



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 September 2016
EMA/546104/2016
Procedure Management and Committees Support Division

List of nationally authorised medicinal products

Active substance: Zafirlukast

Procedure no.: PSUSA/00003138/201512



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
Accolate 20 mg comprimidos revestidos por película	IE/H/0108/001	2627081	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Accoleit 20 mg compresse rivestite con film	not available	31964012	ASTRAZENECA S.P.A.	IT
Accolate 20 mg filmdoubletta	not available	OGYI-T 5562/02	ASTRAZENECA KFT.	HU
Accolate 20 mg.	not available	044/00801	ASTRAZENECA UK LIMITED	MT
ACCOLATE-20, 20 mg, comprimés pelliculés	not available	0173/05068832	NV ASTRAZENECA SA	LU
Accolate 20 mg comprimidos revestidos por película	IE/H/0108/001	2626984	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Accolate 20 mg filmdoubletta	not available	OGYI-T 5562/01	ASTRAZENECA KFT.	HU
Accolate 20 mg Film-coated Tablets	IE/H/0108/001	PA 970/1/1	ASTRAZENECA UK LIMITED	IE
ACCOLATE-20, 20 mg, filmomhulde tabletten	not available	BE179462	NV ASTRAZENECA SA	BE
ACCOLATE-20, 20 mg, comprimés pelliculés	not available	BE179462	NV ASTRAZENECA SA	BE
ACCOLATE 20 mg	not available	62443.0	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Accolate 20 mg comprimidos revestidos por película	IE/H/0108/001	2627289	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Accolate 20 mg tabletti, kalvopäällysteinen	not available	12143	ASTRAZENECA OY	FI
Accolate™ 20 mg Film-coated Tablets	not available	PL 17901/0001	ASTRAZENECA UK LIMITED	UK