

PACKAGE LEAFLET: INFORMATION FOR THE USER
Dexamfetamine Sulfate 5 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dexamfetamine is and what it is used for
2. What you need to know before you take Dexamfetamine
3. How to take Dexamfetamine
4. Possible side effects
5. How to store Dexamfetamine
6. Contents of the pack and other information.

1. What Dexamfetamine is and what it is used for

Dexamfetamine belongs to a group of medicines called stimulants. These work by increasing activity in the brain. Dexamfetamine works by affecting some of the natural chemicals that are found in the brain. In particular, it increases the activity of chemicals called dopamine and noradrenaline in areas of the brain that play a part in controlling attention and behaviour. Dexamfetamine stimulates activity in the brain, helping to keep people alert and active during the day.

Dexamfetamine is used:

- To treat narcolepsy (being unable to stop yourself falling asleep)
- In children, to treat attention deficit hyperactivity disorder (ADHD).

Dexamfetamine may seem an odd treatment for hyperactive children, as stimulants normally make people more active.

However, at the doses recommended for children with ADHD, Dexamfetamine can have the opposite effect, helping some children to learn to control their behaviour.

2. What you need to know before you take Dexamfetamine

Do not take Dexamfetamine if:

- You are allergic to dexamfetamine sulfate or any of the other ingredients of this medicine (listed in section 6)

- You are allergic to any medicines acting on the nervous system including methylphenidate, pemoline or ephedrine
- You are taking medicines called monoamine oxidase inhibitors (MAOIs) for depression or if you have taken them within the last 2 weeks
- You have ever abused alcohol or drugs
- You have a medical condition called Gilles de la Tourette syndrome or similar movement disorders (dystonias) which cause twitching
- You have porphyria, a disease of the blood
- You have any problems with your heart or blood pressure
- You have hardening of the arteries
- You have problems with your eyesight as a result of increased pressure in your eyes (i.e. glaucoma)
- You are hyperexcitable
- You have an overactive thyroid gland
- You are pregnant, likely to become pregnant or are breast feeding.

If any of the above applies to you do not take Dexamfetamine and talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before taking Dexamfetamine if:

- You have problems with your kidneys
- You have epilepsy
- You have an unstable personality
- Anyone in your family has a movement disorder (dystonias) which cause twitching.

Other medicines and Dexamfetamine

Talk to your doctor before taking Dexamfetamine if you are taking any of the following medicines:

- Medicines for depression including:
 - Those called monoamine oxidase inhibitors (MAOIs) such as Phenelzine or if you have taken them within the last 2 weeks
 - Those called tricyclic anti-depressants (e.g. imipramine)
- Lithium
- Drugs to lower blood pressure (e.g. guanethidine or α -methyltyrosine)
- Medicines to help you give up alcohol (e.g. disulfiram)
- Beta-blockers such as propranolol
- Phenothiazines used to control anxiety
- Medicines for epilepsy such as ethosuximide, phenobarbital and phenytoin
- Haloperidol used for mental illness
- Morphine for the treatment of severe pain
- Norepinephrine (used to increase the rate of contractions)
- Meperidine (used to treat moderate to severe pain)
- Clonidine (used to treat high blood pressure)
- Reserpine (used as antipsychotic and antihypertensive drug)
- Ascorbic acid (used as antioxidant properties)

- Glutamic Acid HCL
 - Ammonium chloride
 - Sodium acid phosphate
 - Thiazides (used to treat hypertension and oedema)
 - Chlorpromazine (used as antipsychotic drug)
 - Any other medicine, including medicines obtained without a prescription.
- If any of the above applies to you, tell your doctor before taking Dexamfetamine.

Drug/laboratory test interactions

This medicine may interfere with your laboratory test results.

Pregnancy and breast-feeding

Available data from the use of Dexamfetamine during the first three months of pregnancy do not indicate increased risk of congenital malformation in the child, but may increase the risk for pre-eclampsia (a condition usually occurring after 20 weeks of pregnancy characterized by high blood pressure and protein in the urine) and preterm birth. Newborns exposed to amphetamine during pregnancy may experience withdrawal symptoms (changes in behaviour, including excessive crying, unstable or irritable mood, hyperexcitability, pronounced exhaustion, trembling, tight muscle tone). Do not take Dexamfetamine if you are breast-feeding.

Driving and using machines

Dexamfetamine may cause dizziness and affect your vision.
If this happens to you, do not drive or use machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Dexamfetamine contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dexamfetamine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

If you need to break the tablets in half, your doctor or pharmacist will show you how to do this.

For narcolepsy in adults:

- The usual starting dose is 10 mg (2 x 5 mg tablets) a day twice a day (i.e. 1 tablet in the morning and 1 in the evening)
- Your doctor may increase your dose each week up to a maximum of 60 mg (12 x 5 mg tablets) a day if necessary.

For narcolepsy in the elderly:

- The usual starting dose is 5 mg (1 x 5 mg tablet) a day
- Your doctor may increase your dose by 5 mg (1 x 5 mg tablet) each week.

For ADHD in children aged 3-5 years:

- The usual starting dose is 2.5 mg (half of a 5 mg tablet) a day
- Your doctor may increase the dose by 2.5 mg (half of a 5 mg tablet) each week.

For ADHD in children aged 6 years and over:

- The usual starting dose is 5-10 mg (1-2 x 5 mg tablets) a day
- Your doctor may increase the dose by 5 mg (1 x 5 mg tablet) each week
- The maximum dose is usually 20 mg (4 x 5 mg tablets) a day, although for older children your doctor may prescribe 40 mg (8 x 5 mg tablets) or more a day.

Medical check-ups in children

Your doctor will check the height and weight of your child whilst they are taking Dexamfetamine.

If you take more Dexamfetamine than you should.

If you take too much immediately go to the nearest hospital casualty department or your doctor. Taking too many tablets can be very serious.

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

If you forget to take Dexamfetamine

Simply take the next dose as planned. Do NOT take a double dose to make up for a forgotten dose.

If you stop taking Dexamfetamine

Do not stop taking Dexamfetamine without first talking to your doctor. Do not suddenly stop taking Dexamfetamine as this can lead to extreme tiredness and depression. Your doctor will stop your treatment gradually.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

- **Seek immediate medical help if you have any unexplained rise in body temperature.**
- **Talk to your doctor as soon as possible if you start experiencing twitches.**

Dexamfetamine can cause the following side-effects:

Effects on the nervous system:

- Sleeplessness and restlessness
- Nightmares and panic attacks
- Nervousness
- Confusion and delirium
- Delusions
- Aggression and irritability
- Happiness
- Dizziness
- Headache
- Impaired vision
- Widening of the pupils
- Altered sexual drive and ability
- Dry mouth
- Lack of appetite
- Sweating
- Convulsions
- Tremor and twitches
- Excessive reflex reactions.
- Lack of coordination of muscle movements
- Abnormal moods
- Loss of contact with reality
- Mental disorders including mood disorders and schizophrenia
- Distortion of the sense of taste

Effects on the heart and circulation

- Fast heartbeat, palpitations
- Chest pains
- Changes in blood pressure (with possible bleeding into the brain)
- Damaged heart muscle following long term use
- Fatal heart and circulatory system collapse (after a very high temperature, upset salt and water balance and transient hyperactivity).
- Heart Attack
- Cardiovascular collapse
- Stroke
- Increased acidity in the blood.

Effects on the stomach

- Stomach pain
- Stomach cramps
- Feeling sick
- Diarrhoea
- Nausea.

Other effects:

- Kidney damage
- Paralysis
- Slowed growth in children
- Muscular pains.
- Hypersensitivity
- Serious allergic reaction
- Inflammation and injury of the large intestine
- Weight loss
- Damaged skeletal muscle tissue
- Skin rash
- Loss of hair from the head or body
- Rapid swelling
- Abnormal facial movements
- Abnormal movements
- Movement disorder
- Difficulty moving or coordinating part of the body
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon).

Becoming dependent on your medicine

It is possible to develop tolerance to Dexamfetamine so that more tablets have to be taken to achieve the same effect. This, in turn, can lead to dependence on Dexamfetamine. With increasing doses and dependence, mental instability and behavioural changes can occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexamfetamine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date on the carton after "EXP". The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Dexamfetamine contains

The active substance is dexamfetamine sulfate 5 mg.

The other ingredients are stearic acid, acacia powder, lactose, light liquid paraffin, maize starch, sucrose, purified talc and purified water.

What Dexamfetamine looks like and contents of the pack

Dexamfetamine 5mg Tablets are half scored circular white tablets with bevelled edges marked 'Evans' above and 'DB5' below.

The 5mg Tablets are available in blister strip of 28 tablets in a carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Teva UK Limited
Ridings Point
Whistler Drive
Castleford
WF10 5HX
United Kingdom

Manufacturer:

Tiofarma BV
Benjamin Franklinstraat 5-10
3261 LW Oud-Beijerland
Netherlands

Tiofarma B.V.

Hermanus Boerhaavestraat 1
3261 ME Oud-Beijerland
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