Akineton 5 mg/ml raztopina za injiciranje	not available	H/95/00130/002	DESMA GMBH (ART 57)	SI