

Package leaflet: Information for the user
DEXAMFETAMINE SULFATE 5 MG TABLETS
{ dexamfetamine sulfate }

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)
- **attention deficit hyperactivity disorder** (ADHD) in children. 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 dexamphetamine or any of the other ingredients of this medicine (listed in section 6)
- are allergic to any medicines acting on the nervous system including methylphenidate, pemoline or ephedrine
- are taking medicines called **monoamine oxidase inhibitors** (MAOIs) for depression or if you have taken them within the last 2 weeks (see “Other medicines and Dexamfetamine”)
- have ever abused **alcohol or drugs**
- have a medical condition called Gilles de la Tourette syndrome or similar movement disorders (dystonias), which cause twitching
- have 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 or mania
- have porphyria, a disease of the blood
- have any problems with your heart or blood pressure

- have 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
- have 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)
- have hardening of the arteries
- have problems with your eyesight as a result of **increased pressure in your eyes** (i.e. glaucoma)
- are hyperexcitable
- have an overactive thyroid gland
- have an eating problem, does not feel hungry or does not want to eat (e.g anorexia nervosa)
- 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.

Check with your doctor before taking Dexamfetamine if:

- you have problems with your kidneys
- you have epilepsy
- you have an unstable personality or are hyperexcitable
- anyone in your family has a movement disorder (dystonias) which cause twitching.
- you are female and has started having periods (see the 'Pregnancy and breast-feeding' section below)
- you have high blood pressure
- you have a heart problem which is not in the 'Do not take' section above
- you have a mental health problem which is not in the 'Do not take' section above. This may include mood swings, unusual aggression, hallucinations, delusions, paranoia, agitation and anxiety, feelings of guilt or depression.

Warnings and Precautions

Other medicines and Dexamfetamine

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor 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; in such case, **do NOT take Dexamfetamine** and talk to your doctor (see "Do NOT take Dexamfetamine").
 - those called tricyclic anti-depressants (e.g. imipramine)
 - lithium.
- drugs to lower **blood pressure** (e.g. guanethidine or 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 to treat **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 an antipsychotic and antihypertensive drug
- ascorbic acid used for its antioxidant properties
- glutamic acid HCL
- ammonium chloride
- sodium acid phosphate

- thiazides used to treat **high blood pressure** and **swelling**
- chlorpromazine used as antipsychotic drug.

If any of the above applies to you, talk to your doctor before taking Dexamfetamine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do NOT take Dexamfetamine if you are pregnant, likely to become pregnant or are 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 behavior including excessive crying, unstable or irritable mood, hyperexcitability and pronounced exhaustion).

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.

3. How to take Dexamfetamine

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

How much to take

For narcolepsy in adults:

- The usual starting dose is 10 mg (2 x 5 mg tablets) a day, taken 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.
- Their 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.
- Their 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 the doctor may prescribe 40 mg (8 x 5 mg tablets) or more a day.

Medical check-ups in children

- There may be lack of weight gain
- Your doctor will check the height and weight of your child whilst they are taking Dexamfetamine.
- If your child is not growing as expected, then your doctor may stop treatment with Dexamfetamine 5 mg Tablets for a short time.

If you take more Dexamfetamine than you should

If you take too much, **go to the nearest hospital casualty department immediately or contact your doctor at once**. 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

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

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:

Serious side-effects:

- Confusion and reduced awareness of surrounding (Delirium)
- Convulsions or Fits (characterized by jerking/twitching of a hand, arm or leg or jerking/twitching affecting the whole body)
- loss of contact with reality
- changes in blood pressure ((increase or decrease in blood pressure)
- cardiomyopathy (damaged heart muscle following long term use)
- intracranial haemorrhage (possible bleeding in the brain)
- fatal heart and circulatory system collapse (after a very high temperature, upset salt and water balance and transient hyperactivity)
- high body temperature
- heart attack (characterised by pressure, tightness and pain in chest)
- severe allergic reaction (trouble breathing, wheezing, tightness of the throat, hives, swelling of lips or tongue), sudden death
- cardiovascular collapse which may lead to fatal outcome (chest discomfort, irregular heart beat and fainting)
- stroke (Sudden numbness or weakness in the face, arm, or leg, especially on one side of the body)
- increased acidity in the blood (fatigue, drowsiness & confusion)
- kidney damage (characterized by reduced urine output, swelling in legs, ankle and face)
- slowed growth in children

- damaged skeletal muscle tissue (characterised by dark red or brown coloured urine, general weakness, muscle stiffness or aching, muscle tenderness, muscle weakness)
- difficulty moving or coordinating part of the body
- itchy red skin lesions (erythema multiforme) or scaly skin patches (exfoliative dermatitis)

Other side-effects

- sleeplessness and restlessness
- nightmares and panic attacks
- nervousness
- confusion
- aggression and irritability
- happiness
- dizziness
- headache
- impaired vision
- widening of the pupils
- altered sexual drive and ability
- dry mouth
- lack of appetite
- sweating
- tremor and twitches
- hyperactivity
- excessive reflex reactions
- lack of coordination of muscle movements
- abnormal moods
- mental disorders including mood disorders
- distortion of the sense of taste.
- fast heartbeat, palpitations (feeling like heart is beating too hard or too fast)
- chest pains
- stomach pain
- stomach cramps
- feeling sick
- diarrhoea
- nausea
- muscle pain
- hypersensitivity
- inflammation and injury of the large intestine
- weight loss
- skin rash
- hair loss from the head or body
- abnormal facial movements
- abnormal movements
- movement disorder
- Not known (frequency cannot be estimated from the available data):- 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, pharmacist or nurse. 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 which is stated on the carton and bottle label or blister. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 microcrystalline cellulose, calcium hydrogen phosphate dihydrate, povidone, maize starch, magnesium stearate.

What Dexamfetamine looks like and contents of the pack

Dexamfetamine is plain white uncoated flat bevelled edged tablet, with one side plain and one side scored and embossed with "D5". The tablets are available in either bottles of 28 or 100 tablets or blisters of 28 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

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