



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 November 2019  
EMA/637806/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: carteolol

Procedure no.: PSUSA/00000574/201903

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Carteol 10 mg/ml collirio, soluzione	not available	026057012	SIFI S.P.A.	IT
Carteol 20 mg/ml collirio, soluzione	not available	026057024	SIFI S.P.A.	IT
CARTEABAK 2 %, collyre en solution	NL/H/3077/002	358 138-0	LABORATOIRES THEA	FR
CARTEABAK 2 %, collyre en solution	NL/H/3077/002	361 992-9	LABORATOIRES THEA	FR
CARTEABAK 20 mg/ml colírio, solução	FR/H/0235/002	4929386	LABORATOIRES THEA	PT

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CARTEABAK 20 mg/ml colírio, solução	FR/H/0235/002	4929485	LABORATOIRES THEA	PT
CARTEABAK 2% Collirio, soluzione	NL/H/3077/002	037506033	LABORATOIRES THEA	IT
CARTEABAK 2% Collirio, soluzione	NL/H/3077/002	037506045	LABORATOIRES THEA	IT
Carteabak 2 % oogdruppels, oplossing.	NL/H/3077/002	RVG 29950	LABORATOIRES THEA	NL
Carteabak 2% collyre en solution.	NL/H/3077/002	BE259436	LABORATOIRES THEA	BE

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Carteabak 2% oogdruppels, oplossing.	NL/H/3077/002	BE259436	LABORATOIRES THEA	BE
Carteabak 2% collyre en solution	NL/H/3077/002	2004010030	LABORATOIRES THEA	LU
ARTEOPTIC 2% očná roztoková instilácia	not available	64/0144/99-S	LABORATOIRES THEA	SK
Arteoptic, 20 mg/ml, krople do oczu, roztwór	not available	7565	LABORATOIRES THEA	PL
Arteoptic® 2 % Augentropfen	not available	4092.01.00	LABORATOIRES THEA	DE

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Arteoptic® 1 % Augentropfen	not available	4092.00.00	LABORATOIRES THEA	DE
CARTEOL L.P. 1 %, collyre à libération prolongée en récipient unidose	FR/H/0388/001	34009 360 065 7 7	LABORATOIRE CHAUVIN	FR
CARTEOL L.P. 1 %, collyre à libération prolongée en récipient unidose	FR/H/0388/001	34009 360 066 3 8	LABORATOIRE CHAUVIN	FR
Fortidose 1% collirio a rilascio prolungato, in contenitori monodose	FR/H/0388/001	039626027	BAUSCH & LOMB IOM S.P.A	IT
ARTEOPTIC 10 mg/ml colirio de liberación prologada en envase unidosis	FR/H/0388/001	71069	LABORATOIRE CHAUVIN	ES

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CARTEOL 1 %, collyre en solution	not available	34009 343 807 9 2	LABORATOIRE CHAUVIN	FR
CARTEOL 2 %, collyre en solution	not available	34009 343 809 1 4	LABORATOIRE CHAUVIN	FR
CARTEOL 1 %, collyre en solution	not available	34009 343 808 5 3	LABORATOIRE CHAUVIN	FR
CARTEOL 1 %, collyre en solution	not available	34009 327 821 0 9	LABORATOIRE CHAUVIN	FR
CARTEOL 2 %, collyre en solution	not available	34009 343 811 6 4	LABORATOIRE CHAUVIN	FR
CARTEOL 2 %, collyre en solution	not available	34009 327 822 7 7	LABORATOIRE CHAUVIN	FR

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Teoptic 2% w/v Eye Drops, Solution	not available	PL 20162/0008	LABORATOIRES THEA	UK
CARTEABAK 1 %, collyre en solution	NL/H/3077/001	358 138-0	LABORATOIRES THEA	FR
CARTEABAK 1 %, collyre en solution	NL/H/3077/001	361 992-9	LABORATOIRES THEA	FR
CARTEABAK 10 mg/ml colírio, solução	FR/H/0235/001	4929188	LABORATOIRES THEA	PT
CARTEABAK 10 mg/ml colírio, solução	FR/H/0235/001	4929287	LABORATOIRES THEA	PT

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CARTEABAK 1% Collirio, soluzione	NL/H/3077/001	037506019	LABORATOIRES THEA	IT
CARTEABAK 1% Collirio, soluzione	NL/H/3077/001	037506021	LABORATOIRES THEA	IT
Carteabak 1 % oogdruppels, oplossing.	NL/H/3077/001	RVG 29949	LABORATOIRES THEA	NL
Carteabak 1% collyre en solution.	NL/H/3077/001	BE259427	LABORATOIRES THEA	BE
Carteabak 1 % oogdruppels, oplossing.	FR/H/0235/001	BE259427	LABORATOIRES THEA	BE



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Carteabak 1% collyre en solution	NL/H/3077/001	2004010029	LABORATOIRES THEA	LU
CARTEOL L.P. 2 %, collyre à libération prolongée en récipient unidose	FR/H/0388/002	34009 360 089 3 9	LABORATOIRE CHAUVIN	FR
CARTEOL L.P. 2 %, collyre à libération prolongée en récipient unidose	FR/H/0388/002	34009 360 090 1 1	LABORATOIRE CHAUVIN	FR
Fortidose 1% collirio a rilascio prolungato, in contenitori monodose	FR/H/0388/001	039626015	BAUSCH & LOMB IOM S.P.A	IT
Fortidose 2% collirio a rilascio prolungato, in contenitori monodose	FR/H/0388/002	039626041	BAUSCH & LOMB IOM S.P.A	IT

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Fortidose 2% collirio a rilascio prolungato, in contenitori monodose	FR/H/0388/002	039626039	BAUSCH & LOMB IOM S.P.A	IT
Physioglau 2% Unidoses, colírio de libertação prolongada, em recipiente unidose	FR/H/0388/002	5192935	BAUSCH & LOMB, S.A.	PT
Physioglau 2% Unidoses, colírio de libertação prolongada, em recipiente unidose	FR/H/0388/002	5192943	BAUSCH & LOMB, S.A.	PT
ARTEOPTIC 20 mg/ml colirio de liberación prolongada en envase unidosis	FR/H/0388/002	71070	LABORATOIRE CHAUVIN	ES
ARTEOPTIC 2% Oční kapky, roztok	not available	64/979/97-C	LABORATOIRES THEA	CZ

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Carteol 10 mg/ml collirio, soluziune	not available	026057036	SIFI S.P.A.	IT
Carteol 20 mg/ml collirio, soluziune	not available	026057048	SIFI S.P.A.	IT
FORTINOL EP 2% picături oftalmice cu eliberare prelungită 20 mg/ml	FR/H/0244/002	7497/2015/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	RO
FORTINOL EP 2% picături oftalmice cu eliberare prelungită 20 mg/ml	FR/H/0244/002	7497/2015/02	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	RO
ARTEOPTIC 2% colirio de liberación prolongada	FR/H/0244/002	66383	BAUSCH & LOMB, S.A.	ES

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CARTEOL L.P. 2%, collyre à libération prolongée	FR/H/0244/002	34009 357 895 2 5	LABORATOIRE CHAUVIN	FR
ARTEOPTIC LA 2% collyre à libération prolongée	FR/H/0244/002	BE 271476	BAUSCH & LOMB PHARMA	BE
ARTEOPTIC LA 2% oogdruppels met verlengde afgifte	FR/H/0244/002	BE271476	BAUSCH & LOMB PHARMA	BE
FORTINOL 2%, collirio a rilascio prolungato	FR/H/0244/002	038373027	BAUSCH & LOMB IOM S.P.A	IT
FORTINOL 2%, collirio a rilascio prolungato	FR/H/0244/002	038373039	BAUSCH & LOMB IOM S.P.A	IT

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PHYSIOGLAU 2% 20 mg/ml Colírio de libertação prolongada	FR/H/0244/002	5177183	BAUSCH & LOMB, S.A.	PT
ARTEOPTIC LA 2% collyre à libération prolongée	FR/H/0244/002	0180/08039742 0376554	BAUSCH & LOMB PHARMA	LU
Carteol LP 2%, 20 mg/ml, krople do oczu o przedłużonym uwalnianiu	FR/H/0244/002	11830	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	PL
CARTEOL LP 2% očná instilácia s predĺženým uvoľňovaním	FR/H/0244/002	64/0288/05-S	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	SK
CARTEOL LP 2% oční kapky s prodlouženým účinkem	FR/H/0244/002	64/382/05-C	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	CZ

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ARTEOPTIC LA 2% Augentropfen mit verlängerter Wirkungsdauer	FR/H/0244/002	BE 271476	BAUSCH & LOMB PHARMA	BE
Teoptic 2%, oogdruppels, oplossing 20 mg/ml	not available	RVG 13379	LABORATOIRES THEA	NL
CARTEOL – 1 % - Augentropfen	not available	BE 142913	MYLAN EPD BVBA/SPRL	BE
CARTEOL – 2 % - Augentropfen	not available	BE 142922	MYLAN EPD BVBA/SPRL	BE
CARTEOL – 1 % - Augentropfen	not available	2010/040760	MYLAN EPD BVBA/SPRL	LU
CARTEOL – 2 % - Augentropfen	not available	2010/049999	MYLAN EPD BVBA/SPRL	LU

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CARTEOL 1 % Collyre en solution	not available	2010/040760	MYLAN EPD BVBA/SPRL	LU
CARTEOL 1% - Oogdruppels, oplossing	not available	BE 142913	MYLAN EPD BVBA/SPRL	BE
CARTEOL 1 % Collyre en solution	not available	BE 142913	MYLAN EPD BVBA/SPRL	BE
CARTEOL 2% - Oogdruppels, oplossing	not available	BE 142922	MYLAN EPD BVBA/SPRL	BE
CARTEOL 2 % Collyre en solution	not available	2010/049999	MYLAN EPD BVBA/SPRL	LU
CARTEOL 2 % Collyre en solution	not available	BE 142922	MYLAN EPD BVBA/SPRL	BE

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CARTEOL Monodose, 1 %, Oogdruppels, oplossing	not available	BE 229485	MYLAN EPD BVBA/SPRL	BE
CARTEOL Monodose, 2 %, Oogdruppels, oplossing	not available	BE 229494	MYLAN EPD BVBA/SPRL	BE
CARTEOL Monodose, 2%, collyre en solution	not available	BE 229494	MYLAN EPD BVBA/SPRL	BE
CARTEOL Monodose, 1%, collyre en solution	not available	BE 229485	MYLAN EPD BVBA/SPRL	BE
Teoptin 1%, oogdruppels, oplossing 10 mg/ml	not available	RVG 13378	LABORATOIRES THEA	NL
Carteololhydrochlorid THEA 20 mg/ml Augentropfen, Lösung	NL/H/4035/001	99939.00.00	LABORATOIRES THEA	DE



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Carteolol hydrochloride Thea 20 mg/ml, eye drops, solution.	NL/H/4035/001	PL 20162/0027	LABORATOIRES THEA	UK
Carteolol hydrochloride Thea 20 mg/ml, eye drops, solution	NL/H/4035/001	PA 1107/016/001	LABORATOIRES THEA	IE
Carteolol hydrochloride Thea 20 mg/ml oogdruppels, oplossing	NL/H/4035/001	RVG 120919	LABORATOIRES THEA	NL
Teoptic 1% w/v Eye Drops, Solution	not available	PL 20162/0007	LABORATOIRES THEA	UK
Carteol 10 mg/ml collirio, soluzione	not available	026057036	SIFI S.P.A.	IT

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Carteol 20 mg/ml collirio, soluzione	not available	026057048	SIFI S.P.A.	IT
ARTEOPTIC 1% colirio de liberación prolongada	FR/H/0244/001	66366	BAUSCH & LOMB, S.A.	ES
CARTEOL L.P. 1%, collyre à libération prolongée	FR/H/0244/001	34009 357 889 2 4	LABORATOIRE CHAUVIN	FR
FORTINOL 1%, collirio a rilascio prolungato	FR/H/0244/001	038373015	BAUSCH & LOMB IOM S.P.A	IT
PHYSIOGLAU 1%, 10 mg/ml colírio de libertação prolongada	FR/H/0244/001	5177084	BAUSCH & LOMB, S.A.	PT

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Carteol 10 mg/ml collirio, soluzione	not available	026057012	SIFI S.P.A.	IT
Carteol 20 mg/ml collirio, soluzione	not available	026057024	SIFI S.P.A.	IT