



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2019
EMA/218030/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexamfetamine

Procedure No.: PSUSA/00000986/201809

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



| 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 |
|---|------------------------------|-------------------------------|--|--|
| Dexamfetamine Sulfate 1mg/ml Oral Solution | not available | PL 00156/0034 | MARTINDALE PHARMACEUTICALS LTD | UK |
| Dexamfetamine Sulfate 5 mg Tablets | not available | PL 44710/0011 | KINEDEXE UK LIMITED | UK |
| Dexamfetaminesulfaat DMB 5 mg, tabletten | not available | RVG 115446 | TIOFARMA BV | NL |
| Attentin 10 mg Tablette Dexamfetaminhemisulfat Zur Anwendung bei Kindern und Jugendlichen ab 6 Jahren | not available | 94042.00.00 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | DE |
| Attentin 20 mg Tablette Dexamfetaminhemisulfat Zur Anwendung bei Kindern und Jugendlichen ab 6 Jahren | not available | 94043.00.00 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | DE |
| Attentin 10 mg tabletter | UK/H/5007/002 | 15-10771 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | NO |
| Attentin 20 mg tabletter | UK/H/5007/003 | 15-10772 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | NO |
| Amfexa 20 mg tablets | UK/H/5007/003 | PL 11243/0024 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | UK |
| Attentin, tabletter 10 mg | UK/H/5007/002 | 56271 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | DK |
| Attentin, tabletter 20 mg | UK/H/5507/003 | 56272 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | DK |
| Attentin 20 mg tabletit | UK/H/5007/003 | 33555 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | FI |

| 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 |
|---|------------------------------|-------------------------------|--|--|
| Attentin 10 mg tabletter | UK/H/5007/002 | 53180 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | NO |
| Attentin 20 mg tabletter | UK/H/5007/003 | 53181 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | SE |
| Attentin 10 mg Tabletten | UK/H/5007/002 | 2017040061 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | LU |
| Attentin 20 mg Tabletten | UK/H/5007/003 | 2017040062 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | LU |
| Amfexa 10 mg comprimidos | UK/H/5007/002 | 81758 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | ES |
| Amfexa 20 mg comprimidos | UK/H/5007/003 | 81759 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | ES |
| Attentin 10 mg töflur | UK/H/5007/002 | IS/1/17/018/02 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | IS |
| Attentin 20 mg töflur | UK/H/5007/003 | IS/1/17/018/03 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | IS |
| Amfexa 10 mg tablets | UK/H/5007/002 | PL 11243/0023 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | UK |
| Attentin 10 mg tabletit | UK/H/5007/002 | 33554 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | FI |
| Attentin, tabletter 5 mg | UK/H/5007/001 | 49372 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | DK |
| Attentin 5 mg tabletit | UK/H/5007/001 | 30066 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | FI |
| Attentin 5 mg Tabletten | UK/H/5007/001 | 2014120350 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | LU |
| Amfexa 5 mg tabletten | UK/H/5007/001 | RVG 110336 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | NL |

| 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 |
|---|------------------------------|-------------------------------|--|--|
| Attentin 5 mg tableter | UK/H/5007/001 | 11-8529 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | NO |
| Attentin 5 mg tablett | UK/H/5007/001 | MTNR. 46616 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | SE |
| Amfexa 5 mg Tablets | UK/H/5007/001 | PL 11243/0021 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | UK |
| Attentin 5 mg, Tablette Dexamfetaminhemisulfat Zur Anwendung bei Kindern und Jugendlichen ab 6 Jahren | not available | 74643.00.00 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | DE |
| Amfexa 5 mg comprimidos | UK/H/5007/001 | 79582 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | ES |
| Attentin 5 mg töflur | UK/H/5007/001 | IS/1/17/018/01 | MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG | IS |
| Dexamfetamine Sulfate 1 mg/ ml Oral Solution | NO/H/0246/001 | PL 41094/0009 | ESSENTIAL PHARMACEUTICALS LIMITED | UK |
| Dexamfetamine EssPharm 1 mg/ml mixtúra lausn | NO/H/0246/001 | IS/1/15/060/01 | ESSENTIAL PHARMACEUTICALS LIMITED | IS |
| Dexamfetamine EssPharm 1 mg/ml mikstur, oppløsning | NO/H/0246/001 | 13-9893 | ESSENTIAL PHARMACEUTICALS LIMITED | NO |
| Dexamfetamine Sulfate 5 mg Tablets | not available | PL 00289/2278 | TEVA UK LIMITED | UK |