



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2018
EMA/417850/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: flupirtine

Procedure no.: PSUSA/00010225/201710



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
Katadolon retard, 400 mg Retardtabletten	not available	84353.00.00	TEVA GMBH	DE
Flupirtinmaleat-ratiopharm® 100 mg Hartkapseln	not available	85132.00.00	RATIOPHARM GMBH	DE
Flupirtin-Aristo 100 mg Hartkapseln	DE/H/3428/001	85837.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Flupirtinmaleat TAM 100 mg Hartkapseln	DE/H/3519/001	86797.00.00	TAMARANG, S.A.	DE
Katadolon® retard, 400 mg Retardtabletten	not available	84349.00.00	TEVA GMBH	DE
Flupirtinmaleat Tamarang 100 mg Hartkapseln	DE/H/3504/001	86545.00.00	TAMARANG, S.A.	DE
Katadolon® 100 mg, Hartkapsel	not available	9639.01.00	TEVA GMBH	DE
Trancopal® Dolo Suppositorien 150 mg / Zäpfchen	not available	9643.01.01	TEVA GMBH	DE
Trancopal® Dolo 100 mg / Hartkapsel	not available	9643.01.00	TEVA GMBH	DE
Katadolon® Zäpfchen 150 mg, Zäpfchen	not available	9639.01.01	TEVA GMBH	DE
Flupirtinmaleat Winthrop® 400 mg Retardtabletten 400 mg, Retardtablette	not available	63281.00.00	TEVA GMBH	DE
Trancolong ® 400 mg / Retardtablette	not available	63282.00.00	TEVA GMBH	DE
Katadolon® S long 400 mg, Retardtablette	not available	56166.00.00	TEVA GMBH	DE
FLUPIGIL 100 MG HARTKAPSELN	DE/H/3034/001	82447.00.00	MEDA PHARMA GMBH & CO. KG	DE

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Flupirtinmaleat-Hormosan 100 mg Hartkapseln	DE/H/3430/001	85839.00.00	HORMOSAN PHARMA GMBH	DE
Flupigil 100 mg Hartkapseln	not available	86900.00.00	MEDA PHARMA GMBH & CO. KG	DE
Katadolon, 100 mg kővakapslid	not available	423903	TEVA PHARMA B.V.	EE
Katadolon 100 mg kietosios kapsulės	not available	LT/1/03/2294/003	TEVA PHARMA B.V.	LT
Katadolon 100 mg kietosios kapsulės	not available	LT/1/03/2294/001	TEVA PHARMA B.V.	LT
Katadolon 100 mg kietosios kapsulės	not available	LT/1/03/2294/002	TEVA PHARMA B.V.	LT
Flupirtinmaleat TAM 100 mg Hartkapseln	DE/H/3519/001	2013080280	TAMARANG, S.A.	LU
Katadolon 100 mg cietās kapsulas	not available	03-0090	TEVA PHARMA B.V.	LV
Katadolon , 100 mg, kapsułki twarde	not available	11504	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL
Metanor 100 mg cápsulas	not available	2268993	MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A.	PT
Metanor 100 mg cápsulas	not available	2269090	MEDA PHARMA – PRODUTOS FARMACÊUTICOS, S.A.	PT
Katadolon Tvrdé kapsuly	not available	07/0125/04-S	TEVA PHARMACEUTICALS SLOVAKIA S.R.O	SK