



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 February 2018
EMA/85572/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pitavastatin

Procedure no.: PSUSA/00010502/201707



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
Trolise 2 mg Filmdabletten	UK/H/1555/001	ZUL.NR.: 1-30154	KOWA PHARMACEUTICAL EUROPE CO. LTD	AT
Trolise 4 mg Filmdabletten	UK/H/1555/002	ZUL.NR.: 1-30155	KOWA PHARMACEUTICAL EUROPE CO. LTD	AT
Trolise 1 mg Filmdabletten	UK/H/1555/003	ZUL.NR.: 1-30156	KOWA PHARMACEUTICAL EUROPE CO. LTD	AT
Livazo 2 mg Filmdabletten	UK/H/1555/001	75160.00.00	KOWA PHARMACEUTICAL EUROPE CO. LTD	DE
Livazo 4 mg Filmdabletten	UK/H/1555/002	75161.00.00	KOWA PHARMACEUTICAL EUROPE CO. LTD	DE
Livazo 1 mg Filmdabletten	UK/H/1555/003	79602.00.00	KOWA PHARMACEUTICAL EUROPE CO. LTD	DE
Livazo 2mg comprimidos recubiertos con película	UK/H/1555/01/DC	73.038	KOWA PHARMACEUTICAL EUROPE CO. LTD	ES
Livazo 4mg comprimidos recubiertos con película	UK/H/1555/002	73.039	KOWA PHARMACEUTICAL EUROPE CO. LTD	ES
Alipza 1mg comprimidos recubiertos con película	UK/H/1556/03/DC	73058	KOWA PHARMACEUTICAL EUROPE CO. LTD	ES
Alipza 4mg comprimidos recubiertos con película	UK/H/1556/002	73040	KOWA PHARMACEUTICAL EUROPE CO. LTD	ES
Alipza 2mg comprimidos recubiertos con película	UK/H/1556/001	73041	KOWA PHARMACEUTICAL EUROPE CO. LTD	ES
Livazo 1mg comprimidos recubiertos con película	UK/H/1555/03/DC	73.037	KOWA PHARMACEUTICAL EUROPE CO. LTD	ES
Livazo 2mg tabletti, kalvopäällysteinen	UK/H/1555/01/DC	MTNR:25467	KOWA PHARMACEUTICAL EUROPE CO. LTD	FI
Livazo 4mg tabletti, kalvopäällysteinen	UK/H/1555/002	MTNR:25468	KOWA PHARMACEUTICAL EUROPE CO. LTD	FI
Livazo 1mg tabletti, kalvopäällysteinen	UK/H/1555/003	MTNR: 28478	KOWA PHARMACEUTICAL EUROPE CO. LTD	FI
TROLISE 2 mg, comprimé pelliculé	UK/H/1555/001	NL36650	KOWA PHARMACEUTICAL EUROPE CO. LTD	FR
TROLISE 4 mg, comprimé pelliculé	UK/H/1555/002	NL36651	KOWA PHARMACEUTICAL EUROPE CO. LTD	FR
Lippiza 1 mg, comprimé pelliculé	UK/H/1556/003	NL39485	KOWA PHARMACEUTICAL EUROPE CO. LTD	FR
Lippiza 4 mg, comprimé pelliculé	UK/H/1556/002	NL36653	KOWA PHARMACEUTICAL EUROPE CO. LTD	FR

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LIPPIZA 2 mg, comprimé pelliculé	UK/H/1556/001	NL36652	KOWA PHARMACEUTICAL EUROPE CO. LTD	FR
TROLISE 1 mg, comprimé pelliculé	UK/H/1555/003	NL39484	KOWA PHARMACEUTICAL EUROPE CO. LTD	FR
Livazo 2 mg δισκία επικαλυμμένα με λεπτό υμένιο	UK/H/1555/001	19212/15-03-2011	KOWA PHARMACEUTICAL EUROPE CO. LTD	GR
Livazo 4 mg δισκία επικαλυμμένα με λεπτό υμένιο	UK/H/1555/002	19213/15-03-2011	KOWA PHARMACEUTICAL EUROPE CO. LTD	GR
Pitava 1 mg δισκία επικαλυμμένα με λεπτό υμένιο	UK/H/1556/003	14087/23-02-2012	KOWA PHARMACEUTICAL EUROPE CO. LTD	GR
Pitava 4 mg δισκία επικαλυμμένα με λεπτό υμένιο	UK/H/1556/002	14086/23-02-2012	KOWA PHARMACEUTICAL EUROPE CO. LTD	GR
Pitava 2 mg δισκία επικαλυμμένα με λεπτό υμένιο	UK/H/1556/001	14085/23-02-2012	KOWA PHARMACEUTICAL EUROPE CO. LTD	GR
Livazo 1 mg δισκία επικαλυμμένα με λεπτό υμένιο	UK/H/1555/003	10786/10/15-03-2011	KOWA PHARMACEUTICAL EUROPE CO. LTD	GR
Livazo 2mg film-coated tablets.	UK/H/1555/001	PA 1532/001/001	KOWA PHARMACEUTICAL EUROPE CO. LTD	IE
Livazo 4mg film-coated tablets.	UK/H/1555/002	PA 1532/001/002	KOWA PHARMACEUTICAL EUROPE CO. LTD	IE
Livazo 1mg film-coated tablets.	UK/H/1555/03/DC	PA 1532/001/003	KOWA PHARMACEUTICAL EUROPE CO. LTD	IE
Livazo 2mg compresse rivestite con film	UK/H/1555/001	040363020	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 2mg compresse rivestite con film	UK/H/1555/001	040363032	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 2mg compresse rivestite con film	UK/H/1555/001	040363119	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 2mg compresse rivestite con film	UK/H/1555/001	040363044	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT

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Livazo 2mg compresse rivestite con film	UK/H/1555/01/DC	040363018/	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 4mg compresse rivestite con film	UK/H/1555/002	040363069	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 4mg compresse rivestite con film	UK/H/1555/002	040363071	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 4mg compresse rivestite con film	UK/H/1555/02/DC	040363057/	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 1mg compresse rivestite con film	UK/H/1556/003	040322099	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 1mg compresse rivestite con film	UK/H/1556/003	040322101	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 1mg compresse rivestite con film	UK/H/1556/003	040322125	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 1mg compresse rivestite con film	UK/H/1556/003	040322137	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 1mg compresse rivestite con film	UK/H/1556/03/DC	040322087/	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 4mg compresse rivestite con film	UK/H/1556/002	040322063	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 4mg compresse rivestite con film	UK/H/1556/002	040322075	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 4mg compresse rivestite con film	UK/H/1556/02/DC	040322051/	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 2mg compresse rivestite con film	UK/H/1556/001	040322024	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 2mg compresse rivestite con film	UK/H/1556/001	040322036	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 2mg compresse rivestite con film	UK/H/1556/001	040322113	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 2mg compresse rivestite con film	UK/H/1556/001	040322048	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Alipza 2mg compresse rivestite con film	UK/H/1556/01/DC	040322012/	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 1mg compresse rivestite con film	UK/H/1555/003	040363095	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT

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Livazo 1mg compresse rivestite con film	UK/H/1555/003	040363107	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 1mg compresse rivestite con film	UK/H/1555/003	040363121	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 1mg compresse rivestite con film	UK/H/1555/003	040363133	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 1mg compresse rivestite con film	UK/H/1555/03/DC	040363083/	KOWA PHARMACEUTICAL EUROPE CO. LTD	IT
Livazo 2mg filmomhulde tabletten	UK/H/1555/001	RVG 103768	KOWA PHARMACEUTICAL EUROPE CO. LTD	NL
Livazo 4mg filmomhulde tabletten	UK/H/1555/002	RVG 103769	KOWA PHARMACEUTICAL EUROPE CO. LTD	NL
Livazo 1mg filmomhulde tabletten	UK/H/1555/003	RVG 106928	KOWA PHARMACEUTICAL EUROPE CO. LTD	NL
Livazo 2 mg tablett, filmdrasjert	UK/H/1555/001	08-6220	KOWA PHARMACEUTICAL EUROPE CO. LTD	NO
Livazo 4 mg tablett, filmdrasjert	UK/H/1555/002	08-6221	KOWA PHARMACEUTICAL EUROPE CO. LTD	NO
Livazo 1 mg tablett, filmdrasjert	UK/H/1555/003	10-7330	KOWA PHARMACEUTICAL EUROPE CO. LTD	NO
Livazo, 2 mg, tabletki powlekane	UK/H/1555/001	18362	KOWA PHARMACEUTICAL EUROPE CO. LTD	PL
Livazo, 4 mg, tabletki powlekane	UK/H/1555/002	18363	KOWA PHARMACEUTICAL EUROPE CO. LTD	PL
Livazo, 1 mg, tabletki powlekane	UK/H/1555/03/DC	18361	KOWA PHARMACEUTICAL EUROPE CO. LTD	PL
Livazo 2mg comprimidos revestidos por película	UK/H/1555/001	5324553	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Livazo 2mg comprimidos revestidos por película	UK/H/1555/01/DC	5324546	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Livazo 4mg comprimidos revestidos por película	UK/H/1555/002	5324561	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Alipza 1mg comprimidos revestidos por película	UK/H/1556/003	5324603	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Alipza 1mg comprimidos revestidos por película	UK/H/1556/003	5324579	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT

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
Alipza 4mg comprimidos revestidos por película	UK/H/1556/002	5324637	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Alipza 2mg comprimidos revestidos por película	UK/H/1556/001	5324629	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Alipza 2mg comprimidos revestidos por película	UK/H/1556/001	5324611	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Livazo 1mg comprimidos revestidos por película	UK/H/1555/003	5324538	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Livazo 1mg comprimidos revestidos por película	UK/H/1555/003	5324520	KOWA PHARMACEUTICAL EUROPE CO. LTD	PT
Livazo 2 mg filmdragerade tabletter	UK/H/1555/001	28030	KOWA PHARMACEUTICAL EUROPE CO. LTD	SE
Livazo 4 mg filmdragerade tabletter	UK/H/1555/002	28031	KOWA PHARMACEUTICAL EUROPE CO. LTD	SE
Livazo 1 mg filmdragerade tabletter	UK/H/1555/003	43753	KOWA PHARMACEUTICAL EUROPE CO. LTD	SE
Livazo 2mg film-coated tablets	UK/H/1555/001	PL 32363/0001	KOWA PHARMACEUTICAL EUROPE CO. LTD	UK
Livazo 4mg film-coated tablets	UK/H/1555/002	PL 32363/0002	KOWA PHARMACEUTICAL EUROPE CO. LTD	UK
Alipza 1mg film-coated tablets	UK/H/1556/003	PL 32363/0012	KOWA PHARMACEUTICAL EUROPE CO. LTD	UK
Alipza 4mg film-coated tablets	UK/H/1556/002	PL 32363/0004	KOWA PHARMACEUTICAL EUROPE CO. LTD	UK
Alipza 2mg film-coated tablets	UK/H/1556/001	PL 32363/0003	KOWA PHARMACEUTICAL EUROPE CO. LTD	UK
Livazo 1mg film-coated tablets	UK/H/1555/003	PL 32363/0011	KOWA PHARMACEUTICAL EUROPE CO. LTD	UK