



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2019
EMA/132912/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00010442/201807



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 0,15mg/0,03mg + 0,01 mg filmom obalené tablety	FR/H/0516/001	17/0017/15-S	TEVA PHARMACEUTICALS SLOVAKIA S.R.O	SK
Seasonique 150 microgrammes/30 microgrammes + 10 microgrammes, comprimé pelliculé	FR/H/516/01	NL42237	TEVA SANTÉ	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	FR/H/0516/001	PL 00289/1900	TEVA UK LIMITED	UK

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Tablets				
Seasonique 150 Mikrogramm/30 Mikrogramm + 10 Mikrogramm Filmdabletten	FR/H/516/01	136021	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	AT
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 filmdablette	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/516/01	80340	TEVA PHARMA S.L.U.,	ES
Seasonique Filmovertukne tabletter	FR/H/0516/001	56336	TEVA PHARMA B.V.	DK
Seasonique, (150 mikrogramów+30	FR/H/516/01	22353	TEVA PHARMACEUTICALS POLSKA SP. Z O.O.	PL

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mikrogramów) i 10 mikrogramów, tabletki powlekane				
Seasonique, 150 mikrogrammi / 30 mikrogrammi + 10 mikrogrammi õhukese polümeerikattega tabletid	FR/H/0516/001	894715	TEVA B.V	EE
Seasonique, comprimés pelliculés	FR-H-516-01-DC	2016040084	TEVA PHARMA BELGIUM N.V./S.A	LU
Seasonique, filmomhulde tablet	FR/H/0516/001	BE469475	TEVA PHARMA BELGIUM N.V./S.A	BE
Seasonique, filmomhulde tabletten	FR/H/516/01	RVG 117453	TEVA B.V	NL
Seasonique® 150 Mikrogramm/30 Mikrogramm + 10 Mikrogramm, Filmtabletten	FR/H/516/01	87675.00.00	TEVA GMBH	DE