Checklist 1: checklist before prescribing Amfexa® 5 mg, 10 mg and 20 mg Tablets

It is recommended that this checklist be used in conjunction with the SmPCs for Amfexa® Tablets:

- Amfexa® 5 mg Tablets SmPC
- Amfexa® 10 mg Tablets SmPC
- Amfexa® 20 mg Tablets SmPC

As outlined in the Amfexa® Tablets SmPCs in more detail, there are some specific concurrent conditions where the use of Amfexa® Tablets is contraindicated. In addition, there are some conditions which require specific special warnings and precautions when Amfexa® Tablets are used; these include some cardiovascular, cerebrovascular and neuropsychiatric disorders. [1,2,3]

- Blood pressure and pulse should be recorded on a centile chart at each dose adjustment and then at least every 6 months
- Height, weight and appetite should be recorded at least 6 monthly with maintenance of a growth chart
- Development of *de novo* or worsening of pre-existing psychiatric disorders should be monitored at every dose adjustment and then at least every 6 months and at every visit

Potential abuse, dependency, misuse or diversion of dexamfetamine by the patient should be carefully evaluated at every visit. [1,2,3]

Additional information can be found in the Amfexa® Tablets SmPCs, the specific section of the SmPCs to refer to is indicated by the red numbers in the checklist.

As you work through the checklist, it may also be useful for you to discuss the Amfexa® Tablets patient information leaflet (PIL) with your patient and their parent(s) or guardian(s). The PILs can be accessed as follows:

- 5mg Amfexa® 5 mg Tablets PIL
- 10mg Amfexa® 10 mg Tablets PIL
- 20mg Amfexa® 20 mg Tablets PIL

Date of assessment: Name:

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Date of birth: Gender: Age:

Patients with any of the following conditions, comorbidities and/or co-medications should not receive Amfexa® Tablets:

Contraindications 4.3	
The following are contraindicated:	
	Evaluated
Hypersensitivity to the active substance or any of the excipients listed in section 6.1	☐
Hypersensitivity or idiosyncrasy to sympathomimeticamines	☐
Glaucoma	☐
Phaeochromocytoma	☐
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 and channelopathies (disorders caused by the dysfunction of ion channels).	☐
Advanced arteriosclerosis.	☐
During or within 14 days after treatment with a monoamine oxidase inhibitor (MAOI)	☐
Hyperthyroidism or thyrotoxicosis	☐
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	☐
Gilles de la Tourette syndrome or similar dystonias	☐
Cerebrovascular disorders (cerebral aneurysm, vascular abnormalities including vasculitis or stroke)	☐
Porphyria	☐
History of drug abuse or alcohol abuse	☐

Special warnings and precautions for use (4.4)

Please consider the following prior to treatment with Amfexa® Tablets:

Family history	
	Evaluated
Family history of sudden cardiac or unexplained death or malignant arrhythmia	☐
Family history of tics or Tourette's syndrome	☐
Family history of suicide, bipolar disorder, and depression	☐

Patient's history and physical exam	
Baseline evaluation of patient's cardiovascular status, including blood pressure and heart rate. Concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms and accurate recording of pre-treatment height and weight on a growth chart	☐

Cardiovascular (view section 4.4)	
History of cardiovascular disease	☐
Known cardiac structural abnormalities, cardiomyopathy, serious heart rhythm abnormalities or increased blood pressure or heart rate	☐
Underlying medical condition which might be compromised by increases in blood pressure or heart rate	☐

Psychiatric/neurological disorders (view section 4.4)	
Pre-existing psychotic or manic symptoms	☐
Pre-existing psychiatric disorders	☐
Aggressive or hostile behaviour	☐
Motor or verbal tics or Tourette's syndrome	☐
Anxiety, agitation or tension	☐
Depressive symptoms (screen for risk for bipolar disorder by detailed psychiatric history including family history of suicide, bipolar disorder and depression	☐
Bipolar disorder	☐
Presence of epilepsy. Epileptic patients with history of seizures, prior EEG abnormalities in absence of seizures	☐
History of drug dependency or abuse of CNS stimulants	☐
History of drug misuse or diversion of CNS stimulants	

Other medical conditions such as (view section 4.4)	
Known intolerance to excipients	☐
Known renal or hepatic insufficiency	☐
Presence of leukopenia, thrombocytopenia, anaemia or other alterations, including those indicative of serious renal or hepatic disorders	☐
Pregnancy (view section 4.6)	☐
Breast feeding (view section 4.6)	☐

Potential drug-drug interactions (view section 4.5)	
Gastrointestinal acidifying agents (guanethidine, reserpine, glutamic acid HCl, ascorbic acid, fruit juices, etc.) lower the absorption of amphetamines.	☐
Urinary acidifying agents (ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the ionized species of the amphetamine molecule, thereby increasing urinary excretion. Both groups of agents can lower blood levels and efficacy of amphetamines	☐
Gastrointestinal alkalinizing agents (sodium bicarbonate, etc.) increase the absorption of amphetamines, thereby decreasing urinary excretion and therefore potentiate the actions of amphetamines.	☐
Urinary alkalinizing agents (acetazolamide, some thiazides) increase the concentration of the non-ionized species of the amfetamine molecule, thereby decreasing urinary excretion and therefore potentiate the actions of amphetamines.	☐
Clonidine	☐
Coumarin anticoagulants	☐
Anticonvulsants	☐
Antidepressants	☐
Antihistamines	☐
Adrenergic blockers	☐
Lithium	☐
Alpha-methyltyrosine	☐
Haloperidol	☐

Disulfiram	☐
Vasopressors	☐
Antihypertensive drugs	☐
Noradrenaline	☐
Morphine	☐
Meperidine	☐
MAO-inhibitors	☐
Halogenated narcotics	☐
Phenothiazines	☐
Alcohol	☐

Record any additional information here: _____

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If you need to report any Adverse Drug Reaction please inform the regulatory authority https://medicinesauthority.gov.mt/reportingadversereactions or the local representative:
EJ Busuttil Ltd
Busuttil Buildings, Triq l-Ghadam, Central Business District Zone 1
Birkirkara
Tel 00356 21447184
rp@ejbusuttil.com