



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/619421/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): hydrochlorothiazide / spironolactone

Procedure No.: PSUSA/00001662/202101



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
Ondolen Forte 50 mg + 50 mg comprimidos	not available	4703294	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Ondolen Forte 50 mg + 50 mg comprimidos	not available	4703492	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Ondolen Forte 50 mg + 50 mg comprimidos	not available	5855192	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
Ondolen Forte 50 mg + 50 mg comprimidos	not available	5855093	A. MENARINI PORTUGAL, FARMACÊUTICA, S.A.	PT
ALDACTAZIDE 25 mg + 25 mg compresse	not available	022702017	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Spironothiazid® 50 mg, Filmtabletten	not available	891.00.00	DESMA GMBH	DE
Spiridazide 25 mg + 25 mg Capsule Rigide	not available	022447 015	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
ALDACTAZIDE 25 mg + 25 mg compresse	not available	022702017	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Spironothiazid® 100 mg, Filmtabletten	not available	891.02.00	DESMA GMBH	DE