

UK 675-8643-PIL

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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

1. What Dexamfetamine sulfate 5mg tablet is and what it is used for

Dexamfetamine sulfate 5mg tablets contain the active substance dexamfetamine sulfate.

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)
- To treat attention deficit hyperactivity disorder (ADHD) 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 treatment program which typically includes psychological, educational and social measures. Dexamfetamine 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 you or your child does not feel better or if you feel worse after a month. The doctor may decide that a different treatment is needed.

2. What you need to know before you take Dexamfetamine sulfate 5mg tablet

Do not take Dexamfetamine if you:

- are allergic (hypersensitive) to dexamfetamine or other amfetamine compounds or any of the other ingredients of this medicine (listed in section 6)
- have a thyroid problem
- have increased pressure in the eyes (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- have an eating problem, do not feel hungry or do not want to eat (e.g anorexia nervosa)
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- have advanced arteriosclerosis
- have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease, or were 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 mental health problems such as:
 - o a psychopathic or borderline personality disorder
 - o abnormal thoughts or visions or schizophrenia
 - o signs of a severe mood disorder like:
 - suicidal feelings
 - severe depression
 - mania
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) - see the 'Other medicines and Dexamfetamine' section below
- have ever abused alcohol, prescription medicines, or street drugs
- or anyone in the family has the medical condition called Tourette's syndrome (hard-to-control, repeated twitching of any parts of the body or repeats sounds and words), or have similar movement disorders (dystonias), which can cause twitching, motor or verbal tics
- have porphyria.
- are pregnant, likely to become pregnant or are breast-feeding

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Dexamfetamine if:

- you have a disease of the blood or liver, or kidney problems
- you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- you are hyperexcitable or have an unstable personality
- you are female and have 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 (persecution complex), agitation and anxiety, feelings of guilt or depression.

Checks that your doctor will make before Dexamfetamine is used

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

- any other medicines you are 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 you are feeling, such as feeling high or low, having strange thoughts or if you have 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 you are at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check your 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 Dexamfetamine is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Children and Adolescents

Dexamfetamine is not for use as a treatment for ADHD in children under 6 years of age. It is not known if it is safe or of benefit for children under age of 6 years.

Effect on weight/growing

- Dexamfetamine 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 Dexamfetamine for a short time.

Having an operation

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

Drug/laboratory test interactions

This medicine may interfere with your laboratory test results.

Other medicines and Dexamfetamine

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

Monoamine oxidase inhibitors

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

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

- 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
- medicinal products 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 you are taking are included in the list above, ask your doctor or pharmacist for advice before taking this medicine.

Dexamfetamine with alcohol

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

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 whilst you are pregnant, particularly during the first three months of pregnancy. Do not take Dexamfetamine if you 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.

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 sulfate 5mg tablet

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

The recommended dose for narcolepsy in adults:

- The usual starting dose is 10 mg (2 x 5 mg tablets) a day, taken as two separate doses (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.

The recommended dose 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.

The recommended dose for ADHD in children and adolescents aged 6-17 years:

- The recommended dose is between 5 (1 x 5 mg tablet) and 20 mg (4 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

This medicinal product is intended for oral use. The tablet can be divided into equal doses, your doctor or pharmacist will show you how to do this. 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 Dexamfetamine 5 mg Tablets properly

If Dexamfetamine 5 mg Tablets 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.

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

Do not take a double dose to make up for forgotten 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 on 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.

Very common: may affect more than 1 in 10 people

- decreased appetite, reduced weight gain and weight loss during prolonged use in children
- difficulty in sleeping
- nervousness

Common: may affect up to 1 in 10 people

- 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, excitement, anorexia, anxiety, depression, irritability

Rare: may affect up to 1 in 1,000 people

- angina pectoris (severe pain in the chest)
- difficulties in visual sharpening and focus, blurred vision, dilation of the pupils.
- reduced height increase during prolonged use in children
- fatigue
- rash, hives

Very rare: may affect up to 1 in 10,000 people

- 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 preexisting 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 blood 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 (overactive or overresponsive reflexes), stroke, shaking (tremor)
- confusion, dependence, dysphoria (uneasiness), emotional instability, euphoria, impaired cognitive test performance, altered libido, night terrors, obsessive-compulsive behaviour, panic states, paranoia (persecution complex), 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).

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

5. How to store Dexamfetamine sulfate 5mg tablet

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

Store below 25°C.

Do not use this medicine after the expiry date on the carton. 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 to protect the environment.

6. Contents of the pack and other information

What Dexamfetamine contains

- The active substance is dexamfetamine sulfate
Each tablet contains 5mg dexamfetamine sulfate.
- The other ingredients are lactose monohydrate, maize starch, acacia powder, sucrose, talc, stearic acid, light liquid paraffin and purified water.

What Dexamfetamine looks like and content of the pack

Dexamfetamine is a white to off-white round tablet, with a score line on one side.
Pack size: 28 tablets
Box containing tablets packed in blisters made of PVC-PVDC/Aluminium.

Marketing Authorisation Holder:

Waymade PLC,
Sovereign House,
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Manufacturer:

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