



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2019
EMA/398799/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: levonorgestrel / ethinylestradiol, ethinylestradiol
(combination pack)

Procedure no.: PSUSA/00010442/201901

Temporary visiting address Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands

For deliveries refer to www.ema.europa.eu/how-to-find-us

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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
Seasonique (0,03 mg + 0,15 mg) + (0,01 mg) comprimidos revestidos por película	FR/H/0516/001	5666854	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Seasonique 0,15 mg/0,03 mg + 0,01 mg filmom obložene tablete	FR/H/0516/001	HR-H-184612604	PLIVA HRVATSKA D.O.O.	HR
Seasonique 0,15 mg/0,03 mg in 0,01 mg filmsko obložene tablete	FR/H/0516/001	H/16/02191/001	TEVA PHARMA B.V.	SI
Seasonique 150 microgrammes/30 microgrammes + 10 microgrammes, comprimé pelliculé	FR/H/0516/001	34009 300 105 1 8	THERAMEX IRELAND LIMITED	FR
Seasonique 150 microgrammi / 30 microgrammi + 10 microgrammi , compresse rivestite con film	FR/H/516/01	042139016	TEVA ITALIA S.R.L.	IT
Seasonique 150 micrograms/30 micrograms + 10 micrograms, film-coated tablet	FR/H/0516/001	53026	TEVA B.V	SE
Seasonique 150 micrograms/30 micrograms and 10 micrograms Film-coated Tablets	FR/H/0516/001	PL 49876/0012	THERAMEX IRELAND LIMITED	UK
Seasonique 150 Mikrogramm/30 Mikrogramm + 10 Mikrogramm	FR/H/516/01	136021	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	AT

Filmtabletten				
Seasonique 150 mikrog/30 mikrog + 10 mikrog filmdragerad tablett	FR/H/0516/001	33439	TEVA B.V	FI
Seasonique 150 mikrog/30 mikrog+ 10 mikrog tabletti, kalvopäällysteinen	FR/H/0516/001	33439	TEVA B.V	FI
Seasonique 150 mikrogrami/30 mikrogrami + 10 mikrogrami apvalkotās tabletes	FR/H/0516/001	15-0334	TEVA B.V	LV
Seasonique 150 mikrogramm/30 mikrogramm + 10 mikrogramm filmtablette	FR/H/0516/001	OGYI-T-22930/01	TEVA GYÓGYSZERGYÁR ZRT	HU
Seasonique 150 mikrogramŭ/30 mikrogramŭ + 10 mikrogramŭ potahované tablety	FR/H/0516/001	17/523/15-C	TEVA PHARMACEUTICALS CR, S.R.O.	CZ
Seasonique 150/30 micrograme + 10 micrograme comprimate filmate	FR/H/516/01	7793/2015/01	TEVA PHARMACEUTICALS S.R.L	RO
Seasonique comprimidos recubiertos con película	FR/H/0516/001	80340	THERAMEX IRELAND LIMITED	ES
Seasonique Filmovertrukne tabletter	FR/H/0516/001	56336	TEVA PHARMA B.V.	DK
Seasonique, 150 mikrogrammi / 30 mikrogrammi + 10 mikrogrammi õhukese polümeerikattega tabletid	FR/H/0516/001	894715	TEVA B.V	EE
Seasonique, comprimés pelliculés	FR/H/0516/001	BE469475	THERAMEX IRELAND LIMITED	BE

Seasonique, comprimés pelliculés	FR/H/0516/001	2016040084	THERAMEX IRELAND LIMITED	LU
Seasonique, filmomhulde tablet	FR/H/0516/001	BE469475	THERAMEX IRELAND LIMITED	BE
Seasonique, filmomhulde tabletten	FR/H/516/01	RVG 117453	TEVA B.V	NL
Seasonique, Filmtablette	FR/H/0516/001	BE469475	THERAMEX IRELAND LIMITED	BE
Seasonique, Filmtablette	FR/H/0516/001	2016040084	THERAMEX IRELAND LIMITED	LU
Seasonique® 150 Mikrogramm/30 Mikrogramm + 10 Mikrogramm, Filmtabletten	FR/H/0516/001	87675.00.00	THERAMEX IRELAND LIMITED	DE
Seasonique	FR/H/516/01/DC	22353	THERAMEX IRELAND LIMITED	PL
Seasonique 0,15mg/0,03 mg + 0,01 mg filmom obalené tablety	FR/H/516/01/DC	17/0017/15/S	THERAMEX IRELAND LIMITED	SK