



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 September 2020
EMA/470429/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: lidocaine / phenazone

Procedure no.: PSUSA/00002359/202001



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
OTIPAX, solution pour instillation auriculaire	not available	34009 301 000 5 9	BIOCODEX	FR
OTIPAX, solution pour instillation auriculaire	not available	34009 327 906 6 1	BIOCODEX	FR
Otipax picături auriculare, soluție	not available	7879/2015/01	BIOCODEX	RO
ОТИПАКС 4g/100g + lg/100g капки за уши, разтвор	not available	II – 6492	BIOCODEX	BG
OTIPAX 40 mg/10 mg/1 g ausų lašai (tirpalas)	not available	LT/1/95/1174/001	BIOCODEX	LT
OTIPAX, solution pour instillation auriculaire	not available	2008099923	BIOCODEX	LU
OTIPAX Ušní kapky, roztok	not available	69/369/01-C	BIOCODEX	CZ
Otigo 40 mg/10 mg/g ear drops, solution	LV/H/0127/001	PL 44696/0009	RENASCENCE PHARMA LIMITED	UK
Finoten 40 mg/10 mg/g ausu pilieni, šķīdums	LV/H/0127/001	15-0185	SOPHARMA AD	LV

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
Finoten 40 mg/10 mg/g kõrvatilgad, lahus	LV/H/0127/001	881115	SOPHARMA AD	EE
Finoten 40 mg/10 mg/g ausu lasai (tirpalas)	LV/H/0127/001	LT/1/15/3798/001	SOPHARMA AD	LT
Otofix 40 mg/g+10 mg/g ear drops, solution	not available	20140038	SOPHARMA AD	BG
Otipax 40 mg / 10 mg/g ausu pilieni, šķīdums	not available	95-0222	BIOCODEX	LV
Otipax fülcsepp	not available	OGYI-T-6180/01	BIOCODEX	HU
OTIPAX® solution, ear drops	not available	MA239/00201	BIOCODEX	MT
Otirelax 45,5 mg/11,4 mg/ml picături auriculare soluție	not available	2097/2009/01	S.C. ROMPHARM COMPANY S.R.L.	RO
OTIRELAX 45,5 mg/ml + 11,4 mg/ml picături auriculare, soluție	not available	12384/2019/01	S.C. ROMPHARM COMPANY S.R.L.	RO