



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2023
EMA/312210/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): inactivated leptospire vaccine

Procedure No. PSUSA/00010813/202211



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
Spirolept 200 miljoen E/ml, suspensie voor injectie in een voorgevulde spuit. Geïnactiveerd leptospiravaccin.	FR/H/0652/001	RVG 124202	IMAXIO PARIS	NL
SPIROLEPT 200 millions U/ml, suspension injectable en seringue préremplie. Vaccin leptospires inactivé	FR/H/0652/001	6 417 599 8	IMAXIO PARIS	FR