



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 June 2018  
EMA/418646/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: ketotifen (oral formulations)

Procedure no.: PSUSA/00001813/201710



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
ZADITEN SYRUP 1MG/5ML	not available	18425	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
ZADITEN® 1 mg, gélule	not available	34009 323 035 0 2	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN® 1 mg, gélule	not available	34009 351 585 1 2	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN® 1 mg, gélule	not available	34009 323 034 4 1	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN® 1 mg, gélule	not available	34009 351 584 5 1	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN® 1 mg/5 ml, solution buvable	not available	34009 324 489 5 1	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN® 1 mg/5 ml, solution buvable	not available	34009 324 495 5 2	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN® L.P. 2 mg, comprimé pelliculé à libération prolongée	not available	34009 336 921 4 8	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	FR
ZADITEN®	not available	46030/11-06-2014	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	GR
ZADITEN®	not available	21007/11-06-2014	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	GR
Zaditen 1 mg cápsula	not available	9489732	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	PT
Zaditen 1 mg cápsula	not available	9489724	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	PT
Zaditen 0,2 mg/ml	not available	9506907	SIGMA-TAU INDUSTRIE	PT

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
xarope			FARMACEUTICHE RIUNITE S.P.A.	
Zaditen® 1 mg/5 ml Sirup	not available	2001086498	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	LU
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
ZADITEN TABLETS 1 MG	not available	PL 48053/0008	ALFASIGMA S.P.A.	UK
ZADITEN ELIXIR 1mg / 5ml	not available	PL 48053/0009	ALFASIGMA S.P.A.	UK
ZADITEN 0,2 mg/ml sciroppo	not available	024574030	ALFASIGMA S.P.A.	IT
ZADITEN 2 mg compresse a rilascio prolungato	not available	024574042	ALFASIGMA S.P.A.	IT
Zaditen 1 mg/5 ml, syrop	not available	R/1209	ALFASIGMA S.P.A.	PL
Zaditen 1 mg, tabletki	not available	R/1208	ALFASIGMA S.P.A.	PL
Zaditen SRO 2 mg Filmtabletten	not available	1-19771	ALFASIGMA S.P.A.	AT
Zaditen – Sirup für Kinder	not available	16.660	ALFASIGMA S.P.A.	AT
Zaditen 1mg/5ml oral solution	not available	PA 2206/004/001	ALFASIGMA S.P.A.	IE

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Zaditen 1 mg Tablets	not available	PA 2206/004/002	ALFASIGMA S.P.A.	IE
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/ml, druppelvloeistof	not available	RVG 14490	ALFASIGMA S.P.A.	NL
Zaditen	not available	28.00.01	ALFASIGMA S.P.A.	DE
Zastén 0,2 mg/ml solución oral	not available	55.805	ALFASIGMA S.P.A.	ES
Zastén 1 mg comprimidos	not available	55.623	ALFASIGMA S.P.A.	ES