



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 October 2021
EMA/PRAC/604922/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): ethinylestradiol / gestodene

Procedure No.: PSUSA/00001308/202103



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
Minulet, dragees	not available	RVG 12575	PFIZER B.V.	NL
Gynera, 0,03 mg + 0,075 mg, comprimido revestido	not available	8689117	BAYER PORTUGAL LDA	PT
Gynera, 0,03 mg + 0,075 mg, comprimido revestido	not available	8689109	BAYER PORTUGAL LDA	PT
Yaluvea 0,06 mg / 0,015 mg Filmtabletten	NL/H/1901/001	80000.00.00	HORMOSAN PHARMA GMBH	DE
GINODEN 0,075 mg + 0,03 mg compresse rivestite	not available	026435038	BAYER SPA	IT
Femodene 0,075 / 0,030 mg, überzogene Tabletten	not available	1988050202	BAYER SA NV	LU
Femodene 0,075 / 0,030 mg, comprimés enrobés	not available	1988050202	BAYER SA NV	LU
Logest 0,075 mg/ 0,02 mg drajeuri	not available	6335/2014/01	BAYER AG	RO
MINESSE 60 micrograms / 15 micrograms film-coated tablets	FR/H/0158/001	PA 0822/144/001	PFIZER HEALTHCARE IRELAND	IE
Minesse® 15 Mikrogramm/60 Mikrogramm Filmtabletten	FR/H/0158/001	1-23620	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
MINESSE 0,06 mg/0,015 mg comprimidos recubiertos con película.	FR/H/0158/001	63.239	WYETH FARMA, S.A	ES
MINESSE 60 microgrammes/15 microgrammes, comprimé pelliculé	FR/H/0158/001	34009 351 576 2 1	PFIZER HOLDING FRANCE	FR
MINESSE 60 microgrammes/15 microgrammes, comprimé pelliculé	FR/H/0158/001	34009 351 575 6 0	PFIZER HOLDING FRANCE	FR
MINESSE 60 microgramas/15 microgramas comprimidos revestido por película	FR/H/0158/001	3191087	LABORATÓRIOS PFIZER, LDA.	PT
MINESSE 60 microgrammi/15 microgrammi compresse rivestite con film.	FR/H/0158/001	034922017	PFIZER ITALIA S.R.L.	IT
MINESSE 60 microgrammi/15 microgrammi compresse rivestite con film.	FR/H/0158/001	034922031	PFIZER ITALIA S.R.L.	IT
MINESSE 60 microgrammi/15 microgrammi compresse rivestite con film.	FR/H/0158/001	034922029	PFIZER ITALIA S.R.L.	IT
MINESSE 60 microgramas/15 microgramas comprimidos revestido por película	FR/H/0158/001	3191186	LABORATÓRIOS PFIZER, LDA.	PT
MINESSE 60 microgramas/15 microgramas	FR/H/0158/001	3750080	LABORATÓRIOS PFIZER,	PT

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comprimidos revestido por película			LDA.	
Logest, 75/20 mikrogrammi kaetud tabletid	not available	248299	BAYER AG	EE
Harmonet 0,075 mg/0,020 mg comprimés enrobés	not available	BE174115	PFIZER S.A. (BELGIUM)	BE
Harmonet 0,075 mg/0,020 mg comprimés enrobés	not available	2006119098	PFIZER S.A. (BELGIUM)	LU
Harmonet 0,075mg/0,02 mg comprimidos recubiertos	not available	61.975	WYETH FARMA, S.A	ES
Femoden, 75/30 mikrogrammi kaetud tabletid	not available	206298	BAYER AG	EE
HARMONET 0,020 mg/0,075 mg obalené tablety	not available	17/058/99-C	PFIZER, SPOL. S R.O.	CZ
Triodena - Dragees	not available	1-18522	BAYER AUSTRIA GMBH	AT
TRIMINULET 0,050 mg + 0,03 mg 0,070 mg + 0,04 mg 0,100 mg + 0,03 mg compresse rivestite	not available	027359013	PFIZER ITALIA S.R.L.	IT
Harmonet 0,02 mg + 0,075 mg comprimido revestido	not available	2493781	LABORATÓRIOS PFIZER, LDA.	PT
Harmonet 0,02 mg + 0,075 mg comprimido revestido	not available	5131909	LABORATÓRIOS PFIZER, LDA.	PT
Harmonet 0,02 mg + 0,075 mg comprimido revestido	not available	5131917	LABORATÓRIOS PFIZER, LDA.	PT
Harmonet 0,02 mg + 0,075 mg comprimido revestido	not available	2493682	LABORATÓRIOS PFIZER, LDA.	PT
Karissa Zilnic 75 micrograme/20 micrograme drajeuri	not available	11584/2019/01	GEDEON RICHTER ROMÂNIA S.A.	RO
Karissa Zilnic 75 micrograme/20 micrograme drajeuri	not available	11584/2019/02	GEDEON RICHTER ROMÂNIA S.A.	RO
Meliane 0,075 mg / 0,02 mg comprimidos recubiertos.	not available	61.973	BAYER HISPANIA SL	ES
Kosidina 0,075 mg/0,030 mg 21+7, tabletten	NL/H/3352/002	RVG 116281	SANDOZ B.V.	NL
HARMONET 0,075 mg + 0,02 mg compresse rivestite	not available	030758015	PFIZER ITALIA S.R.L.	IT
Minulet tabletti, päällystetty	not available	9971	PFIZER OY	FI
Logest, 0,075 mg + 0,02 mg, tabletki	not available	4189	BAYER AG	PL

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powlekane				
Harmonet húðaðar töflur	not available	950056	PFIZER APS	IS
Логест 0,02 mg/0,075 mg обвити таблетки	not available	9800303	BAYER AG	BG
Logest 0,02 mg/0,075 mg obložene tablete	not available	H/00/00937/001	BAYER D.O.O	SI
Minulet 75 micrograms/30 micrograms coated tablets	not available	PA 822/93/1	PFIZER HEALTHCARE IRELAND	IE
Harmonet 75 mikrogramm/20 mikrogramm bevont tablettá	not available	OGYI-T-6969/01	PFIZER KFT.	HU
Harmonet 75 mikrogramm/20 mikrogramm bevont tablettá	not available	OGYI-T-6969/02	PFIZER KFT.	HU
Minulet, overtrukne tabletter	not available	12921	PFIZER APS	DK
Triodene, überzogene Tabletten	not available	0442/88080360	BAYER SA NV	LU
Triodene, comprimés enrobés	not available	0442/88080360	BAYER SA NV	LU
Tri-Gynera, (0,03 mg + 0,05 mg) + (0,04 mg + 0,07 mg) + (0,03 mg + 0,10 mg), comprimidos revestidos	not available	8770107	BAYER PORTUGAL LDA	PT
Tri-Gynera, (0,03 mg + 0,05 mg) + (0,04 mg + 0,07 mg) + (0,03 mg + 0,10 mg), comprimidos revestidos	not available	8770115	BAYER PORTUGAL LDA	PT
Fedra 0,075 mg + 0,02 mg compresse rivestite.	not available	029551013	BAYER SPA	IT
Harmonet 75/20 mikrogrammi kaetud tablettid	not available	256799	PFIZER EUROPE MA EEIG	EE
Meliane Diario 0,075 mg/0,02 mg comprimidos recubiertos	not available	62.031	BAYER HISPANIA SL	ES
Harmonet 75 mikrogrammi/20 mikrogrammi apvalkotās tabletes	not available	98-0658	PFIZER EUROPE MA EEIG	LV
Gynovin 0,075 mg / 0,03 mg comprimidos recubiertos	not available	59.044	BAYER HISPANIA SL	ES
Logest 0,075 mg/0,02 mg obalené tablety	not available	17/530/96-C	BAYER AG	CZ
Lunafem 0,075 mg /0,02 mg obalené tablety	not available	17/215/07-C	BAYER AG	CZ
Tri-Minulet Coated* Tablets	not available	PA 822/099/001	PFIZER HEALTHCARE IRELAND	IE
Minulet® - Dragees 75 Mikrogramm/ 30	not available	1-18411	PFIZER CORPORATION	AT

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
Mikrogramm überzogene Tabletten			AUSTRIA GESELLSCHAFT M.B.H.	
HARMONET, comprimé enrobé	not available	34009 339 221 3 9	PFIZER HOLDING FRANCE	FR
HARMONET, comprimé enrobé	not available	34009 339 220 7 8	PFIZER HOLDING FRANCE	FR
Meliane 0,020 mg/0,075 mg bevont tableta	not available	OGYI-T-6814/01	BAYER AG	HU
Meliane 0,020 mg/0,075 mg bevont tableta	not available	OGYI-T-6814/02	BAYER AG	HU
Harmonette® – Dragees 75 Mikrogramm/ 20 Mikrogramm überzogene Tabletten	not available	1-21827	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Minulet 0,03 mg + 0,075 mg comprimido revestido	not available	5131941	LABORATÓRIOS PFIZER, LDA.	PT
Minulet 0,03 mg + 0,075 mg comprimido revestido	not available	8692004	LABORATÓRIOS PFIZER, LDA.	PT
Minulet 0,03 mg + 0,075 mg comprimido revestido	not available	8692012	LABORATÓRIOS PFIZER, LDA.	PT
Minulet 75 mikrogramov/30 mikrogramov obložene tablete	not available	H/94/01029/001	PFIZER EUROPE MA EEIG	SI
Mirelle 60 microgrammes / 15 microgrammes , comprimés pelliculés	FR/H/0159/001	BE212222	BAYER SA NV	BE
Mirelle 60 Mikrogramm/15 Mikrogramm, Filmtabletten	FR/H/0159/001	BE212222	BAYER SA NV	BE
Mirelle 60 Mikrogramm/15 Mikrogramm, Filmtabletten	FR/H/0159/001	2010049761	BAYER SA NV	LU
Arianna 60 microgrammi / 15 microgrammi compresse rivestite con film	FR/H/0159/001	034921015	BAYER SPA	IT
Arianna 60 microgrammi / 15 microgrammi compresse rivestite con film	FR/H/0159/001	034921039	BAYER SPA	IT
MICROGESTE 60 microgramas/15 microgramas comprimido revestido por película	FR/H/0159/001	3245487	BAYER PORTUGAL LDA	PT
Arianna 60 microgrammi / 15 microgrammi compresse rivestite con film	FR/H/0159/001	034921027	BAYER SPA	IT
MELODIA 60 microgrammes / 15 microgrammes, comprimé pelliculé	FR/H/0159/001	34009 351 578 5 0	BAYER HEALTHCARE	FR

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MELODIA 60 microgrammes / 15 microgrammes, comprimé pelliculé	FR/H/0159/001	34009 351 577 9 9	BAYER HEALTHCARE	FR
MICROGESTE 60 microgramas/15 microgramas comprimido revestido por película	FR/H/0159/001	3245388	BAYER PORTUGAL LDA	PT
Mirelle 60 microgram / 15 microgram, filmomhulde tablet	FR/H/0159/001	BE212222	BAYER SA NV	BE
Mirelle 15 Mikrogramm/60 Mikrogramm - Filmtabletten	FR/H/0159/001	1-23621	BAYER AUSTRIA GMBH	AT
Mirelle 60 microgrammes / 15 microgrammes , comprimés pelliculés	FR/H/0159/001	2010049761	BAYER SA NV	LU
MELODENE-15 0,06 mg/ 0,015 mg comprimidos recubiertos con película.	FR/H/0159/001	63.176	BAYER HISPANIA SL	ES
Minulet 0,075 mg/0,030 mg comprimés enrobés	not available	BE142502	PFIZER S.A. (BELGIUM)	BE
Minulet 0,075 mg/0,030 mg comprimés enrobés	not available	2006109087	PFIZER S.A. (BELGIUM)	LU
Milvane, 0,05 mg + 0,03 mg; 0,07 mg + 0,04 mg; 0,10 mg + 0,03 mg, tabletki powlekane	not available	4340	BAYER AG	PL
Tri-Minulet comprimés enrobés	not available	2006119118	PFIZER S.A. (BELGIUM)	LU
Minigeste, 0,02 mg + 0,075 mg, comprimido revestido	not available	2494185	BAYER PORTUGAL LDA	PT
Minigeste, 0,02 mg + 0,075 mg, comprimido revestido	not available	2494086	BAYER PORTUGAL LDA	PT
Meliane - Dragees	not available	1-21825	BAYER AUSTRIA GMBH	AT
Harmonet tabletti, päällystetty	not available	12110	PFIZER OY	FI
Nobabelle Cala 0.075 mg/0.030 mg tabletten	NL/H/2955/001-002/DC	RVG 114150	EGIS PHARMACEUTICALS PLC	NL
Nobabelle Daily 75 mikrogramm/30 mikrogramm tableta	NL/H/2955/001-002/DC	OGYI-T-22785/10-12	EGIS PHARMACEUTICALS PLC	HU
Nobabelle Daily 75 mikrogramm/30 mikrogramm tableta	NL/H/2955/001-002/DC	OGYI-T-22785/10-12	EGIS PHARMACEUTICALS PLC	HU
Nobabelle Daily 75 mikrogramm/30 mikrogramm tableta	NL/H/2955/001-002/DC	OGYI-T-22785/10-12	EGIS PHARMACEUTICALS PLC	HU
Harmonet, overtrukne tabletter	not available	16935	PFIZER APS	DK

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
MINESSE 0,060 mg/0,015 mg potahované tablety	not available	17/123/00-C	PFIZER, SPOL. S R.O.	CZ
Alessia® HEXAL® 0,06 mg/ 0,015 mg Filmtabletten	DE/H/5834/001	78488.00.00	HEXAL AG	DE
MINULET0,075 mg + 0,03mg compresse rivestite	not available	026286029	PFIZER ITALIA S.R.L.	IT
Tri-Minulet comprimés enrobés	not available	BE142511	PFIZER S.A. (BELGIUM)	BE
Tri-Minulet comprimidos recubiertos	not available	60.387	WYETH FARMA, S.A	ES
Gynovin - Dragees	not available	1-18412	BAYER AUSTRIA GMBH	AT
Triodene, überzogene Tabletten	not available	BE143631	BAYER SA NV	BE
Triodene, comprimés enrobés	not available	BE143631	BAYER SA NV	BE
Triodene, omhulde tabletten	not available	BE143631	BAYER SA NV	BE
Minulet 75 mikrogramm/30 mikrogramm bevont tableta	not available	OGYI-T-2382/02	PFIZER KFT.	HU
Harmonet, 75 mikrogramów (µg) + 20 mikrogramów (µg), tabletki drażowane	not available	4871	PFIZER EUROPE MA EEIG	PL
Tri-Minulet (0,03 mg + 0,05 mg) + (0,04 mg + 0,07 mg) + (0,03 mg + 0,1 mg) comprimidos revestidos	not available	8773317	LABORATÓRIOS PFIZER, LDA.	PT
Tri-Minulet (0,03 mg + 0,05 mg) + (0,04 mg + 0,07 mg) + (0,03 mg + 0,1 mg) comprimidos revestidos	not available	8773309	LABORATÓRIOS PFIZER, LDA.	PT
Trigynovin comprimidos recubiertos	not available	60.309	BAYER HISPANIA SL	ES
MELIANE, comprimé enrobé	not available	34009 339 218 2 8	BAYER HEALTHCARE	FR
MELIANE, comprimé enrobé	not available	34009 339 219 9 6	BAYER HEALTHCARE	FR
Harmonet 0,075 mg/0,020 mg drajeuri (gestoden/etinilestradiol)	not available	3697/2011/01	PFIZER EUROPE MA EEIG	RO
Harmonet 0,075 mg/0,020 mg drajeuri (gestoden/etinilestradiol)	not available	3697/2011/02	PFIZER EUROPE MA EEIG	RO
MINULET, comprimé enrobé	not available	34009 330 513 1 0	PFIZER HOLDING FRANCE	FR
MINULET, comprimé enrobé	not available	34009 330 512 5 9	PFIZER HOLDING FRANCE	FR
Femoden dragerade tabletter	not available	9970	BAYER OY	FI
Femoden päällystetyt tabletit	not available	9970	BAYER OY	FI
Meliane dragerade tabletter	not available	12108	BAYER OY	FI
Meliane päällystetyt tabletit	not available	12108	BAYER OY	FI
Etinilestradiol + Gestodeno Stallpharma	not available	5628631	SOLUFARMA - PRODUTOS	PT

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0,02 mg + 0,075 mg Comprimidos revestidos			FARMACÊUTICOS UNIPESOAL, LDA.	
Etinilestradiol + Gestodeno Stallpharma 0,02 mg + 0,075 mg Comprimidos revestidos	not available	5628649	SOLUFARMA - PRODUTOS FARMACÊUTICOS UNIPESOAL, LDA.	PT
Etinilestradiol + Gestodeno Stallpharma 0,02 mg + 0,075 mg Comprimidos revestidos	not available	5628656	SOLUFARMA - PRODUTOS FARMACÊUTICOS UNIPESOAL, LDA.	PT
Milvane compresse rivestite	not available	027358011	BAYER SPA	IT
MINULET 0,030 mg/0,075 mg obalené tablety	not available	17/200/89-C	PFIZER, SPOL. S R.O.	CZ
Minulet 0,075 mg/0,03 mg comprimidos recubiertos	not available	59.148	WYETH FARMA, S.A	ES
Femoden bevont tableta	not available	OGYI-T-2360/02	BAYER AG	HU
Femoden bevont tableta	not available	OGYI-T-2360/01	BAYER AG	HU
Femodene 0,075 / 0,030 mg, überzogene Tabletten	not available	BE143622	BAYER SA NV	BE
Femodene 0,075 / 0,030 mg, omhulde tabletten	not available	BE143622	BAYER SA NV	BE
Femodene 0,075 / 0,030 mg, comprimés enrobes	not available	BE143622	BAYER SA NV	BE
Harmonet 75 mikrogramai / 20 mikrogramų dengtos tabletės	not available	LT/1/98/0362/002	PFIZER EUROPE MA EEIG	LT
Harmonet 75 mikrogramai / 20 mikrogramų dengtos tabletės	not available	LT/1/98/0362/001	PFIZER EUROPE MA EEIG	LT
Meliane 0,075 / 0,020 mg, comprimés enrobes	not available	1995110340	BAYER SA NV	LU
Meliane 0,075 / 0,020 mg, überzogene Tabletten	not available	1995110340	BAYER SA NV	LU
Meliane 0,075 / 0,020 mg, überzogene Tabletten	not available	BE174124	BAYER SA NV	BE
Meliane 0,075 / 0,020 mg, omhulde tabletten	not available	BE174124	BAYER SA NV	BE
Meliane 0,075 / 0,020 mg, comprimés enrobes	not available	BE174124	BAYER SA NV	BE
Logest 0,02 mg / 0,075 mg obložene	not available	HR-H-466196823-01	BAYER DOO	HR

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tablete				
Femovan® 0,030 mg / 0,075 mg überzogene Tabletten	not available	6138.00.00	JENAPHARM GMBH & CO KG	DE