**Patient Information Leaflet**

**SCHEDULING STATUS** **S6**

**Amfexa 5 mg tablets**
**Amfexa 10 mg tablets**
**Amfexa 20 mg tablets**
Dexamfetamine sulfate

**Contains Sugar:** Isomalt (E953) 147,5 mg per 5 mg tablet
Isomalt (E953) 147,7 mg per 10 mg tablet
Isomalt (E953) 137,7 mg per 20 mg tablet

**Read all of this leaflet carefully before you start using Amfexa.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Amfexa has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**What is in this leaflet:**



## 1. WHAT AMFEXA IS AND WHAT IT IS USED FOR

**What Amfexa is**

Amfexa contains the active substance dexamfetamine sulfate.

Amfexa is a psychostimulant. It improves activity in parts of the brain. This medicine can help to improve attention span, concentration, and reduce impulsive behaviour.

**What it is used for**

Amfexa is used to treat attention-deficit/hyperactivity disorder (ADHD).

- It is used in children and adolescents aged 6-17 years.
- It is not indicated in all children with ADHD
- It is used only after when another medicine called methylphenidate was not sufficiently effective.
- It should be used as part of a treatment programme which typically includes psychological, educational and social measures.

Amfexa treatment must only be initiated by and used under the supervision of a specialist in childhood or adolescent behavioural disorders.

You must talk to a doctor if your child does not feel better or if they feel worse after a month. The doctor may decide that a different treatment is needed.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE AMFEXA

**Do not use Amfexa if your child:**

- is allergic (hypersensitive) to dexamfetamine or other amfetamine compounds or any of the other ingredients of Amfexa (listed in section 6)
- has a thyroid problem
- has increased pressure in the eyes (glaucoma)
- has a tumour of the adrenal gland (phaeochromocytoma)
- has an eating problem, does not feel hungry or does not want to eat (e.g. anorexia nervosa)
- has very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- has advanced thickening and hardening of the arteries (arteriosclerosis)
- has ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease, or was born with a heart problem
- has had a problem with the blood vessels in the brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- has mental health problems such as:
  - a psychopathic or borderline personality disorder

- abnormal thoughts or visions or schizophrenia
- signs of a severe mood disorder like:
  - suicidal feelings
  - severe depression
  - mania

- is currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) – see the 'Other medicines and Amfexa' section below
- has ever abused alcohol, prescription medicines, or street drugs
- or anyone in your family has Tourette's syndrome or other motor or verbal tics
- has hard-to-control, repeated twitching of any parts of the body or repeats sounds and words
- has porphyria
- pregnant or breastfeeding

Do not use this medicine if any of the above applies to your child. If you are not sure, talk to your doctor or pharmacist before you use Amfexa. This is because this medicine can make these problems worse.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Amfexa if your child:

- has a disease of the blood or liver, or kidney problems
- is hyperexcitable or has an unstable personality
- has had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- is female and has started having periods (see the 'Pregnancy and breast-feeding' section below)
- has high blood pressure
- has a heart problem which is not in the 'Do not use' section above
- has a mental health problem which is not in the 'Do not use' section above. This may include mood swings, unusual aggression, hallucinations, delusions, paranoia, agitation and anxiety, feelings of guilt or depression.

Tell your doctor or pharmacist if any of the above applies to your child before starting treatment. This is because this medicine can make these problems worse. Your doctor will want to monitor how the medicine affects your child.

**Checks that your doctor will make before Amfexa is used**

These checks are to decide if this is the correct medicine for your child. Your doctor will talk to you

about:

- any other medicines your child is taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how your child is feeling, such as feeling high or low, having strange thoughts or if your child has had any of these feelings in the past
- whether there is a family history of 'tics' (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behaviour problems you or other family members have ever had.

Your doctor will discuss whether your child is at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check your child's mental health history, and check if any of your family has a history of suicide, bipolar disorder or depression.
It is important that you provide as much information as you can. This will help your doctor decide if Amfexa is the correct medicine for your child. Your doctor may decide that other medical tests are needed before they start taking this medicine.

**Effect on weight/growing**

Amfexa may cause reduced weight in some children and adolescents.

- There may be lack of weight gain.
- Your doctor will carefully watch the height and weight of your child, as well as how well your child is eating.
- If your child is not growing as expected, then your doctor may stop treatment with Amfexa for a short time.

**Having an operation**

Tell your doctor if your child is going to have an operation. Amfexa should not be taken on the day of surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

**Drug testing**

This medicine may give a positive result when testing for drug use.

**Drug/laboratory test interactions**

This medicine may interfere with your laboratory test results.

**Children and adolescents**

Amfexa is not for use as a treatment for ADHD in children under 6 years of age, and adults. It is not known if it is safe or of benefit for these people.

**Other medicines and Amfexa**

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

Monoamine oxidase inhibitors

Do not use this medicine if your child is taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or has taken an MAOI in the last 14 days. Taking an MAOI with dexamfetamine may cause a sudden increase in blood pressure.

If your child is taking other medicines, this medicine may affect how well they work or may cause side effects. If your child is taking any of the following medicines, check with your doctor or pharmacist before using Amfexa:

- other medicines for depression, e.g., tricyclic antidepressants and selective serotonin reuptake inhibitors
- medicines for severe mental health problems, e.g., phenothiazines and haloperidol
- medicines for epilepsy, e.g., anticonvulsants like phenobarbital, phenytoin, primidone, and ethosuximide
- medicines that help to give up alcohol, e.g., disulfiram
- medicines used to reduce or increase blood pressure, e.g., guanethidine, clonidine, reserpine, or alpha-methyltyrosine, or beta-blockers such as propranolol
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots, e.g., coumarin anticoagulants
- any medicines that contain glutamic acid HCl, ascorbic acid, ammonium chloride, sodium acid phosphate, sodium bicarbonate, acetazolamide, thiazides
- any of the following medicines: beta-blockers, antihistamines, lithium, noradrenaline, morphine, and meperidine.

If you are in any doubt about whether any medicines your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking this medicine.

**Amfexa with alcohol**

Alcohol must not be consumed while taking this medicine. Remember that some foods and medicines contain alcohol.

**Pregnancy and breast-feeding**

Amfexa is contraindicated during pregnancy. Amfexa may affect an unborn baby.

If your daughter is pregnant or breast-feeding, she may be pregnant or is planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- Your doctor will discuss reliable contraception
- If your daughter is pregnant she may have to stop taking this medicine.
- It is possible that this medicine is passed into human breast milk. Therefore, your doctor will decide whether your daughter should stop breast-feeding or stop taking this medicine.

**Driving and using machines**

Your child may feel dizzy, have problems focusing, or have blurred vision when taking this medicine. If so, it may be dangerous to do things such as drive, use machines, ride a bike or horse, or climb trees.

**Amfexa contains isomalt (E953)**

If you have been told by your doctor that your child cannot tolerate some sugars, talk to your doctor before using this medicine.

## 3. HOW TO TAKE AMFEXA

**How much to take**

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The normal recommended dose is between 5 mg and 20 mg.

- Your doctor will usually start treatment with a low dose of one tablet Amfexa. This will be increased gradually by one tablet Amfexa at weekly intervals, as required.
- The maximum daily dose is 20 mg (in rare cases, 40 mg may be needed).

**How to take**

The medicine is intended for oral use.

Your child should take Amfexa tablets with a drink of water, preferably with or immediately after

meals. Amfexa tablets should be taken at the same time in relation to the meals. The last dose should, in general, not be given too late after lunch in order to prevent disturbances in falling asleep.

The tablets have a score line and can be divided, if needed. The score line is only there to help you break the tablet if there is difficulty swallowing it whole. To split it, place the tablet onto a hard surface with the cross-scored, smooth side downwards and then push carefully with your index finger at the centre of its top side. The tablet then breaks into four parts.

If your child does not feel better, tell your doctor. They may decide a different treatment is needed.

**Long-term treatment**
Your doctor will decide how long the treatment is given. If your child takes this medicine for more than a year, your doctor should stop treatment for a short time, e.g., during a school holiday. This will show if the medicine is still needed.

**Not using Amfexa properly**
If Amfexa is not used properly, it may cause abnormal behaviour. It may also mean that your child starts to depend on the medicine. Tell your doctor if your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

This medicine is only for your child. Do not give this medicine to anyone else, even if their symptoms seem similar.

**If your child takes more Amfexa than they should**
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Signs of overdose may include: excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat, and reduced breathing.

**If your child forgets to take Amfexa**
Do not use a double dose to make up for a forgotten dose. If your child forgets a dose, wait until it is time for the next dose.

**If your child stops taking Amfexa**
If your child suddenly stops taking this medicine, this can lead to extreme tiredness, depression,

mood disorders, agitation, sleep disturbances, increased appetite, or involuntary movements. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Amfexa.

**If you have any further questions on the use of this medicine, ask your doctor or pharmacist.**

## 4. POSSIBLE SIDE EFFECTS

This medicine can have side effects. Not all side effects reported for Amfexa are included in this leaflet. Should your child's general health worsen or if he/she experience any untoward effects while taking Amfexa, please consult your health care provider for advice. Your doctor will talk to you about these side effects.

**Frequent:**

- decreased appetite, reduced weight gain and weight loss during prolonged use in children
- difficulty in sleeping
- nervousness
- irregular or increased heartbeat, a more noticeable heartbeat
- abdominal pain and/or cramps, nausea, vomiting, dry mouth
  These effects usually occur at the beginning of treatment and may be alleviated by taking the medicine with meals.
- changes in blood pressure and heart rate (usually increases)
- joint pain
- A feeling of dizziness or "spinning", jerky or involuntary movements, headache, hyperactivity
- abnormal behaviour, aggression, excitation, anorexia, anxiety, depression, irritability

**Less Frequent:**

- angina pectoris
- difficulties in visual sharpening and focus, blurred vision, dilation of the pupils.
- reduced height increase during prolonged use in children
- fatigue
- rash, hives
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness, changes in blood cell counts (leukopenia, thrombocytopenia, thrombocytopenic purpura)
- cardiac arrest
- Tourette's syndrome

- abnormal liver function ranging from hepatic enzyme elevations to hepatic coma
- muscle cramps
- convulsions, involuntary movements (choreoathetoid movements), bleeding inside the skull (intracranial haemorrhage)
- hallucinations, psychosis/psychotic reactions, suicidal behaviour or suicide, tics, worsening of pre-existing tics
- itchy red skin lesions (erythema multiforme) or scaly skin patches (exfoliative dermatitis), recurring rash, which happens in the same place each time the medicine is taken (fixed drug eruption)
- inflammation of the blood vessels of the spinal cord and brain (cerebral vasculitis) and/or occlusion

**Not known: frequency cannot be estimated from the available data**

- heart muscle disease (cardiomyopathy), heart attack
- inflammation of parts of the large intestine when the blow flow is reduced (ischaemic colitis), diarrhoea
- chest pain, growth retardation during prolonged use, increased body temperature, allergic reactions including serious allergic reaction which causes swelling of the face or throat (angioedema) and serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis), sudden death
- disturbance of the acid-base balance of the body (acidosis)
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
- difficulty in controlling movements (ataxia), dizziness, abnormal or impaired sense of taste, concentration difficulties, hyperreflexia, stroke, shaking (tremor)
- confusion, dependence, dysphoria, emotional instability, euphoria, impaired cognitive test performance, altered libido, night terrors, obsessive-compulsive behaviour, panic states, paranoia, restlessness
- renal damage
- impotence
- sweating, hair loss
- circulatory failure
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon).

**Reporting of side effects**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows

continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.
Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via Adcock.AEReports@adcock.com.

## 5. HOW TO STORE AMFEXA

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the box after "EXP". The expiry date refers to the last day of that month.

Store at or below 25 °C.
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Amfexa contains:**

- The active substance is dexamfetamine sulfate 5 mg / 10 mg / 20 mg.
- The other ingredients are:

  Amfexa 5 mg/10 mg/20 mg
  isomalt (E953)
  magnesium stearate

  Additionally in Amfexa 5 mg
  Crospovidone

  Additionally in Amfexa 10 mg
  iron oxide, yellow (E172)

  Additionally in Amfexa 20 mg
  iron oxide, red (E172)

**What Amfexa looks like and the contents of the pack:**

**Amfexa 5 mg tablets**

White, round, cloverleaf-shaped tablets of 8,4 mm with a notched, cross-scored line on the top side and a cross-scored line embossed with “S” on each quarter on the rear side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes: 20, 30, 50, or 100 tablets

Boxes containing tablets packed in white, opaque blisters made of PVC/PE/PVdC heat-sealed to aluminium foil.

**Amfexa 10 mg tablet**

Yellow, 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 “M” on each quarter on the rear side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes: 20, 30 or 50 tablets

Boxes containing tablets packed in white, opaque blisters made of PVC/PVdC heat-sealed to aluminium foil.

**Amfexa 20 mg tablets**

Reddish, 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 “L” on each quarter on the rear side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes: 20 or 30 tablets

Boxes containing tablets packed in white, opaque blisters made of PVC/PVdC heat-sealed to aluminium foil.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Adcock Ingram Limited
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**Registration number:**

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|---|---|
| Amfexa 5 mg tablets | 52/1.2/0871 |
| Amfexa 10 mg tablets | 52/1.2/0872 |
| Amfexa 20 mg tablets | 52/1.2/0873 |

[The following information should be included in a box]

The professional information is available by scanning the QR code with a smartphone or via the following URL www.amfexa.co.za.

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