



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMADOC-1700519818-2229021
Human Medicines Division

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holder(s) and applicant(s) in the member states for sodium oxybate-containing syrup and oral solution for alcohol dependence

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMA/REF/0000278933

Please note that this draft list of products may be updated during the procedure to reflect any amended information on concerned products/MAH(s)/applicant(s).

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Member State EU/EEA	Marketing authorisation holder	Applicant	Product name	INN/Active substance	Strength	Pharmaceutical form	Route of administration
Austria	Debregeas Et Associes Pharma		Alcover	sodium oxybate	175 mg/ml	syrup	oral use
France		-	-	sodium oxybate	175 mg/ml	syrup	oral use
Italy	Laboratorio Farmaceutico C.T. S.R.L.		Alcover	sodium oxybate	175 mg/ml	oral solution	oral use