



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/203429/2017 Corr.1¹
Procedure Management and Business Support

Medicinal products recommended for maintenance and marketing authorisation applications for which bioequivalence vis-à-vis the EU reference medicinal product has been established as adopted by the CHMP on 23 March 2017

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1450
EMEA/H/A31/1450/C/003787/0005

¹ 12 April 2017



<u>MA (EU) number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Pack size</u>
EU/1/14/961/001	Tadalafil Mylan	10 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	4 tablets
EU/1/14/961/002	Tadalafil Mylan	20 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	2 tablets
EU/1/14/961/003	Tadalafil Mylan	20 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	4 tablets
EU/1/14/961/004	Tadalafil Mylan	20 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	8 tablets
EU/1/14/961/005	Tadalafil Mylan	20 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	12 tablets
EU/1/14/961/006	Tadalafil Mylan	20 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	24 tablets
EU/1/14/961/008	Tadalafil Mylan	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	28 tablets
EU/1/14/961/009	Tadalafil Mylan	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	56 tablets
EU/1/14/961/010	Tadalafil Mylan	10 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	12 tablets
EU/1/14/961/011	Tadalafil Mylan	10 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	24 tablets
EU/1/14/961/012	Tadalafil Mylan	5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	14 tablets
EU/1/14/961/013	Tadalafil Mylan	5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	28 tablets
EU/1/14/961/014	Tadalafil Mylan	5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	30 tablets
EU/1/14/961/015	Tadalafil Mylan	5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	56 tablets
EU/1/14/961/016	Tadalafil Mylan	5 mg	Film-coated tablet	Oral use	blister (PVC/PE/PVdC-Alu)	98 tablets

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Czech Republic	SVUS Pharma a.s.		MORYSA 10 MG POTAHOVANÉ TABLETY	memantine	10 mg	Film-coated tablet	Oral use
Czech Republic	SVUS Pharma a.s.		MORYSA 20 MG POTAHOVANÉ TABLETY	memantine	20 mg	Film-coated tablet	Oral use
Denmark		Alternova A/S	Hydrokortison Alternova	hydrocortisone	10 mg	Tablet	Oral use
Denmark		Alternova A/S	Hydrokortison Alternova	hydrocortisone	20 mg	Tablet	Oral use
France	Pharmascope Ltd.		Memantin Pharmascope 10 mg Filmtabletten	memantine	10 mg	Film-coated tablet	Oral use
France	Pharmascope Ltd.		Memantin Pharmascope 20 mg Filmtabletten	memantine	20 mg	Film-coated tablet	Oral use
Germany	Pharmascope Ltd.		Memantin Pharmascope 10 mg Filmtabletten	memantine	10 mg	Film-coated tablet	Oral use
Germany	Pharmascope Ltd.		Memantin Pharmascope 20 mg Filmtabletten	memantine	20 mg	Film-coated tablet	Oral use
Hungary	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Hungary	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Poland	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Poland	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
Portugal	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Portugal	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Romania	Pharmascope Ltd.		Memantin Pharmascope 10 mg Filmtabletten	memantine	10 mg	Film-coated tablet	Oral use
Romania	Pharmascope Ltd.		Memantin Pharmascope 20 mg Filmtabletten	memantine	20 mg	Film-coated tablet	Oral use
Slovak Republic	SVUS Pharma a.s.		Morysa	memantine	10 mg	Film-coated tablet	Oral use
Slovak Republic	SVUS Pharma a.s.		Morysa	memantine	20 mg	Film-coated tablet	Oral use
Sweden	Pharmascope Ltd.		Memantine Pharmascope	memantine	10 mg	Film-coated tablet	Oral use
Sweden	Pharmascope Ltd.		Memantine Pharmascope	memantine	20 mg	Film-coated tablet	Oral use
Sweden	Alternova A/S		Bendro-flumetiazid Alternova	bendro- flumethiazide	2.5 mg	Tablet	Oral use
Sweden		BBS Consult Aps	Hydrokortison BBS	hydrocortisone	10 mg	Tablet	Oral use
Sweden		BBS Consult Aps	Hydrokortison BBS	hydrocortisone	20 mg	Tablet	Oral use
The Netherlands	Pharmascope Ltd.		Memantine Pharmascope 10 mg filmomhulde tabletten	memantine	10 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Applicant	Invented name	Active Substance	Strength	Pharmaceutical form	Route of administration
The Netherlands	Pharmascope Ltd.		Memantine Pharmascope 20 mg filmomhulde tabletten	memantine	20 mg	Film-coated tablet	Oral use
United Kingdom	Dawa Limited		Memantine Dawa 10mg film-coated tablets	memantine	10 mg	Film-coated tablet	Oral use
United Kingdom	Dawa Limited		Memantine Dawa 20mg film-coated tablets	memantine	20 mg	Film-coated tablet	Oral use
United Kingdom	Dawa Limited		Paracetamol 1000 mg Film Coated Tablets	paracetamol	1000 mg	Film-coated tablet	Oral use