



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 January 2024  
EMA/16935/2024  
Human Medicines Division

## List of nationally authorised medicinal products

Active substance(s): ebastine

Procedure No. PSUSA/00001191/202305



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
Estivan 10 mg filmomhulde tabletten	not available	BE175366	ALMIRALL, S.A.	BE
Estivan 20 mg filmomhulde tabletten	not available	BE248701	ALMIRALL, S.A.	BE
Estivan Lyo 10 mg lyophilisat oral	not available	BE271223	ALMIRALL, S.A.	BE
Estivan Lyo 20 mg lyophilisat oral	not available	BE271232	ALMIRALL, S.A.	BE
EBASTEL 10 mg Film-coated tablets	not available	19242	ALMIRALL, S.A.	CY
Ebastel 10 mg Filmtablette	not available	32331.00.00	ALMIRALL, S.A.	DE
Ebastel 20 mg Filmtablette	not available	32331.01.00	ALMIRALL, S.A.	DE
Ebastin Aristo 10 mg Schmelztabletten	DK/H/2266/001	88990.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Ebastin Aristo 20 mg Schmelztabletten	DK/H/2266/002	88991.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Kestine Flash, frysetørrede tabletter	not available	36004	ALMIRALL, S.A.	DK
Kestine Flash, frysetørrede tabletter	not available	36005	ALMIRALL, S.A.	DK
Kestine, fillovertrukne tabletter	not available	33417	ALMIRALL, S.A.	DK
Kestine, fillovertrukne tabletter	not available	15951	ALMIRALL, S.A.	DK
Kestine 10 mg, õhukese polümeerikattega tabletid	not available	240498	ALMIRALL, S.A.	EE
Kestine, 20 mg õhukese polümeerikattega tabletid	not available	329600	ALMIRALL, S.A.	EE
Bactil 10 mg Comprimidos recubiertos con película	not available	59.034	LABORATORIOS ALMIRALL, S.L.	ES

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
Bactil Flas 10 mg Liofilizados orales	not available	82.485	LABORATORIOS ALMIRALL, S.L.	ES
Bactil Forte 20 mg Comprimidos recubiertos con película	not available	63.365	LABORATORIOS ALMIRALL, S.L.	ES
Bactil Forte Flas 20 mg Liofilizados orales	not available	82.486	LABORATORIOS ALMIRALL, S.L.	ES
Ebastel 1 mg/ml solución oral	not available	58.358	ALMIRALL, S.A.	ES
Ebastel 10 mg comprimidos recubiertos con película	not available	58.357	ALMIRALL, S.A.	ES
Ebastel Flas 10 mg Liofilizados orales	not available	66.281	ALMIRALL, S.A.	ES
Ebastel Forte 20 mg comprimidos recubiertos con película	not available	63.366	ALMIRALL, S.A.	ES
Ebastel Forte Flas 20 mg Liofilizados orales	not available	66.282	ALMIRALL, S.A.	ES
Kestine 10 mg tabletti, kalvopäällysteinen	not available	11789	ALMIRALL, S.A.	FI
Kestine 20 mg filmdragerade tabletter	not available	17726	ALMIRALL, S.A.	FI
Kestine Lyo 10 mg tabletti, kylmäkuivattu	not available	18930	ALMIRALL, S.A.	FI
Kestine Lyo 20 mg tabletti, kylmäkuivattu	not available	18931	ALMIRALL, S.A.	FI
KESTIN 10 mg, comprimé pelliculé	not available	34009 559 586 0 4	ALMIRALL, SAS	FR
KESTIN 10 mg, comprimé pelliculé	not available	34009 340 352 0 3	ALMIRALL, SAS	FR
KESTIN 10 mg, comprimé pelliculé	not available	34009 340 353 7 1	ALMIRALL, SAS	FR
KESTIN 10 mg, comprimé pelliculé	not available	34009 340 354 3 2	ALMIRALL, SAS	FR
KESTIN 10 mg, comprimé pelliculé	not available	34009 340 356 6 1	ALMIRALL, SAS	FR
KESTINLYO 10 mg,	not available	34009 367 588 5 8	ALMIRALL, SAS	FR

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
lyophilisat oral				
KESTINLYO 10 mg, lyophilisat oral	not available	34009 367 589 1 9	ALMIRALL, SAS	FR
KESTINLYO 10 mg, lyophilisat oral	not available	34009 367 591 6 9	ALMIRALL, SAS	FR
KESTINLYO 10 mg, lyophilisat oral	not available	34009 566 183 5 4	ALMIRALL, SAS	FR
KESTINLYO 10 mg, lyophilisat oral	not available	34009 566 184 1 5	ALMIRALL, SAS	FR
Kestine Flash 10 mg επιγλώσσιο δισκίο	not available	2231303	GALENICA SA	GR
Kestine 10 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	2231301	GALENICA SA	GR
KESTINE FLASH 20 mg επιγλώσσιο δισκίο	not available	2231304	GALENICA SA	GR
KESTINE® 20 mg επικαλυμμένα με λεπτό υμένιο δισκία	not available	2231302	GALENICA SA	GR
Kestine 10 mg og 20 mg filmuhúðaðar töflur.	not available	940211	ALMIRALL, S.A.	IS
Kestine 20 mg filmuhúðaðar töflur	not available	IS/1/03/112/01	ALMIRALL, S.A.	IS
Kestine Flash 10 mg og 20 mg frostþurrkaðar töflur	not available	IS/1/07/101/01	ALMIRALL, S.A.	IS
Kestine Flash 20 mg frostþurrkaðar töflur	not available	IS/1/07/101/02	ALMIRALL, S.A.	IS
CLEVER 1 mg/ml sciroppo	not available	029353113	ALMIRALL, S.A.	IT
KESTINE 1 mg/ml sciroppo	not available	034930115	ALMIRALL, S.A.	IT
KESTINE 10 mg liofilizzato orale	not available	034930141	ALMIRALL, S.A.	IT
KESTINE 10 mg liofilizzato orale	not available	034930127	ALMIRALL, S.A.	IT
KESTINE 10 mg liofilizzato orale	not available	034930139	ALMIRALL, S.A.	IT

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KESTINE 10 mg liofilizzato orale	not available	034930154	ALMIRALL, S.A.	IT
KESTINE 10 mg liofilizzato orale	not available	034930166	ALMIRALL, S.A.	IT
KESTINE 20 mg liofilizzato orale	not available	034930192	ALMIRALL, S.A.	IT
KESTINE 20 mg liofilizzato orale	not available	034930178	ALMIRALL, S.A.	IT
KESTINE 20 mg liofilizzato orale	not available	034930180	ALMIRALL, S.A.	IT
KESTINE 20 mg liofilizzato orale	not available	034930204	ALMIRALL, S.A.	IT
KESTINE 20 mg liofilizzato orale	not available	034930216	ALMIRALL, S.A.	IT
Kestine 10 mg plèvele dengtos tabletės	not available	LT/1/98/2295/001	ALMIRALL, S.A.	LT
Kestine 10 mg plèvele dengtos tabletės	not available	LT/1/98/2295/002	ALMIRALL, S.A.	LT
Kestine 20 mg plèvele dengtos tabletės	not available	LT/1/98/2295/003	ALMIRALL, S.A.	LT
Estivan 10 mg comprimés pelliculés	not available	0065/11010928	ALMIRALL, S.A.	LU
Estivan 20 mg comprimés pelliculés	not available	0065/11010929	ALMIRALL, S.A.	LU
Estivan Lyo 10 mg lyophilisat oral	not available	0065/11010930	ALMIRALL, S.A.	LU
Estivan Lyo 20 mg lyophilisat oral	not available	0065/11010931	ALMIRALL, S.A.	LU
Kestine 10 mg apvalkotās tabletes	not available	02-0115	ALMIRALL, S.A.	LV
Kestine 10 mg apvalkotās tabletes	not available	99-0237	ALMIRALL, S.A.	LV
Kestine 20 mg apvalkotās tabletes	not available	04-0041	ALMIRALL, S.A.	LV
Kestine 10, filmomhulde tabletten 10 mg	not available	RVG 17708	ALMIRALL, S.A.	NL
Kestine 20, filmomhulde tabletten 20 mg	not available	RVG 27500	ALMIRALL, S.A.	NL

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
Kestine Smelt 10, lyophilisaat voor oraal gebruik 10 mg	not available	RVG 29927	ALMIRALL, S.A.	NL
Kestine Smelt 20, lyophilisaat voor oraal gebruik 20 mg	not available	RVG 29928	ALMIRALL, S.A.	NL
Kestine ® 10 mg tabletter, filmdrasjerte	not available	94-616	ALMIRALL, S.A.	NO
Kestine ® 20 mg tabletter, filmdrasjerte	not available	02-1300	ALMIRALL, S.A.	NO
Kestine 10 mg smeltetabletter	not available	03-2238	ALMIRALL, S.A.	NO
Kestine 20 mg smeltetabletter	not available	03-2239	ALMIRALL, S.A.	NO
Kestine 1 mg/ml solução oral	not available	4435384	ALMIRALL, S.A.	PT
Kestine 1 mg/ml solução oral	not available	5225677	ALMIRALL, S.A.	PT
Kestine 10 mg comprimidos revestidos por película	not available	3234283	ALMIRALL, S.A.	PT
Kestine 10 mg liofilizado oral	not available	5198783	ALMIRALL, S.A.	PT
Kestine 10 mg liofilizado oral	not available	5198882	ALMIRALL, S.A.	PT
Kestine 10 mg liofilizado oral	not available	5198981	ALMIRALL, S.A.	PT
Kestine 10 mg liofilizado oral	not available	5199088	ALMIRALL, S.A.	PT
Kestine 10 mg liofilizado oral	not available	5199187	ALMIRALL, S.A.	PT
Kestine 20 20 mg comprimidos revestidos por película	not available	4062683	ALMIRALL, S.A.	PT
Kestine 10 mg filmdragerad tablett	not available	12715	ALMIRALL, S.A.	SE
Kestine 10 mg frystorkad tablett	not available	20129	ALMIRALL, S.A.	SE

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
Kestine 20 mg filmdragerad tablett	not available	18624	ALMIRALL, S.A.	SE
Kestine 20 mg frystorkad tablett	not available	20130	ALMIRALL, S.A.	SE