



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/619644/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): dexamfetamine

Procedure no.: EMEA/H/N/PSR/S/0029

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MAH	Product Short Name	Product Number (where available)	Active Substance(s)	Sequence Number	Customer Reference	Legal basis	Org EV Code	Product EV Code	Auth Number
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5139204	2017040062
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4498451	53180
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5148270	IS/1/17/018/02
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5598838	33554
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4421070	15-10771
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4425157	56271
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	AMFEXA	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5597811	PL 11243/0023

MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	TENTIN	N/A	N/A	0018	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD7863406	RVG 124800
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0022	N/A	Generic application (Article 10(1) of Directive No 2001/83/EC)	ORG1920	PRD4399725	94042.00.00
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4421071	15-10772
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4498452	53181
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5148273	IS/1/17/018/03
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5139205	2017040062
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4429718	33555
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4425158	56272

MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	AMFEXA	N/A	N/A	0028	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4425156	PL 11243/0024
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4397599	2014120350
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4397601	11-8529
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4397597	30066
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4397602	46616
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD5147871	IS/1/17/018/01
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4397596	49372
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	AMFEXA	N/A	N/A	0059	N/A	Well-established use application (Article 10a of Directive No 2001/83/EC)	ORG1920	PRD4397603	PL 11243/0021

MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0022	N/A	Generic application (Article 10(1) of Directive No 2001/83/EC)	ORG1920	PRD4399726	94043.00.00
MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	ATTENTIN	N/A	N/A	0017	N/A	Generic application (Article 10(1) of Directive No 2001/83/EC)	ORG1920	PRD4399724	74643.00.00