



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 April 2019  
EMA/224876/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: rilmenidine

Procedure no.: PSUSA/00002643/201808

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Tenaxum 1 mg tabletta	not available	OGYI-T-5802/01	EGIS PHARMACEUTICALS PLC	HU
Hyperlex 1 mg tabletta	not available	OGYI-T-9041/02	LES LABORATOIRES SERVIER (SURESNES)	HU
Hyperlex 1 mg tabletta	not available	OGYI-T-9041/01	LES LABORATOIRES SERVIER (SURESNES)	HU
TENAXUM 1 mg tabletes	not available	02-0344	LES LABORATOIRES SERVIER (SURESNES)	LV
Rilmenidin Sanova 1 mg Tabletten	not available	137167	SANOVA PHARMA GESMBH	AT
Hyperium 1 mg, tablets	not available	MA 066/01301	LES LABORATOIRES SERVIER (SURESNES)	MT
TENAXUM 1 mg comprimate	not available	8080/2006/01	LES LABORATOIRES SERVIER (SURESNES)	RO
RILMENIDINE BIOGARAN 1 mg, comprimé	not available	3400937808088	BIOGARAN	FR
RILMENIDINE BIOGARAN 1 mg, comprimé	not available	3400932947461	BIOGARAN	FR

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
RILMENIDINE BIOGARAN 1 mg, comprimé	not available	34009 329 471 7 1	BIOGARAN	FR
RILMENIDINE BIOGARAN 1 mg, comprimé	not available	34009 329 472 3 2	BIOGARAN	FR
RILMENIDINE BIOGARAN 1 mg, comprimé	not available	34009 329 470 0 3	BIOGARAN	FR
TENAXUM 1 mg tabletés	not available	LT/1/99/0094/001	LES LABORATOIRES SERVIER	LT
TENAXUM 1 mg tabletés	not available	LT/1/99/0094/002	LES LABORATOIRES SERVIER	LT
TENAXUM 1 mg tabletés	not available	LT/1/99/0094/003	LES LABORATOIRES SERVIER	LT
ТЕНАКСУМ 1mg таблетки	not available	9600211	LES LABORATOIRES SERVIER (SURESNES)	BG
Iterium 1 mg - Tabletten	not available	1-23813	SERVIER AUSTRIA GMBH	AT
Hyperium 1 mg, comprimé	not available	329 422-6	LES LABORATOIRES SERVIER (SURESNES)	FR

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Hyperium 1 mg, comprimé	not available	329 423-2	LES LABORATOIRES SERVIER (SURESNES)	FR
Hyperium 1 mg, comprimé	not available	329 469-2	LES LABORATOIRES SERVIER (SURESNES)	FR
Hyperium 1 mg, comprimé	not available	372 257-3	LES LABORATOIRES SERVIER (SURESNES)	FR
Hyperium 1 mg, comprimé	not available	558 338-3	LES LABORATOIRES SERVIER (SURESNES)	FR
Hyperium 1 mg, comprimé	not available	329 468-6	LES LABORATOIRES SERVIER (SURESNES)	FR
Hyperium 1mg comprimidos	not available	4588281	SERVIER PORTUGAL, ESPECIALIDADES FARMACÉUTICAS, LDA.	PT
Hyperium 1mg comprimidos	not available	8777714	SERVIER PORTUGAL, ESPECIALIDADES FARMACÉUTICAS, LDA.	PT
Hyperium 1mg comprimidos	not available	8777706	SERVIER PORTUGAL, ESPECIALIDADES FARMACÉUTICAS, LDA.	PT
TENAXUM 1 mg tablety	not available	58/0187/97-S	LES LABORATOIRES SERVIER (SURESNES)	SK

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
HYPERIUM 1 mg, comprimé	not available	2009040324	LES LABORATOIRES SERVIER (SURESNES)	LU
Tenaxum, 1 mg, tabletki	not available	R/7269	LES LABORATOIRES SERVIER (SURESNES)	PL
TENAXUM 1 mg tablety	not available	58/477/97-C	LES LABORATOIRES SERVIER (SURESNES)	CZ