



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 March 2013
EMA/147828/2013
Patient Health Protection

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for flupirtine containing medicinal products

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1363

DRAFT



Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Zentiva k.s. 130 U kabelovn Prague 10237 Czech Republic	Flupizen	100 mg	capsule, hard	oral use
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	KATADOLON	100 mg	capsule, hard	oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Flupirtinmaleat AbZ 100 mg Kapseln	100 mg	capsule, hard	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Flupirtinmaleat AL 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Awegal inject	164,5 mg / 3 ml	solution for injection	intramuscular use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Katadolon inject	164,5 mg / 3 ml	solution for injection	intramuscular use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Katadolon Kinderzäpfchen	75 mg	suppository	rectal use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Katadolon Zäpfchen	150 mg	suppository	rectal use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Trancopal Dolo	100 mg	capsule	oral use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Trancopal Dolo Suppositorien	150 mg	suppository	rectal use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Katadolon S long	400 mg	prolonged release tablet	oral use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Katadolon	100 mg	capsule, hard	oral use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Trancolong	400 mg	prolonged release tablet	oral use
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Katadolon retard	400 mg	prolonged release tablet	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	AWD.pharma GmbH & Co. KG Wasastr. 50 01445 Radebeul Germany	Flupirtinmaleat Winthrop 400 mg Retardtabletten	400 mg	prolonged release tablet	oral use
Germany	CT Arzneimittel GmmbH Graf-Arco-Str. 3 89079 Ulm Germany	Flupirtinmaleat-CT 100 mg Hartkapsel	100 mg	capsule, hard	oral use
Germany	CT Arzneimittel GmmbH Graf-Arco-Str. 3 89079 Ulm Germany	Flupin 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Dr. Kade Pharmazeutische Fabrik GmbH Rigistr. 2 12277 Berlin Germany	Dolokadin einmal täglich	400 mg	prolonged release tablet	oral use
Germany	Hormosan Pharma GmbH Wilhelmshöher Str. 106 60389 Frankfurt Germany	Flupigamma 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Hormosan Pharma GmbH Wilhelmshöher Str. 106 60389 Frankfurt Germany	Flupirtinmaleat-Hormosan 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	MEDA Pharma GmbH & Co. KG Benzstr. 1 61352 Bad Homburg Germany	Flupigil 100 mg Hartkapseln	100 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	MEDA Pharma GmbH & Co. KG Benzstr. 1 61352 Bad Homburg Germany	Flupigil 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Midas Pharma GmbH Rheinstr. 49 55218 Ingelheim Germany	Flupirtinmaleat Midas 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Flupirtinmaleat- ratiopharm 100 mg Hartkapsel	100 mg	capsule, hard	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Miflumal 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Vitapharma Generics GmbH Benzstr. 1 61352 Bad Homburg v. d. H. Germany	Flupirtinmaleat Vitapharma 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Vitapharma Generics GmbH Benzstr. 1 61352 Bad Homburg v. d. H. Germany	Flupivil 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Vitapharma Generics GmbH Benzstr. 1 61352 Bad Homburg v. d. H. Germany	Flupirtinmaleat Viatrix 100 mg Hartkapseln	100 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Winthrop Arzneimittel GmbH Brüningstr. 50 65926 Frankfurt am Main Germany	Flupirtinmaleat Winthrop 400 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Winthrop Arzneimittel GmbH Brüningstr. 50 65926 Frankfurt am Main Germany	Flupimal 100 mg Hertkapseln	100 mg	capsule, hard	oral use
Germany	Winthrop Arzneimittel GmbH Brüningstr. 50 65926 Frankfurt am Main Germany	Flupsadim 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Winthrop Arzneimittel GmbH Brüningstr. 50 65926 Frankfurt am Main Germany	Miphaflumix 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Winthrop Arzneimittel GmbH Brüningstr. 50 65926 Frankfurt am Main Germany	Fluporol 100 mg Hartkapseln	100 mg	capsule, hard	oral use
Germany	Winthrop Arzneimittel GmbH Brüningstr. 50 65926 Frankfurt am Main Germany	Flupirtinmaleat Winthrop 100 mg Hartkapseln	100 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Hungary	ZENTIVA k.s. Ul. kabelovny 130, Dolní Mecholupy 10237 Prague 10 Czech Republic	Flupizen 100 mg kemény kapszula	100 mg	capsule, hard	oral use
Italy	MEDA PHARMA S.p.A., Viale Brenta 18, 20139 Milano Italy	EFIRET	100mg	capsule, hard	oral use
Latvia	Teva Pharma B.V., Computerweg 10, 3542 DR Utrecht The Netherlands	Katadolon 100 mg hard capsules	100 mg	capsule, hard	oral use
Lithuania	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Katadolon	100 mg	capsule, hard	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warsaw Poland	Katadolon	100 mg	capsule, hard	oral use
Portugal	Midas Pharma GmbH Rheinstrasse, 49 55218 Ingelheim Germany	Flupirtina Midas	100 mg	capsule, hard	oral use
Portugal	Sanofi-Aventis - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park, Edifício 7 - 3° Piso 2740-244 Porto Salvo Portugal	Flupirtina Winthrop	100 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Meda Pharma - Produtos Farmacêuticos, S.A. Rua do Centro Cultural, 13 1749-066 Lisboa Portugal	Metanor	100 mg	capsule, hard	oral use
Romania	Zentiva k.s. U Kabelovny 130, Dolní Měcholupy 102 37, Praga 10, Czech Republic	FLUPIZEN 100 mg	100mg	capsule	oral use
Slovak Republic	Zentiva k.s. U Kabelovny 130 102 37 Praha 10 Czech Republic	Flupizen 100 mg tvrdé kapsuly	100 mg	capsule, hard	oral use
Slovak Republic	TEVA Pharmaceuticals Slovakia, s.r.o. Teslova 26 821 02 Bratislava Slovak Republic	Katadolon	100 mg	capsule, hard	oral use