

## PRESCRIBING INFORMATION

**AMFEXA® (dexamfetamine sulfate)** 5-20mg tablets.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

**Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MEDICE UK on 0204 582 2845, [pv-uk@medice.co.uk](mailto:pv-uk@medice.co.uk)**

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

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

**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 when response to previous methylphenidate treatment is considered clinically inadequate. Treatment should be under the supervision of a specialist in childhood and/or adolescent behavioural disorders.

**DOSAGE and ADMINISTRATION: Children (aged 6 years and over) and adolescents:** Pre-treatment screening: Prior to prescribing, it is necessary to conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight on a growth chart. 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, although 40mg may in rare cases be necessary for optimum titration. Tablets may be swallowed whole with the aid of liquids or divided along the score lines into four parts. **Children under 6 years:** Not licensed. **Adults:** Amfexa is not licensed for use in adults. **Elderly:** Not licensed. **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. Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period.

**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 concerns for possible precipitation of a mixed/manic episode. Dexamfetamine is associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. 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 antidepressants (tricyclics, SSRIs), disulfiram, adrenergic blockers (e.g. propranolol), lithium,  $\alpha$ -methyltyrosine, haloperidol, alcohol and phenothiazines (e.g. chlorpromazine) and corticosteroids. Caution with co-administration with CYP substrates with narrow therapeutic index and potent inhibitors or inducers of CYP enzymes.

**PREGNANCY, LACTATION and FERTILITY:** 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. Women of childbearing age should discontinue the use of Amfexa tablets when intending to become pregnant.

**DRIVING:** Caution is advised when driving, operating machines or engaging in other potentially hazardous activities as dexamfetamine can cause dizziness, drowsiness and visual disturbances including difficulties with accommodation, diplopia and blurred vision. 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 serious side effects:** Leukopenia, thrombocytopenia, 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.

**LEGAL CATEGORY:** CD (Sch2) POM.

Product	NHS Cost (for 30 pack)	Marketing Authorisation Number:
Amfexa 5mg Tablets	£19.89	PL 11243/0021
Amfexa 10mg Tablets	£39.78	PL 11243/0023
Amfexa 20mg Tablets	£79.56	PL 11243/0024

**MARKETING AUTHORISATION HOLDER:** MEDICE Arzneimittel Pütter GmbH & Co. KG, Kuhlweg 37, 58638 Iserlohn, Germany.

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