



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 September 2025
EMADOC-1700519818-2655853
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): Rosuvastatin/ Omega-3-acid ethyl esters

EURD list No. PSUSA/00010915/202501

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Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Rosuvastatina e Omega 3 SPA Società Prodotti Antibiotici 5 mg/1000 mg capsule molli.	NL/H/4611/001	048417012	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Rosuvastatina e Omega 3 SPA Società Prodotti Antibiotici 5 mg/1000 mg capsule molli.	NL/H/4611/001	048417024	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Rosuvastatina e Omega 3 SPA Società Prodotti Antibiotici 5 mg/1000 mg capsule molli.	NL/H/4611/001	048417036	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Rosuvastatina e Omega 3 SPA Società Prodotti Antibiotici 5 mg/1000 mg capsule molli.	NL/H/4611/001	048417048	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Rosuvastatine/Omega-3 vetzuren ethylesters 90 Kuhnil 5 mg/1000 mg, zachte capsules	NL/H/4611/001	RVG 123886	MEDIKALLA OY MEDIPHARMIA FINLAND	NL