



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 June 2024
EMA/420924/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ketotifen (oral formulations)

Procedure No. PSUSA/00001813/202310



Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zaditen 1 mg gélules	not available	BE112743	ALFASIGMA S.P.A.	BE
Zaditen 1 mg/5 ml sirop	not available	BE117101	ALFASIGMA S.P.A.	BE
Zaditen 1 mg capsules	not available	BE112743	ALFASIGMA S.P.A.	BE
Zaditen retard 2 mg tabletten met verlengde afgifte	not available	BE159275	ALFASIGMA S.P.A.	BE
Zaditen 1 mg/5 ml siroop	not available	BE117101	ALFASIGMA S.P.A.	BE
Zaditen retard 2 mg comprimés à libération prolongée	not available	BE159275	ALFASIGMA S.P.A.	BE

Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zaditen 1 mg/5 ml Sirup	not available	BE117101	ALFASIGMA S.P.A.	BE
Zaditen 1 mg Kapseln	not available	BE112743	ALFASIGMA S.P.A.	BE
Zaditen retard 2 mg Retardtabletten	not available	BE159275	ALFASIGMA S.P.A.	BE
Zasten 0,2 mg/ml solución oral	not available	55.805	ALFASIGMA S.P.A.	ES
ZADITEN 1 mg, gélule	not available	34009 351 584 5 1	ALFASIGMA S.P.A.	FR
ZADITEN 1 mg, gélule	not available	34009 351 585 1 2	ALFASIGMA S.P.A.	FR
ZADITEN 1 mg, gélule	not available	34009 323 034 4 1	ALFASIGMA S.P.A.	FR

Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ZADITEN 1 mg, gélule	not available	34009 323 035 0 2	ALFASIGMA S.P.A.	FR
ZADITEN L.P. 2 mg, comprimé pelliculé à libération prolongée	not available	34009 336 921 4 8	ALFASIGMA S.P.A.	FR
ZADITEN 1 mg/5 ml, solution buvable	not available	34009 324 489 5 1	ALFASIGMA S.P.A.	FR
ZADITEN 1 mg/5 ml, solution buvable	not available	34009 324 495 5 2	ALFASIGMA S.P.A.	FR
Zaditen 1mg/5ml oral solution	not available	PA 2206/004/001	ALFASIGMA S.P.A.	IE
Zaditen 1 mg Tablets.	not available	PA 2206/004/002	ALFASIGMA S.P.A.	IE
ZADITEN 0,2 mg/ml sciroppo	not available	024574030	ALFASIGMA S.P.A.	IT

Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ZADITEN 2 mg compresse a rilascio prolungato	not available	024574042	ALFASIGMA S.P.A.	IT
Zaditen 1 mg, tabletten	not available	RVG 08319	ALFASIGMA S.P.A.	NL
Zaditen 0,2 mg/ml, stroop (suikervrij)	not available	RVG 09520	ALFASIGMA S.P.A.	NL
Zaditen 1 mg cápsula	not available	9489732	ALFASIGMA S.P.A.	PT
Zaditen 1 mg cápsula	not available	9489724	ALFASIGMA S.P.A.	PT
Zaditen 0,2 mg/ml xarope	not available	9506907	ALFASIGMA S.P.A.	PT
ZADITEN Tablets 1 mg	not available	PL 48053/0008	ALFASIGMA S.P.A.	XI

Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ZADITEN ELIXIR 1mg/5ml	not available	PL 48053/0009	ALFASIGMA S.P.A.	XI