



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 June 2015
EMA/485883/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ketotifen (oral formulations)

Procedure no.: PSUSA/00001813/201410



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 (100 ml)		16660	Sigma TAU IFR Spa	AT
Zaditen (200 ml)		16660	Sigma TAU IFR Spa	AT
Zaditen		1-19771	Sigma TAU IFR Spa	AT
Zaditen		BE112743	Sigma TAU IFR Spa	BE
Zaditen		BE117101	Sigma TAU IFR Spa	BE
Zaditen		BE159275	Sigma TAU IFR Spa	BE
Zaditen		324489-5	Sigma TAU IFR Spa	FR
Zaditen		351585-1	Sigma TAU IFR Spa	FR

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		323035-0	Sigma TAU IFR Spa	FR
Zaditen		336921-4	Sigma TAU IFR Spa	FR
Zaditen		28.00.01	Sigma TAU IFR Spa	DE
Zaditen		28.00.01	Sigma TAU IFR Spa	DE
Zaditen		46030/11-06-2014	Sigma TAU IFR Spa	GR
Zaditen		21007/11-06-2014	Sigma TAU IFR Spa	GR
Zaditen		PA 1931/3/2	Sigma TAU IFR Spa	IE

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		PA 1931/3/1	Sigma TAU IFR Spa	IE
Zaditen		024574 030	Sigma TAU IFR Spa	IT
Zaditen		024574042	Sigma TAU IFR Spa	IT
Zaditen		2001086498	Sigma TAU IFR Spa	LU
Zaditen		RVG08319	Sigma TAU IFR Spa	NL
Zaditen		RVG09520	Sigma TAU IFR Spa	NL
Zaditen		RVG14490	Sigma TAU IFR Spa	NL

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		R/1208	Sigma TAU IFR Spa	PL
Zaditen		R/1209	Sigma TAU IFR Spa	PL
Zaditen		9489724	Sigma TAU IFR Spa	PT
Zaditen		9506907	Sigma TAU IFR Spa	PT
Zaditen		9489732	Sigma TAU IFR Spa	PT
Zaditen		55623	Sigma TAU IFR Spa	ES
Zaditen		55805	Sigma TAU IFR Spa	ES

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		PL08381/0010	Sigma TAU IFR Spa	UK
Zaditen		PL08381/0011	Sigma TAU IFR Spa	UK
Ketof		12306.00.00	Hexal Ag	DE
Ketof		12306.00.01	Hexal Ag	DE
Ketof		7514/2006/01	Hexal Ag	RO
Zaditen		18425	Novartis Pharmaceuticals Uk Limited	CY