**Amfexa 5mg (dexafetamine sulfate 5mg)**

Wednesday, 12 July 2023

Dear Pharmacist,

This sheet provides additional information on Amfexa® 5 mg, 10 mg and 20 mg Tablets (dexamfetamine sulfate). Amfexa® Tablets are a branded preparation of dexamfetamine sulfate. Amfexa® Tablets (dexamfetamine sulfate) 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 5 mg presentation), an 'M' (for the 10 mg presentation) or an 'L' (for the 20 mg presentation) on each quarter on the rear side. 1, 2, 3

Amfexa® Tablets (dexamfetamine sulfate) 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. A comprehensive treatment programme typically includes psychological, educational, and social measures.[1]

The initiation of treatment must be under supervision of a specialist in childhood and/or adolescent behavioural disorders. [1]

**Prescription requirements**
**Dexamfetamine is a controlled substance under Medical and Kindred Professions Ordinance Cap. 31, Dangerous Drugs Ordinance Cap. 101 an S.L.101.02 and as such all pharmacists should be aware of the current legislation and requirements associated with the dispensing of controlled substances.**

**Key prescription requirements include:**
- **Using the booklets issued by the Superintendent of Public Health**
- **Signature Date (controlled drug prescriptions are only valid for 28 days from appropriate date) accompanied by the control card unless an Urgent Supply which must be clearly labelled**
- **Prescriber's address**
- **Dose Form of the medicine (tablet, capsules, etc.)**
- **Strength Total quantity**
- **Name of the patient Address of the patient**
- **Age of the patient (if under 12 years old)**

**More detailed information is available from**
**https://healthservices.gov.mt/en/poyc/Pages/360%C2%B0-One-Stop-Shop-Service-Concept/A%20Control-Card-Section.aspx**

**Adverse event reporting**
**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.**

**Consider risk of abuse, dependence, off-label use, misuse and diversion**
There is the potential for abuse, dependence, misuse and diversion of dexamfetamine. As such patients should be carefully monitored for the risk of off-label (diversion, misuse, dependency and abuse) use of dexamfetamine[1]

Dexamfetamine should not be used in patients with known past or present drug or alcohol dependency because of a potential for abuse, misuse, or diversion.[1]

Signs of chronic amphetamine intoxication include severe dermatoses, pronounced sleeplessness, confusion, hyperactivity, and personality changes. The most severe sign of chronic amphetamine intoxication is a psychosis which in most cases can hardly be clinically distinguished from schizophrenia. However, such a psychosis rarely occurs after oral ingestion of amphetamines. There have also been reports of intracerebral bleeding. Serious cardiovascular events observed in association with amphetamine misuse were sudden death, cardiomyopathy, and myocardial infarction.[1]

Signs of improper or problematic dexamfetamine use include.
•If the frequency of prescription presentation is excessive (when considering the prescribed dosage regimen) Note: On initiation of treatment, because of the requirement for titration, patients may return earlier or more frequently than on a monthly basis for prescriptions. Frequency of return should stabilize once a maintenance dose and regimen has been established

•If the substance is prescribed by different physicians/specialists (*or if the substance is unexpectedly frequently prescribed without public reimbursement)*
•The prescription is suspected to be falsified
•The patient finds excuses such as lost prescription

If you have suspicion of abuse, dependence, off-label use, misuse or diversion, please inform the regulatory authority https://medicinesauthority.gov.mt/reportingadversereactions as well as 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

1 https://ejbusuttil-my.sharepoint.com/:b:/p/gilbert/EaBZgEaShttGmCnDp9owB-AByexQRDzji9BvV5MCufdbaQ?e=7lSKpc

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