



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 amfepramone-containing medicinal products

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1501

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 (EEA)	Marketing authorisation holder	Product name	INN/Active substance + Strength	Pharmaceutical form	Route of administration
Denmark	Temmler Pharma GmbH	Regenon	Amfepramone Hydrochloride 25mg Capsule	Capsule, Soft	Oral Use
Germany	Artegodan GmbH	Tenuate Retard	Amfepramone Hydrochloride 75mg Tablet	Prolonged-Release Tablet	Oral Use
Germany	Temmler Pharma GmbH	Regenon	Amfepramone Hydrochloride 25mg Capsule	Capsule, Soft	Oral Use
Germany	Temmler Pharma GmbH	Regenon Retard	Amfepramone Hydrochloride 60mg Capsule	Prolonged-Release Capsule, Hard	Oral Use
Romania	Temmler Pharma GmbH	Regenon	Amfepramone Hydrochloride 25mg Capsule	Capsule, Soft	Oral Use