



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 (MAHs) in the Member States for levamisole-containing medicinal products

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

Procedure number: EMA/REF/0000293746

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

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Member State EU/EEA	Marketing authorisation holder	Product name	INN/active substance	Strength	Pharmaceutical form	Route of administration
Hungary	Gedeon Richter Plc.	Decaris	levamisole hydrochloride	59 mg	tablet	oral use
Hungary	Gedeon Richter Plc.	Decaris	levamisole hydrochloride	177 mg	tablet	oral use
Latvia	Gedeon Richter Plc.	Decaris	levamisole hydrochloride	177 mg	tablet	oral use
Lithuania	Gedeon Richter Plc.	Decaris	levamisole hydrochloride	177 mg	tablet	oral use
Romania	Arena Group S.A.	Levamisol Arena	levamisole hydrochloride	59 mg	tablet	oral use
Romania	Arena Group S.A.	Levamisol Arena	levamisole hydrochloride	177 mg	tablet	oral use