



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 March 2018
EMA/168151/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ceftibuten

Procedure no.: PSUSA/00000611/201707



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
Cedax 36 mg/ml polvo para suspensión oral	not available	59936	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Cedax 400 mg cápsulas duras	not available	59.937	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Cedax 36 mg/ml polvo para suspensión oral	not available	59936	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Cedax 400 mg cápsulas duras	not available	59.937	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Cedax 400 mg kemény kapszula	not available	OGYI-T-4216/01	MSD PHARMA HUNGARY KFT.	HU
Cedax Maxi 36 mg/ml por belsőleges szuszpenzióhoz	not available	OGYI-T-4216/03	MSD PHARMA HUNGARY KFT.	HU
Cedax Baby 36 mg/ml por belsőleges szuszpenzióhoz	not available	OGYI-T-4216/02	MSD PHARMA HUNGARY KFT.	HU
ISOCEF 200 mg capsule rigide	not available	027850167	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 200 mg granulato per sospensione orale	not available	027850179	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 400 mg capsule rigide	not available	027850142	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 400 mg granulato per sospensione orale	not available	027850155	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
CEDAX 400 mg granulato per sospensione orale	not available	027849090	MSD ITALIA S.R.L.	IT
CEDAX 36 mg/ml granulato per sospensione orale, flacone	not available	027849102	MSD ITALIA S.R.L.	IT

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
CEDAX 400 mg granulato per sospensione orale	not available	027849153	MSD ITALIA S.R.L.	IT
CEDAX 400 mg capsule rigide	not available	027849140	MSD ITALIA S.R.L.	IT
CEDAX 200 mg capsule rigide	not available	027849165	MSD ITALIA S.R.L.	IT
CEDAX 200 mg granulato per sospensione orale	not available	027849177	MSD ITALIA S.R.L.	IT
CEDAX 200 mg granulato per sospensione orale	not available	027849088	MSD ITALIA S.R.L.	IT
CEDAX 400 mg capsule rigide	not available	027849076	MSD ITALIA S.R.L.	IT
CEDAX 200 mg capsule rigide	not available	027849064	MSD ITALIA S.R.L.	IT
ISOCEF 200 mg capsule rigide	not available	027850066	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 400 mg capsule rigide	not available	027850078	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 200 mg granulato per sospensione orale	not available	027850080	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 400 mg granulato per sospensione orale	not available	027850092	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
ISOCEF 36 mg/ml granulato per sospensione orale - flacone	not available	027850104	RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.P.A.	IT
Cedax, 400 mg, kapsułki	not available	R/3679	MSD POLSKA SP. Z O.O.	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
Cedax, 36 mg/ml, proszek do sporządzania zawiesiny doustnej	not available	R/3678	MSD POLSKA SP. Z O.O.	PL
Caedax 400 mg cápsulas	not available	4695888	MERCK SHARP & DOHME, LDA.	PT
Caedax 400 mg cápsulas	not available	4695987	MERCK SHARP & DOHME, LDA.	PT
Caedax 400 mg cápsulas	not available	2114080	MERCK SHARP & DOHME, LDA.	PT
Caedax 36 mg/ml pó para suspensão oral	not available	2114288	MERCK SHARP & DOHME, LDA.	PT
CEDAX 400 mg kapsuly	not available	15/0232/93-S	MERCK SHARP & DOHME BV	SK