



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
EMA/206866/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tiagabine

Procedure no.: PSUSA/00002942/202106



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
Gabitril 10 mg compresse rivestite con film	FR/H/0107/002	032951042	TEVA ITALIA S.R.L.	IT
Gabitril 10 mg compresse rivestite con film	FR/H/0107/002	032951030	TEVA ITALIA S.R.L.	IT
GABITRIL 10 mg filmomhulde tabletten	FR/H/0107/002	BE183251	TEVA B.V	BE
Gabitril 10 mg Filmtabletten	FR/H/0107/002	BE183251	TEVA B.V	BE
GABITRIL 10 mg, comprimé pelliculé	FR/H/0107/002	NL 21306	TEVA PHARMA B.V.	FR
GABITRIL 10 mg, comprimés pelliculés	FR/H/0107/002	BE183251	TEVA B.V	BE
GABITRIL 10 mg, comprimés pelliculés	FR/H/0107/002	2009020181	TEVA B.V	LU
Gabitril 10 mg, comprimidos recubiertos con película	FR/H/0107/002	61607	TEVA PHARMA B.V.	ES
Gabitril 10 mg, comprimidos revestidos por película	FR/H/0107/002	2539286	TEVA PHARMA B.V.	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
Gabitril 10 mg, comprimidos revestidos por película	FR/H/0107/002	2539187	TEVA PHARMA B.V.	PT
Gabitril 15 mg compresse rivestite con film	FR/H/0107/003	032951067	TEVA ITALIA S.R.L.	IT
Gabitril 15 mg compresse rivestite con film	FR/H/0107/003	032951055	TEVA ITALIA S.R.L.	IT
GABITRIL 15 mg filmomhulde tabletten	FR/H/0107/003	BE183242	TEVA B.V	BE
Gabitril 15 mg Filmtabletten	FR/H/0107/003	BE183242	TEVA B.V	BE
GABITRIL 15 mg, comprimé pelliculé	FR/H/0107/003	BE183242	TEVA B.V	BE
GABITRIL 15 mg, comprimé pelliculé	FR/H/0107/003	NL 21307	TEVA PHARMA B.V.	FR
GABITRIL 15 mg, comprimés pelliculés	FR/H/0107/003	2009020182	TEVA B.V	LU
Gabitril 15 mg, comprimidos recubiertos con película	FR/H/0107/003	61608	TEVA PHARMA B.V.	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
Gabitril 15 mg, comprimidos revestidos por película	FR/H/0107/003	2539385	TEVA PHARMA B.V.	PT
Gabitril 15 mg, comprimidos revestidos por película	FR/H/0107/003	2539484	TEVA PHARMA B.V.	PT
Gabitril 5 mg compresse rivestite con film	FR/H/0107/001	032951028	TEVA ITALIA S.R.L.	IT
Gabitril 5 mg compresse rivestite con film	FR/H/0107/001	032951016	TEVA ITALIA S.R.L.	IT
GABITRIL 5 mg filmomhulde tabletten	FR/H/0107/001	BE183267	TEVA B.V	BE
Gabitril 5 mg Filmtabletten	FR/H/0107/001	BE183267	TEVA B.V	BE
GABITRIL 5 mg, comprimé pelliculé	FR/H/0107/001	BE183267	TEVA B.V	BE
GABITRIL 5 mg, comprimé pelliculé	FR/H/0107/001	NL 21305	TEVA PHARMA B.V.	FR
GABITRIL 5 mg, comprimés pelliculés	FR/H/0107/001	2009020180	TEVA B.V	LU

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
Gabitril 5 mg, comprimidos recubiertos con película	FR/H/0107/001	61606	TEVA PHARMA B.V.	ES
Gabitril 5 mg, comprimidos revestidos por película	FR/H/0107/001	2871283	TEVA PHARMA B.V.	PT
Gabitril 5 mg, comprimidos revestidos por película	FR/H/0107/001	2539088	TEVA PHARMA B.V.	PT
Gabitril 5 mg, comprimidos revestidos por película	FR/H/0107/001	2538981	TEVA PHARMA B.V.	PT
Gabitril, 10 mg, tabletki powlekane	not available	7643	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL
Gabitril, 15 mg, tabletki powlekane	not available	7645	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL
Gabitril, 5 mg, tabletki powlekane	not available	7644	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL
Gabitril® 10 mg film-coated tablets	not available	PL 16260/0010	CEPHALON UK LTD	XI
Gabitril® 10 mg, film-coated tablet	FR/H/0107/002	PA 0749/199/002	TEVA PHARMA B.V.	IE

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
Gabitril® 15 mg film-coated tablets	not available	PL 16260/0011	CEPHALON UK LTD	XI
Gabitril® 15 mg, film-coated tablet	FR/H/0107/003	PA0749/199/003	TEVA PHARMA B.V.	IE
Gabitril® 5 mg film-coated tablets	not available	PL 16260/0009	CEPHALON UK LTD	XI
Gabitril® 5 mg, film-coated tablet	FR/H/0107/001	PA0749/199/001	TEVA PHARMA B.V.	IE