



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2018
EMA/28946/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: azithromycin (ocular use formulations)

Procedure No.: PSUSA/00010492/201704



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
AZYDROP15mg/g colirio en soluciónen envase unidosis	NL/H/0855/001	69.522	LABORATOIRES THEA	ES
Azyter 15 mg/g Augentropfen im Einzeldosisbehältnis	NL/H/0855/001	1-27282	LABORATOIRES THEA	AT
Azyter 15 mg/g Augentropfen im Einzeldosisbehältnis	NL/H/0855/001	66100.00.00	LABORATOIRES THEA	DE
Azyter 15 mg/g augndropar, lausn í stakskammtaíláti	not available	IS/1/14/084/01	LABORATOIRES THEA	IS
Azyter 15 mg/g kapi za oko, otopina u jednodoznom spremniku	not available	UP/I-530-09/12-01/475	LABORATOIRES THEA	HR
Azyter 15 mg/g kapljice za oko, raztopina v enoodmernem vsebniku	NL/H/0855/001	5363-I-1491/13	LABORATOIRES THEA	SI
Azyter 15 mg/g picaturi oftalmice, solutie în recipient unidoza	NL/H/0855/001	5881/2013/01	LABORATOIRES THEA	RO
Azyter 15 mg/g silmätipat, liuos, kerta-annospakkaus	NL/H/0855/001	29241	LABORATOIRES THEA	FI
Azyter 15 mg/g Οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης	NL/H/0855/001	21320	LABORATOIRES THEA	CY
Azyter 15 mg/g Οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης	NL/H/0855/001	56059/25-08-2015	LABORATOIRES THEA	GR
Azyter 15 mg/g, colírio, solução em recipiente unidose	NL/H/0855/001	5070057	LABORATOIRES THEA	PT

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
Azyter 15 mg/g, collirio, soluzione in contenitore monodose	NL/H/0855/001	038231015/M	LABORATOIRES THEA	IT
AZYTER 15 mg/g, collyre en solution en récipient unidose	NL/H/0855/001	34009 382 038 2 0	LABORATOIRES THEA	FR
AZYTER 15 mg/g, collyre en solution en récipient unidose	NL/H/0855/001	1536/08020041	LABORATOIRES THEA	LU
Azyter 15 mg/g, eye drops, solution in single-dose container	NL/H/0855/001	PL 20162/0012	LABORATOIRES THEA	UK
Azyter 15 mg/g, eye drops, solution, in single-dose container	NL/H/0855/001	PA 1107/4/1	LABORATOIRES THEA	IE
AZYTER 15 mg/g, očná roztoková instilácia v jednodávkovom obale	NL/H/0855/001	15/0353/11-S	LABORATOIRES THEA	SK
Azyter 15 mg/g, oční kapky, roztok, jednodávkový obal	NL/H/0855/001	64/275/11-C	LABORATOIRES THEA	CZ
Azyter 15 mg/g, ögondroppar, lösning i endosbehållare	NL/H/0855/001	45202	LABORATOIRES THEA	SE
Azyter 15 mg/g, oogdruppels, oplossing	NL/H/0855/001	RVG 34031	LABORATOIRES THEA	NL
Azyter 15 mg/g, øyedråper, oppløsning i endosebeholder	NL/H/0855/001	10-7953	LABORATOIRES THEA	NO
Azyter, 15 mg/g, krople do oczu, roztwór w pojemniku jednodawkowym	NL/H/0855/001	14197	LABORATOIRES THEA	PL

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
Azyter, øjendråber, opløsning, enkeltdosisbeholder	NL/H/0855/001	47795	LABORATOIRES THEA	DK
Bazyt 15 mg/g, oogdruppels, oplossing	NL/H/2356/001	RVG 109580	LABORATOIRES THEA	NL
Infectoazit 15 mg/g Augentropfen im Einzeldosisbehältnis	NL/H/2356/001	85076.00.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Азитер 15 mg/g, капки за очи, разтвор в еднoдозова опаковка	NL/H/0855/001/E/001	20120273	LABORATOIRES THEA	BG