A physician's guide to prescribing Amfexa® 5 mg, 10 mg and 20 mg Tablets (dexamfetamine sulfate)

Dear Doctor,

The following information is designed to support the appropriate prescribing, administration and monitoring of Amfexa® 5 mg, 10 mg and 20 mg Tablets (dexamfetamine sulfate).

Amfexa® Tablets are a branded preparation of dexamfetamine sulfate. Amfexa® Tablets are white (for the 5 mg presentation), yellow (for the 10 mg presentation), or reddish (for the 20 mg presentation), round, cloverleaf-shaped tablets of 8.4 mm diameter with a notched, cross-scored line on the top side and a cross-scored line embossed with either an 'S' (for the 5mg presentation), an 'M' (for the 10mg presentation) or an 'L' (for the 20mg presentation) on each quarter on the rear side. The score line is to facilitate breaking for ease of swallowing and not to divide into equal doses. [1]

All healthcare professionals are encouraged to report suspected Adverse Drug Reactions and Medication Errors. The ADR reporting form for HCPs may be downloaded from the Medicines Authority (MMA) website. HCPs may either: fill in the adverse drug reaction form and then send to the Malta Medicines Authority via email on postlicensing.medicinesauthority@gov.mt OR fill it in and send it via free postage to: Malta Medicines Authority Sir Temi Żammit Buildings Malta LifeSciences Park San Ġwann SĠN 3000
Adverse events should also be reported to rp@ejbusuttil.com or by Telephone 00356 21447184.

Amfexa® Tablets are indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate. [1,]

A comprehensive treatment programme typically includes psychological, educational and social measures. [1,]

Diagnosis should be made according to DSM criteria or the guidelines in ICD-10 and should be based on a comprehensive multidisciplinary evaluation of the patient. [1]

Dexamfetamine is not indicated in all children with ADHD and the decision to use dexamfetamine must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age and potential for abuse, misuse or diversion. [1]

Treatment should be under the supervision of a specialist in childhood and/or adolescent behavioural disorders. [1]

Please consider and use the following information, checklists and advice in addition to the information contained within the Summary of Product Characteristics (SmPC) when initiating, monitoring or ceasing use of Amfexa® Tablets:

•Checklist 1: Checklist before prescribing Amfexa® Tablets•
https://ejbusuttil-my.sharepoint.com/:b:/p/gilbert/EcKJALL2-K1IgAYzxxs1ONIBch4wL2ysbJ8HO7E2RWRvuw?e=K9h9mA

Checklist 2: Checklist for monitoring of ongoing therapy with Amfexa® Tablets
https://ejbusuttil-my.sharepoint.com/:b:/p/gilbert/ETJ_qiNz4I1ImMqu24mS3w4B1AqcQOTRsp82xzVya5-tPQ?e=pySAte

Checklist 3: Considerations when ending treatment with Amfexa® Tablets
https://ejbusuttil-my.sharepoint.com/:b:/p/gilbert/EVjG_CwyLNVFuo-r70oE2ncBcLKjHPyT-Sbpt7lfyyNYhA?e=SGPtQn

Dexamphetamine is a Schedule V controlled substance and as such clinicians should be aware of the current legislation and requirements associated with the prescribing of controlled substances. Key prescription requirements include:

- Signature Date (controlled drug prescriptions are only valid for 28 days from appropriate date)
- Prescriber's address Dose Form of the medicine (tablet, capsules, etc.)
- Strength Total quantity (in both words and numbers)
- Treatment period Name of the patient Address of the patient
- Dental wording (where appropriate)
- Instalment direction Age of the patient (if under 12 years old)

Potential abuse, dependency, misuse or diversion of dexamfetamine by the patient should be carefully evaluated at every visit. [1,]

Should you require any further information relating to the use, supply or prescribing of Amfexa® Tablets please contact Medice UK:
Telephone: 0204 582 2845
Email: medicalinformation@medice.co.uk

Or the Local representative
EJ Busuttil Ltd
Busuttil Buildings, Triq l-Ghadam, Central Business District Zone 1
Birkirkara
Tel 00356 21447184
rp@ejbusuttil.com

Further information can be obtained from https://medicinesauthority.gov.mt/rmm

Yours faithfully,
EJ Busuttil Team

References:

1. Amfexa 5mg SPC
https://ejbusuttil-my.sharepoint.com/:b:/p/gilbert/Ed42ie5TOq9Lo9J-nMgVZGwBMf3-79tRe3OvwAyuppAZMg?e=TwvOUT