



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 October 2025
EMADOC-1700519818-2862062
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): dienogest / ethinylestradiol (prolonged-release tablet)

EURD list No. PSUSA/00011084/202503

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An agency of the European Union



Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Kelzy	SE/H/2378/001	142101	EXELTIS GERMANY GMBH	AT
Kelzy	SE/H/2378/001	142101	EXELTIS GERMANY GMBH	AT
Kelzy	SE/H/2378/001	142101	EXELTIS GERMANY GMBH	AT
Kelzy	SE/H/2378/001	142101	EXELTIS GERMANY GMBH	AT
Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	BE662941	EXELTIS GERMANY GMBH	BE

Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	BE662941	EXELTIS GERMANY GMBH	BE
Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	BE662941	EXELTIS GERMANY GMBH	BE
Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	BE662941	EXELTIS GERMANY GMBH	BE
Kelzy 2 mg/0,02 mg tablety s prodlouženým uvolňováním	SE/H/2382/001	17/054/23-C	EXELTIS CZECH S.R.O.	CZ
Kelzy 2 mg /0,02 mg Retardtablette	SE/H/2379/001	7012474.00.00	EXELTIS GERMANY GMBH	DE
Kelzy 2 mg /0,02 mg Retardtablette	SE/H/2379/001	7012474.00.00	EXELTIS GERMANY GMBH	DE
Kelzy 2 mg /0,02 mg Retardtablette	SE/H/2379/001	7012474.00.00	EXELTIS GERMANY GMBH	DE

Kelzy 2 mg /0,02 mg Retardtablette	SE/H/2379/001	7012474.00.00	EXELTIS GERMANY GMBH	DE
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	69221	EXELTIS HEALTHCARE S.L	DK
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	69221	EXELTIS HEALTHCARE S.L	DK
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	69221	EXELTIS HEALTHCARE S.L	DK
Kelzy 2 mg/0,02 mg toimeainet prolongeeritult vabastavad tabletid	SE/H/2382/001	1149924	UAB EXELTIS BALTICS	EE
Kelzy 2 mg/0,02 mg comprimidos de liberación prolongada	SE/H/2380/001	89586	EXELTIS HEALTHCARE S.L	ES
Kelzy 2 mg/0,02 mg comprimidos de liberación prolongada	SE/H/2380/001	89586	EXELTIS HEALTHCARE S.L	ES

Kelzy 2 mg/0,02 mg comprimidos de liberación prolongada	SE/H/2380/001	89586	EXELTIS HEALTHCARE S.L	ES
Kelzyn 2 mg/0,02 mg depottabletti	SE/H/2381/001	42227	EXELTIS HEALTHCARE S.L	FI
Kelzyn 2 mg/0,02 mg depottabletti	SE/H/2381/001	42227	EXELTIS HEALTHCARE S.L	FI
Kelzyn 2 mg/0,02 mg depottabletti	SE/H/2381/001	42227	EXELTIS HEALTHCARE S.L	FI
Jeztiq 2mg/0,02 mg, comprimé à libération prolongée	SE/H/2382/001	34009 302 961 4 1	EXELTIS HEALTHCARE S.L	FR
Jeztiq 2mg/0,02 mg, comprimé à libération prolongée	SE/H/2382/001	34009 302 961 5 8	EXELTIS HEALTHCARE S.L	FR
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/01	EXELTIS MAGYARORSZÁG KFT.	HU

Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/02	EXELTIS MAGYARORSZÁG KFT.	HU
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/01	EXELTIS MAGYARORSZÁG KFT.	HU
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/02	EXELTIS MAGYARORSZÁG KFT.	HU
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/01	EXELTIS MAGYARORSZÁG KFT.	HU
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/02	EXELTIS MAGYARORSZÁG KFT.	HU
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/01	EXELTIS MAGYARORSZÁG KFT.	HU
Kelsee 2 mg/0,02 mg retard tabletta	SE/H/2378/001	OGYI-T-24418/02	EXELTIS MAGYARORSZÁG KFT.	HU

Kelzy 2 mg/0.02 mg prolonged-release tablets	SE/H/2378/001	PA22998/007/001	EXELTIS HEALTHCARE S.L	IE
Kelzy 2 mg/0.02 mg prolonged-release tablets	SE/H/2378/001	PA22998/007/001	EXELTIS HEALTHCARE S.L	IE
Kelzy 2 mg/0.02 mg prolonged-release tablets	SE/H/2378/001	PA22998/007/001	EXELTIS HEALTHCARE S.L	IE
Kelzy 2 mg/0.02 mg prolonged-release tablets	SE/H/2378/001	PA22998/007/001	EXELTIS HEALTHCARE S.L	IE
Kelsee "2 Mg/0.02 Mg Compresse A Rilascio Prolungato"	SE/H/2383/001	051107023	EXELTIS ITALIA SRL	IT
Kelsee "2 mg/0.02 mg Compresse a rilascio prolungato"	SE/H/2383/001	051107035	EXELTIS ITALIA SRL	IT
Kelsee "2 mg/0.02 mg Compresse a rilascio prolungato"	SE/H/2383/001	051107047	EXELTIS ITALIA SRL	IT

KELSEE 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2383/001	051107011	EXELTIS ITALIA SRL	IT
Kelzy 2 mg/0,02 mg pailginto atpalaidavimo tabletės	SE/H/2382/001	LT/1/24/5433/001	UAB EXELTIS BALTICS	LT
Kelzy 2 mg/0,02 mg pailginto atpalaidavimo tabletės	SE/H/2382/001	LT/1/24/5433/002	UAB EXELTIS BALTICS	LT
Kelzy 2 mg/0,02 mg pailginto atpalaidavimo tabletės	SE/H/2382/001	LT/1/24/5433/003	UAB EXELTIS BALTICS	LT
Kelzy 2 mg/0,02 mg pailginto atpalaidavimo tabletės	SE/H/2382/001	LT/1/24/5433/004	UAB EXELTIS BALTICS	LT
Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	2024060153	EXELTIS GERMANY GMBH	LU
Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	2024060153	EXELTIS GERMANY GMBH	LU

Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	2024060153	EXELTIS GERMANY GMBH	LU
Kelsee 2 mg/0,02 mg comprimés à libération prolongée	SE/H/2378/001	2024060153	EXELTIS GERMANY GMBH	LU
Kelzy 2 mg/0,02 mg ilgstošās darbības tabletes	SE/H/2382/001	24-0103	UAB EXELTIS BALTICS	LV
Kelzyn	SE/H/2378/001	RVG 131206	EXELTIS HEALTHCARE S.L	NL
Kelzyn	SE/H/2378/001	RVG 131206	EXELTIS HEALTHCARE S.L	NL
Kelzyn	SE/H/2378/001	RVG 131206	EXELTIS HEALTHCARE S.L	NL
Kelzyn	SE/H/2378/001	RVG 131206	EXELTIS HEALTHCARE S.L	NL

Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	23-15340	EXELTIS HEALTHCARE S.L	NO
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	23-15340	EXELTIS HEALTHCARE S.L	NO
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	23-15340	EXELTIS HEALTHCARE S.L	NO
Kelzy PR, 2 mg + 0,02 mg, tabletki o przedłużonym uwalnianiu	SE/H/2378/001	28402	EXELTIS POLAND SP. Z O.O.	PL
Kelzy PR, 2 mg + 0,02 mg, tabletki o przedłużonym uwalnianiu	SE/H/2378/001	28402	EXELTIS POLAND SP. Z O.O.	PL
Kelzy PR, 2 mg + 0,02 mg, tabletki o przedłużonym uwalnianiu	SE/H/2378/001	28402	EXELTIS POLAND SP. Z O.O.	PL
Kelzy PR, 2 mg + 0,02 mg, tabletki o przedłużonym uwalnianiu	SE/H/2378/001	28402	EXELTIS POLAND SP. Z O.O.	PL

Kelzy 2 mg/0,02 mg comprimidos de libertação prolongada	SE/H/2382/001	5876016	EXELTIS HEALTHCARE S.L	PT
Kelzy 2 mg/0,02 mg comprimidos de libertação prolongada	SE/H/2382/001	5876024	EXELTIS HEALTHCARE S.L	PT
Aulfin	SE/H/2383/001	64500	EXELTIS HEALTHCARE S.L	SE
Dienogest/Ethinylestradiol Exeltis 2mg/0.02 mg	SE/H/2380/001	64497	EXELTIS HEALTHCARE S.L	SE
Dienogest/Ethinylestradiol Exeltis 2mg/0.02 mg	SE/H/2380/001	64497	EXELTIS HEALTHCARE S.L	SE
Dienogest/Ethinylestradiol Exeltis 2mg/0.02 mg	SE/H/2380/001	64497	EXELTIS HEALTHCARE S.L	SE
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	64498	EXELTIS HEALTHCARE S.L	SE

Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	64498	EXELTIS HEALTHCARE S.L	SE
Kelzyn 2 mg/0,02 mg depottabletter	SE/H/2381/001	64498	EXELTIS HEALTHCARE S.L	SE
Mekanna	SE/H/2379/001	64496	EXELTIS HEALTHCARE S.L	SE
Mekanna	SE/H/2379/001	64496	EXELTIS HEALTHCARE S.L	SE
Mekanna	SE/H/2379/001	64496	EXELTIS HEALTHCARE S.L	SE
Mekanna	SE/H/2379/001	64496	EXELTIS HEALTHCARE S.L	SE
Peigit	SE/H/2378/001	64495	EXELTIS HEALTHCARE S.L	SE

Peigit	SE/H/2378/001	64495	EXELTIS HEALTHCARE S.L	SE
Peigit	SE/H/2378/001	64495	EXELTIS HEALTHCARE S.L	SE
Peigit	SE/H/2378/001	64495	EXELTIS HEALTHCARE S.L	SE
Vucanis	SE/H/2382/001	64499	EXELTIS HEALTHCARE S.L	SE
Kelzy	SE/H/2382/001	17/0177/24-S	EXELTIS SLOVAKIA	SK