



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

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

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1458

Please note that this draft Annex I may be updated during the procedure to reflect any amended information on concerned products/MAHs.



Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Estonia	Teva Pharma B.V.	Katadolon	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Aristo Pharma Gmbh	Flupirtin	Flupirtine Maleate 100mg Tablet	Capsule, Hard	Oral Use
Germany	Hormosan Pharma Gmbh	Flupirtinmaleat	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Meda Pharma Gmbh & Co. Kg	Flupigil	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Ratiopharm Gmbh	Flupirtinmaleat Ratiopharm	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Tamarang, S.A.	Flupirtinmaleat Tam	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Tamarang, S.A.	Flupirtinmaleat Tamarang	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Teva Gmbh	Katadolon	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Teva Gmbh	Trancopal Dolo	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Teva Gmbh	Flupirtinmaleat Winthrop	Flupirtine Maleate 400mg Tablet	Prolonged-Release Tablet	Oral Use
Germany	Teva Gmbh	Katadolon Retard	Flupirtine Maleate 400mg Tablet	Prolonged-Release Tablet	Oral Use

Germany	Teva Gmbh	Katadolon S Long	Flupirtine Maleate 400mg Tablet	Prolonged-Release Tablet	Oral Use
Germany	Teva Gmbh	Trancolong	Flupirtine Maleate 400mg Tablet	Prolonged-Release Tablet	Oral Use
Germany	Winthrop Arzneimittel Gmbh	Flupirtinmaleat Winthrop	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Germany	Teva Gmbh	Katadolon	Flupirtine Maleate 150mg Suppository	Suppository	Rectal Use
Germany	Teva Gmbh	Trancopal Dolo Suppositorien	Flupirtine Maleate 150mg Suppository	Suppository	Rectal Use
Latvia	Teva Pharma B.V.	Katadolon	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Lithuania	Teva Pharma B.V.	Katadolon	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Luxembourg	Tamarang, S.A.	Flupirtinmaleat Tam	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Poland	Teva Pharmaceuticals Polska Sp. Z O.O.	Katadolon	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use
Portugal	Meda Pharma – Produtos Farmacêuticos, S.A.	Metanor	Flupirtine Maleate 100mg Capsule	Capsule	Oral Use
Slovakia	Teva Pharmaceuticals Slovakia S.R.O	Katadolon	Flupirtine Maleate 100mg Capsule	Capsule, Hard	Oral Use