



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for etifoxine-containing medicinal products

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1509

Please note that this draft Annex I may be updated during the procedure to reflect any amended information on concerned products/MAHs.

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Member State in EEA	Marketing authorisation holder	Product name	INN/Active substance + Strength	Pharmaceutical form	Route of administration
Bulgaria	Biocodex	Стрезам	Etifoxine Hydrochloride 50mg Capsule	Capsule, Hard	Oral Use
France	Biocodex	Stresam	Etifoxine Hydrochloride 50mg Capsule	Capsule, Hard	Oral Use
Malta	Biocodex	Stresam	Etifoxine Hydrochloride 0.05g Capsule	Capsule, Hard	Oral Use
Romania	Biocodex	Stresam	Etifoxine Hydrochloride 50mg Capsule	Capsule, Hard	Oral Use