



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 October 2015
EMA/706294/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: cilazapril, cilazapril / hydrochlorothiazide

Procedure no.: PSUSA/00000749/201502



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
Co-Inhibace	DE/H/3313/001	2009070443	N.V. Roche S.A.	Luxembourg
Co-Inhibace	DE/H/3313/001	BE173975 \$ BE440431	N.V. Roche S.A.	Belgium
Dynorm	DE/H/3000/001 \$ DE/H/3000/002 \$ DE/H/3000/003 \$ DE/H/3000/004	26199.00.00 \$ 26199.01.00 \$ 26199.02.00 \$ 26199.03.00	Roche Pharma Ag	Germany
Dynorm Plus	DE/H/3313/001	32209.00.00	Roche Pharma Ag	Germany
Inhibace "Roche"	DE/H/3000/001 \$ DE/H/3000/002 \$ DE/H/3000/003	1-19537 \$ 1-19531 \$ 1-19535	Roche Austria Gmbh	Austria
Inhibace	DE/H/3000/001 \$ DE/H/3000/002 \$ DE/H/3000/003 \$ DE/H/3000/004	R/0969 \$ R/0970 \$ R/0971 \$ R/1311	Roche Polska Sp.O.O.	Poland
Inhibace	DE/H/3000/002	4675088 \$ 2076586 \$ 4675187 \$ 2076685	Roche Farmacêutica Química, Lda.	Portugal
Inhibace	DE/H/3000/003	5763487 \$ 2076784	Roche Farmacêutica Química, Lda.	Portugal

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
Inhibace	DE/H/3000/004	2076982 \$ 2078285	Roche Farmacêutica Química, Lda.	Portugal
Inhibace	DE/H/3000/002 \$ DE/H/3000/003 \$ DE/H/3000/004	OGYI-T-1735/01 \$ OGYI-T-1735/02 \$ OGYI-T-1735/03	Roche (Magyarország) Kft	Hungary
Inhibace	DE/H/3000/003	58/511/99-C	Roche S.R.O.	Czech Republic
Inhibace	DE/H/3000/004	58/080/03-C	Roche S.R.O.	Czech Republic
Inhibace	DE/H/3000/002 \$ DE/H/3000/003 \$ DE/H/3000/004	20020669 \$ 20020670 \$ 20020671	Roche Bulgaria EOOD	Bulgaria
Inhibace	DE/H/3000/01 \$ DE/H/3000/04	BE156956 \$ BE448586 \$ BE156922 \$ BE448595	N.V. Roche S.A.	Belgium
Inhibace Plus	DE/H/3013/001	2303683 \$ 2316982	Roche Farmacêutica Química, Lda.	Portugal
Inhibace Plus	DE/H/3013/001	2316883	Roche Farmacêutica Química, Lda.	Portugal

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
Inhibace Plus	DE/H/3313/001	60.649	Roche Farma S.A.	Spain
Inhibace Plus	DE/H/3313/001	58/181/03-C	Roche S.R.O.	Czech Republic
Inhibace Plus	DE/H/3313/001	8207	Roche Polska Sp.O.O.	Poland
Inhibace Plus	DE/H/3313/001	OGYI-T-5286/01	Roche (Magyarország) Kft	Hungary
Inhibace Plus „Roche“	DE/H/3313/001	1-20856	Roche Austria Gmbh	Austria
Inibace	DE/H/3000/2 \$ DE/H/3000/4	027460056 \$ 027460043	Roche S.P.A.	Italy
Inibace Plus	DE/H/3313/001	029103013	Roche S.P.A.	Italy
Initiss		027464041	Sf Group S.R.L.	Italy

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
Initiss Plus		029116011	Sf Group S.R.L.	Italy
Inocar		59328 \$ 59329 \$ 59330	Abbott Laboratories, S.A.	Spain
Inocar Plus		61296	Abbott Laboratories, S.A.	Spain
Vascace	DE/H/3000/001 \$ DE/H/3000/002 \$ DE/H/3000/003 \$ DE/H/3000/004	PA 50/83/1 \$ PA 50/83/2 \$ PA 50/83/3 \$ PA 50/83/4	Roche Products Ltd	Ireland
Vascace Plus	DE/H/3313/001	42006/2-6-2014	Roche Hellas A. E.	Greece
Vascace	DE/H/3000/001 \$ DE/H/3000/002 \$ DE/H/3000/003 \$ DE/H/3000/004	42007/2-6-2014 \$ 48002/2-6-2014 \$ 48003/2-6-2014 \$ 48001/2-6-2014	Roche Hellas A. E.	Greece
Inhibace	DE/H/3000/01 \$ DE/H/3000/04	2009070481 \$ 2009070449	N.V. Roche S.A.	Luxembourg
Justor	FR/H/0561/001 \$ FR/H/0561/002		Chiesi S.A.	France