



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 April 2020
EMA/200603/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: biperiden

Procedure no.: PSUSA/00000415/201908

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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
Akineton® 4 mg Retardtabletten	AT/H/0521/002	91578.00.00	DESMA GMBH	DE
Akineton 4 mg - Retardtabletten	AT/H/0521/002	15.197	DESMA GMBH	AT
Akineton 4 mg compresse a rilascio prolungato	not available	028330037	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Akineton 5 mg/ml stungulyf, lausn.	not available	741796	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IS
Akineton, injektionsvæske, opløsning	not available	02491	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	DK
Akineton 2 mg tablete	not available	H/95/00130/001	DESMA GMBH	SI
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
Akinetón 5mg/ml solución inyectable	not available	28.994	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	ES
Akineton 2 mg tabletter	not available	6035	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SE
Akineton 5 mg/ml injektionsvätska, lösning	not available	6034	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SE
Akineton 2 mg tabletter	not available	3866	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	NO
Akineton fiale 5 mg/ml soluzione iniettabile	not available	016479040	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Akineton, tabletter	not available	02318	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	DK
Akineton 5 mg/ml otopina za injekciju	not available	UP/I-530-09/10-02/283	DESMA D.O.O.	HR
Akineton Tablets 2 mg	not available	PA1253/001/001	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IE
Akineton®	not available	24650/20-4-2010	DESMA GMBH	GR
AKINETON, 5 mg/ml, roztwór do wstrzykiwań	not available	3716	DESMA GMBH	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 Retard Prolonged release Tablets 4 mg	not available	PA1253/002/001	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IE
Akineton®	not available	24649/20-4-2010	DESMA GMBH	GR
Akineton® 2 mg Tabletten	AT/H/0521/001	91577.00.00	DESMA GMBH	DE
Akineton 2 mg - Tabletten	AT/H/0521/001	8.853	DESMA GMBH	AT
Akineton, 2 mg tabletid	not available	340201	DESMA GMBH	EE
Akineton®	not available	06995	DESMA GMBH	CY
Akineton 2 mg Tabletta	not available	OGYI-T-330/01	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	HU
Akineton 2 mg compresse	not available	028330013	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Akineton 5 mg/ml šķīdums injekcijām	not available	94-0027	DESMA GMBH	LV
Akineton 5 mg/ml raztopina za injiciranje	not available	H/95/00130/002	DESMA GMBH	SI
Akineton, injektionsvæske, opløsning	not available	02491	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	DK
Akineton®	not available	24652/20-4-2010	DESMA GMBH	GR
Akineton 5 mg/ml injekcný roztok	not available	27/0127/94-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton, injectie 5 mg/ml	not available	RVG 02197	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	NL
AKINETON 2 mg tabletti	not available	5413	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	FI
AKINETON L.P. 4 mg, comprimé enrobé à libération prolongée	not available	3149889-6	DESMA PHARMA	FR
AKINETON L.P. 4 mg, comprimé enrobé à libération prolongée	not available	3149889-6	DESMA PHARMA	FR
Akineton 2 mg tablettes	not available	94-0311	DESMA GMBH	LV
Akineton® 5 mg Injektionslösung	AT/H/0521/003	91579.00.00	DESMA GMBH	DE
Akineton® 2 mg tablete	not available	UP/I-530-09/10-02/282	DESMA D.O.O.	HR
Akineton, 2 mg, tabletki	not available	R/1932	DESMA GMBH	PL

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Akineton	not available	8232207	DESMA LABORATORIO FARMACÉUTICO SL	PT
Biperiden-neuraxpharm 4 mg Tabletten	not available	42555.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Акинетон SR 4 mg таблетки с удължено освобождаване	not available	9800106	DESMA GMBH	BG
Akineton SR 4 mg tablety s predĺženým uvoľňovaním	not available	27/0079/01-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton SR 4 mg tablety s predĺženým uvoľňovaním	not available	27/0079/01-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton SR 4 mg tablety s predĺženým uvoľňovaním	not available	27/0079/01-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK
Akineton	not available	8920728	DESMA LABORATORIO FARMACÉUTICO SL	PT
Akineton.	not available	8920710	DESMA LABORATORIO FARMACÉUTICO SL	PT
Akineton Retard.	not available	8422220	DESMA LABORATORIO FARMACÉUTICO SL	PT
Akineton Retard.	not available	8422212	DESMA LABORATORIO FARMACÉUTICO SL	PT
Акинетон 5 mg/ml инжекционен разтвор	not available	20020916	DESMA GMBH	BG
Akineton 5 mg/ml oldatos injekció	not available	OGYI-T-4260/01	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	HU
Biperiden-neuraxpharm 4 mg Tabletten	not available	42555.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Akinetón 2 mg comprimidos	not available	26.692	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 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

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 Retard 4 mg comprimidos de liberacion prolongada	not available	51.224	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, tabletten 2 mg	not available	RVG 02196	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 Retard 4 mg comprimidos de liberacion prolongada	not available	51.224	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 SR 4 mg, 4 mg, tabletki o przedłużonym uwalnianiu	not available	8842	DESMA GMBH	PL
Akineton 2 mg töflur.	not available	660766	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IS
Akineton, tabletter	not available	02318	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	DK
Акинетон 2 mg таблетки	not available	20020915	DESMA GMBH	BG
Akineton 2 mg tablety	not available	27/0126/94-S	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	SK