AMFEXA® 5 mg, 10 mg and 20 mg TABLETS

PRESCRIBING INFORMATION: Please refer to Summary of Product Characteristics (SmPC) before prescribing.

ACTIVE INGREDIENT: Dexamfetamine sulfate 5 mg, 10 mg or 20 mg.

Pharmaceutical Form: 5mg white tablet, 10mg yellow tablet, 20mg reddish tablet

INDICATION: Attention-deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-17 years as part of a comprehensive treatment programme under the supervision of a specialist in childhood and/or adolescent behavioural disorders when response to previous methylphenidate treatment is considered clinically inadequate.

DOSAGE and ADMINISTRATION: Children (aged 6 years and over) and adolescents: Careful dose titration is necessary at the start of treatment with dexamfetamine and should be started at the lowest possible dose. The recommended starting dose is 5mg once or twice daily, increasing, if necessary, by weekly increments of 5mg in the daily dose. The regimen that achieves satisfactory symptom control with the lowest daily dose should be employed. Maximum daily dose is usually 20mg. Tablets may be swallowed whole with the aid of liquids or divided along the score lines into four parts. **Children under 6 years:** Not recommended. **Adults:** Amfexa is not licensed for use in adults. **Elderly:** Not recommended. **Long-term use (more than 12 months):** It is recommended that the long-term usefulness of Amfexa should be re-evaluated by de-challenging at least once yearly to assess the patient's condition. **Patients with renal or hepatic insufficiency:** No experience of use in this patient group; special caution with titration and dosage.

CONTRAINDICATIONS: Known hypersensitivity to dexamfetamine, excipients (contains isomalt; fructose intolerant patients should not take Amfexa) or sympathomimetic amines; glaucoma, phaeochromocytoma, concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of MAOI treatment, hyperthyroidism or thyrotoxicosis, Gilles de la Tourette syndrome or similar dystonias, porphyria, cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke), symptomatic cardiovascular disease, structural cardiac abnormalities and/or moderate or severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life- threatening arrhythmias, channelopathies, advanced arteriosclerosis, severe depression, anorexia nervosa/anorexic disorders, suicidal ideation, hyperexcitability, psychotic symptoms, severe and episodic (Type I) Bipolar (affective) Disorder (that is not well-controlled), schizophrenia, psychopathic/borderline personality disorder, a history of drug abuse or alcohol abuse.

SPECIAL WARNINGS and PRECAUTIONS: Growth, psychiatric and cardiovascular status should be recorded at baseline and a comprehensive history taken. Monitor on dose adjustment and at least six- monthly intervals. Patients should be monitored for risk of diversion, misuse and abuse; do not use in patients with known drug or alcohol dependency. Monitor cardiovascular status carefully as sudden death has been reported. Stimulants are not recommended in the presence of serious cardiac problems. Caution in patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate. Patients who develop symptoms of cardiac disease should undergo prompt evaluation. In the case of emergent psychiatric symptoms, or exacerbation of pre- existing psychiatric disorders, dexamfetamine should not be given unless the benefits outweigh the risks. Emergent suicidal ideation or behaviour should be evaluated immediately. Particular

care should be taken in treating ADHD patients with comorbid bipolar disorder because of concerns for possible precipitation of a mixed/ manic episode. Use with caution in patients with epilepsy as it may increase frequency of seizures. May induce a positive laboratory result for amfetamines during 'anti-doping' tests. In the event of adverse haematological effects, discontinuation should be considered. Careful supervision is required during withdrawal and long term follow up for abrupt withdrawal checking for changes in EEG during sleep.

INTERACTIONS: Gastrointestinal and urinary acidifying agents, gastrointestinal and urinary alkalinising agents, clonidine, sedative antihistamines, guanethidine, beta-blockers, opiates, halogenated narcotics, noradrenaline, meperidine, coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone, ethosuximide), some anti-depressants (tricyclics, SSRIs), disulfiram, adrenergic blockers (e.g. propranolol), lithium, α-methyltyrosine, haloperidol, alcohol and phenothiazines (e.g. chlorpromazine) and corticosteroids.

FERTILITY, PREGNANCY and LACTATION: Dexamfetamine is not recommended in pregnancy and should not be used by breast feeding mothers when the risk to the child outweighs the benefit of therapy for the mother.

DRIVING: Caution is advised when driving, operating machines or engaging in other potentially hazardous activities. This medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. Consult SmPC for further information.

UNDESIRABLE EFFECTS: Very common: Decreased appetite, reduced weight gain and weight loss (during prolonged use), insomnia, nervousness. **Common:** Arrhythmia, palpitations, tachycardia, abdominal pain and cramps, nausea, vomiting, dry mouth, changes in blood pressure and heart rate (usually increases), arthralgia, vertigo, dyskinesia, headache, hyperactivity, abnormal behaviour, aggression, excitation, anorexia, anxiety, depression, irritability. **Other side-effects:** Angina pectoris, cardiac arrest, cardiomyopathy, myocardial infarction, ischaemic colitis, hyperpyrexia, sudden death, abnormal liver function, hypersensitivity, rhabdomyolysis, convulsions, intracranial haemorrhage, stroke, neuroleptic malignant syndrome, psychosis, suicidal behaviour, renal damage, erythema multiforme, cerebral vasculitis and / or occlusion, cardiovascular collapse, toxic hypermetabolic state, withdrawal symptoms. In overdoses, individual patient response may vary widely, and toxic manifestations may occur with quite small overdoses. **Consult SmPC for all side-effects.**

PHARMACEUTICAL PRECAUTIONS: Store below 25°C in original packaging.

DATE OF REVISION OF PI: September 2023.

LEGAL CATEGORY: CD (Sch2) POM.

Product	NHS Cost (for 30 pack)	Marketing Authorisation Number:
Amfexa 5 mg Tablets	£19.89	PL11243/0021
Amfexa 10 mg Tablets	£39.78	PL11243/0023
Amfexa 20 mg Tablets	£79.56	PL11243/0024

MARKETING AUTHORISATION HOLDER: Medice Arzneimittel Pütter GmbH & Co. KG, Kuhloweg 37, 58638 Iserlohn, Germany. Marketed in the UK by: Medice UK, The Rotunda, 1 Old London Road, Hertford, Herts SG137LA; Tel: 0204 582 2845; Email:

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Information about this product, including adverse reactions, precautions, contraindications and method of use can be found at http://www.medicines.org.uk/emc/.

Amfexa is a registered trademark of Medice GmbH.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Medice UK. Medical Information: Tel 02045822845.