



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1987499
Pharmacovigilance Risk Assessment Committee (PRAC)
Case number:EMA/PSUR/0000257844

List of nationally authorised medicinal products

Active substance(s): tibolone

Procedure No. PSUSA/00002947/202412



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
Livial 2,5 mg Tabletten	not available	BE158593	ORGANON BELGIUM B.V.	BE
Livial 2,5 mg comprimés	not available	BE158593	ORGANON BELGIUM B.V.	BE
Livial 2,5 mg tabletten	not available	BE158593	ORGANON BELGIUM B.V.	BE
Livial 2,5 mg tablett	not available	11701	N.V. ORGANON	FI
Livial 2,5 mg tabletti	not available	11701	N.V. ORGANON	FI
Livial, 2,5 mg tabletten	not available	RVG 11146	N.V. ORGANON	NL
Ливиал 2,5 mg таблетки	not available	20000198	N.V. ORGANON	BG
Livial 2,5 mg tabletter	not available	13115	N.V. ORGANON	SE
LIVIAL 2,5 mg, comprimé	not available	34009 354 358 6 6	ORGANON_FRANCE	FR
LIVIAL 2,5 mg, comprimé	not available	34009 354 359 2 7	ORGANON_FRANCE	FR
LIVIAL 2,5 mg, comprimé	not available	34009 360 942 8 4	ORGANON_FRANCE	FR
LIVIAL 2,5 mg, comprimé	not available	34009 360 943 4 5	ORGANON_FRANCE	FR
Livial 2,5 mg tabletta	not available	OGYI-T-20953/01	ORGANON HUNGARY KFT.	HU
Livial 2,5 mg tabletta	not available	OGYI-T-20953/02	ORGANON HUNGARY KFT.	HU
Livial, tabletter	not available	12136	N.V. ORGANON	DK
Livial, 2,5 mg, tabletki	not available	R/1580	ORGANON POLSKA SP. Z O.O.	PL
Livial 2,5 mg tabletter	not available	95-3901	N.V. ORGANON	NO
Livial 2.5 mg tablets	not available	13428	N.V. ORGANON	CY
Liviella 2,5 mg Tabletten	not available	33692.00.00	ORGANONHEALTHCARE GMBH	DE
Livial 2,5 mg tabletės	not available	LT/1/98/2570/001	N.V. ORGANON	LT
Livial® 2.5 mg tablets	not available	PL 00025/0599	ORGANON PHARMA (UK) LIMITED	XI
LIVIAL® 2,5 mg tablety	not available	54/249/91-C	N.V. ORGANON	CZ
Livial 2,5 mg comprimés	not available	2011041112	ORGANON BELGIUM B.V.	LU
Livial 2,5 mg tablete	not available	H/98/00931/001	N.V. ORGANON	SI
Livial 2,5 mg töflur	not available	950170	N.V. ORGANON	IS
Livial 2.5mg tablets	not available	PA23198/021/001	ORGANON PHARMA	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
			(IRELAND) LIMITED	
Liviel – Tabletten	not available	1-20657	ORGANONHEALTHCARE GMBH	AT
Boltin 2,5 mg comprimidos	not available	60.100	ORGANONSALUD, S.L.	ES
Livial 2,5 mg tablety	not available	54/0249/91-CS	N.V. ORGANON	SK
Livial 2,5 mg comprimidos	not available	8777300	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Livial 2,5 mg comprimidos	not available	8777318	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
LIVIAL 2,5 mg compresse	not available	028035018	ORGANON ITALIA S.R.L.	IT
Livial 2,5 mg δισκία	not available	43544/18-09-2009	N.V. ORGANON	GR
Livial 2,5 mg comprimate	not available	2157/2009/01	ORGANON BIOSCIENCES S.R.L.	RO
Livial 2,5 mg comprimate	not available	2157/2009/02	ORGANON BIOSCIENCES S.R.L.	RO