

Applications received in the week: 10th November 2025 till the 16th November 2025

AA Licence Number	Product Name	Active Ingredient/s	Source Country Authorisation Number	Source Country
AA1134/00101	Nocutil Nasal Spray Solution 0.1mg/ml	Desmopressin acetate	OGYI-T-6796/02	Hungary
AA1161/01402	Ernyom Tablets 4mg	Perindopril tert-butylamine	12631/2019/01	Romania
AA770/15405	PREDNISOLONE ZENTIVA LAB Orodispersible Tablet 20mg	Prednisolone	34009 391 065 9 5	France
AA770/27401	Perphyl Syrup 667mg/ml	Lactulose	5632278	Portugal
AA770/12002	Dilaclan Capsule 500mg	Amoxicillin trihydrate	5714555	Portugal
AA770/00603	Metformin Basi Tablet, film coated 500mg	Metformin	5459540	Portugal
AA1343/05901	Trandate comprimidos recubiertos Tablet, film coated 200mg	Labetalol hydrochloride	54528	Spain

AA1161/01505	SIMVASTATINA ARENA Tablet, film coated 40mg	Simvastatine	11937/2019/01-03	ROMANIA
AA729/41501	Posaconazole Devatis Oral Suspension 40mg/ml	Posaconazole	2200832.00.00	Germany
AA1330/03803	Valsartan Teva Tablet, film coated 80mg	Valsartan	PA0749/084/002	Ireland
AA1330/03804	Valsartan Teva Tablet, film coated 160mg	Valsartan	PA0749/084/003	Ireland
AA807/12201	Dutasteride Capsule 0.5mg	Dutasteride	RVG 119311	Netherlands
AA1411/13801	MYCOSTATIN Oral Suspension 100,000 I.U/ml	Nystatin	A.I.C. N° 010058030	Italy

Applicant
Gebro Pharma GmbH
Farmarosib SRL
JV Healthcare Limited
Target Healthcare Limited

Farmarosib SRL

Cherubino Ltd

Azure Pharmaceuticals
Ltd

Azure Pharmaceuticals
Ltd

Aurobindo Pharma
(Malta) Limited

EJ BUSUTTIL LTD