

Amfexa 5mg (dexafetamine sulfate 5mg)

Information for parents and carers

What is ADHD?

ADHD is a medical condition that can affect children, adolescents, and adults. It is considered one of the most common developmental disorders in children.

Children with ADHD may find it unusually difficult to concentrate, pay attention, sit still, follow directions, and control impulsive behaviour. Whilst all young children are at times distractible, restless and find it difficult to follow instructions, children with ADHD have these symptoms more often and to a greater extent than other children their age. This can lead to difficulties both at home and at school.

A diagnosis of ADHD will be made by a child psychiatrist or a paediatrician specializing in neurodevelopmental disorders following a thorough assessment of your child's symptoms and the taking of a detailed history. A diagnosis is made according to the criteria described in either the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) or the *International Classification of Diseases* (ICD).

How is ADHD managed?

A first step to managing ADHD may include providing information and counselling to patients, parents, and other carers to understand the disorder, its causes and possible treatment options. Another option is behavioural therapy for the child and their family, which may sometimes be extended to include teachers or other carers.

ADHD may be treated with medicines prescribed by a doctor, which include stimulants (e.g., methylphenidate or amfetamines, like dexafetamine [Amfexa®]) and non-stimulant medicines (e.g., atomoxetine).

As for all medicines, stimulants such as Amfexa (dexafetamine) must be used in the correct way. Stimulants are controlled substances. This means that there are additional requirements by the national authorities that regulate their use and prescription. For this reason, stimulants must be handled with caution and care.

What do you have to consider while your child is on stimulant therapy?

As with all prescription medicines, it is important that your child takes Amfexa (dexafetamine) according to the instructions contained within the Patient Information Leaflet provided with your child's medicine and following the doctor's advice.

If not used correctly, stimulant medicines can cause several possible side effects; for example, if taken at high doses or used when not prescribed, they can cause serious health consequences.

Because of Amfexa® (dexafetamine) has stimulant properties, this medicine has the potential for:

- Abuse (deliberately using the medicine for reasons other than treatment of ADHD),
- Dependence (treatment becoming less effective with long-term use and child requiring increased amount to obtain the same level of symptom control)
- Misuse (deliberately not using the medicine according to your child's doctor's instructions)
- Diversion (use of the medicine by people other than your child who was prescribed the medicine)

How do I know if the medication is being used inappropriately? Some symptoms (side-effects) may indicate improper or excessive use of stimulants, but the presence of the symptoms does not always mean that your child is abusing their medication. Some of these symptoms may be side-effects associated with the normal use of their medication. If your

Amfexa 5mg (dexafetamine sulfate 5mg)

child is taking too much of their medication, they may experience the following side effects: euphoria, hyperactivity, agitation or irritability, anxiety and nervousness, difficulty sleeping, decreased appetite, reduced weight gain or weight loss during prolonged use in children, changes in blood pressure and heart rate (usually increases), a feeling of dizziness or “spinning”, jerky or involuntary movements, dilated pupils, dry mouth and dry nose. If you are concerned about any symptoms or side-effects that your child is experiencing, please talk to your child’s doctor.

What can I do to help my child?

Monitor how much medicine your child is taking, and how often. A simple method for monitoring use of medication is by regularly counting their pills and making sure it is aligned with what their doctor has prescribed. Be sure that your child’s medication is stored in a safe place, including at school. Do not allow anyone else other than your child to use the medicine. Talk to your child about possible risks and dangers arising from taking stimulant medicines regularly, including the dangers of using it improperly and the laws relating to someone else using their medication. Provide an open atmosphere where your child feels safe and will speak to you about problems or concerns, they have over the use of their medication.

For further information please refer to the Patient Information Leaflet that was provided with your child’s medicine - [PIL](#)

Reporting of side effects If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet inside the pack.

You can also report side effects directly at the Malta ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal or contacting the local representative.

By reporting side effects, you can help provide more information on the safety of this medicine.

Local Distributor

EJ Busuttil Ltd

Busuttil Buildings, Triq l-Ghadam, Central Business District Zone 1

Birkirkara

Tel 00356 21447184

rp@ejbusuttil.com