

Dexamfetamine Tablets

Dexamfetamine sulfate

Tablet, uncoated 5 mg

What is in this leaflet

Please read this leaflet carefully before you start using Dexamfetamine Tablets.

This leaflet answers some common questions about Dexamfetamine Tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Dexamfetamine Tablets against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Dexamfetamine Tablets are 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 Tablets are used for:

The treatment of well-established and proven narcolepsy. It is also indicated for children with refractory hyperkinetic states under the supervision of a physician specialising in child psychiatry.

Your doctor may have prescribed Dexamfetamine Tablets for another reason.

Ask your doctor if you have any questions about why Dexamfetamine Tablets has been prescribed for you.

This medicine is available only with a doctor's prescription.

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, please tell your doctor or pharmacist.

Before you use Dexamfetamine Tablets

When you must not use it

Do not use Dexamfetamine Tablets if you:

- have ever had heart disease such as a heart attack, irregular heartbeat, pain and discomfort in the chest, heart failure, heart disease, or was born with a heart problem
- have moderate to severe high blood pressure
- have a hyperactive thyroid gland (hyperthyroidism)
- have tumour of the adrenal gland tissue (phaeochromocytoma)
- are allergic to dexamphetamine sulfate, amfetamines or any of the other ingredients listed in the “Other ingredients” section of this leaflet
- have problems with your eyesight as a result of increased pressure in your eyes (i.e. glaucoma)
- have porphyria, a disease of the blood
- have tics (muscle twitching in the face and shoulders)
- have a medical condition called Gilles de la Tourette syndrome or similar movement disorders (dystonias), which cause twitching
- have anxiety, tension or agitation
- 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 ever abused alcohol or suffered with drug dependence
- are currently taking have taken medicines called monoamine oxidase inhibitors (MAOIs) within the past 14 days for depression (see 'Taking other medicines' Section).
- are pregnant, likely to become pregnant or are breast-feeding.

If you are not sure whether you should start using Dexamfetamine Tablets, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you have other medical conditions or heart disease such as chest pain (angina), heart attack (myocardial infarction), irregular heartbeats, family history of sudden death, other heart problem which is not in the ‘When you must not use it’ section above
- you have high blood pressure
- you have depression, bipolar illness, or psychosis or other mental illness
- you have a mental health problem which is not in the ‘When you must not

use it' section above. This may include mood swings, unusual aggression, hallucinations, delusions, paranoia, agitation and anxiety, feelings of guilt or depression.

- you have epilepsy
- you are experiencing growth difficulties
- anyone in your family has a movement disorder (dystonias, tics or Tourette syndrome) which cause twitching
- you have problems with your kidneys
- you are female and has started having periods (see the 'Pregnancy and breast-feeding' section below)

If you have not told your doctor about any of the above, tell them before you start using Dexamfetamine Tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Dexamfetamine Tablets.

Some medicines may interfere with Dexamfetamine Tablets. These include:

- 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 'When you must not use it' Section above).
 - 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 (Pethidine) used to treat moderate to severe pain
- Clonidine
- Reserpine used as an antipsychotic and antihypertensive drug
- Ascorbic acid
- Glutamic acid HCl
- Urinary acidifying agents such as ammonium chloride, sodium acid phosphate
- Gastrointestinal alkalisng agents such as sodium bicarbonate
- Urinary alkalisng agents such as acetazolamide
- Thiazides used to treat high blood pressure and swelling
- Chlorpromazine used as antipsychotic drug
- Other stimulants such as atomoxetine that is used to treat Attention Deficit Hyperactivity Disorder (ADHD)

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

These medicines may be affected by Dexamfetamine Tablets or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Dexamfetamine Tablets.

How to use Dexamfetamine Tablets

How much to take

Always take 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 is:

For narcolepsy:

Adults: Oral, 5 mg to 20 mg a day in divided doses as needed and tolerated. The usual starting dose is 5 mg a day, given in divided doses. Dose may be increased if necessary, by 5 mg a day at weekly intervals to a suggested maximum of 20 mg a day.

Elderly: Start with 5 mg a day and increase by increments of 5 mg at weekly intervals to a suggested maximum of 20 mg a day.

Children up to 6 years of age:
Dosage has not been established.

Children 6 to 12 years of age
Oral, 5 mg a day, the dosage being increased by 5 mg a day at one-week intervals until the desired response is obtained or until the adult dose is reached.

For attention-deficit hyperactivity disorders:

Children up to 3 years of age:
Use is not recommended.

Children 3 to 5 years of age:
Oral, 2.5 mg once a day, the dosage being increased by 2.5 mg a day at one-week intervals until the desired response is obtained.

Children 6 years of age and over:
Oral, 5 mg one or two times a day, the dosage being increased by 5 mg a day at one-week intervals until the desired response is obtained.

When to take it

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

Tablet is generally taken daily, and may be increased by increments each day at one-weekly intervals until the desired response is obtained or suggested maximum dosage is achieved.

How long to take it

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

If symptoms persist, see your doctor.

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.

If you forget to take it

Take your dose as soon as you remember and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

Do not try to make up for a missed dose by taking more than one dose at a time. This may increase the chance of you getting an unwanted effect.

Avoid taking Dexamfetamine Tablets in the afternoon or evening as it may lead to inability to sleep.

The medicine is only intended for the use of the person it has been prescribed for. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Dexamfetamine Tablets

Things you must do

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

Tell any other doctors that are treating you that you are being given Dexamfetamine Tablets.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Dexamfetamine Tablets.

If you become pregnant while you are undergoing therapy with Dexamfetamine Tablets, tell our doctor or pharmacist.

Tell your doctor if you have any conditions listed in the 'When you must not use it' section above.

Things you must not do

Do not give Dexamfetamine Tablets to anyone else, even if they have the same condition as you.

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.

Things to be careful of

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 Tablets if you are pregnant, likely to become pregnant or are breast-feeding.

Available data from the use of Dexamfetamine Tablets 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 characterised by high blood pressure and protein in the urine) and preterm birth. New-borns exposed to amphetamine during pregnancy may experience withdrawal symptoms (changes in behaviour including excessive crying, unstable or irritable mood, hyperexcitability and pronounced exhaustion).

Dexamfetamine Tablets 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.

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

Dexamfetamine Tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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, please tell your doctor or pharmacist.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Dexamfetamine Tablets.

Do this even if there are no signs of discomfort or poisoning.

Taking too many tablets can be very serious. Symptoms of overdose include dilated pupils, shallow rapid breathing, fever, chills, sweating, overactive or overresponsive body reflexes, restlessness, aggression, anxiety, confusion and reduced awareness of surrounding (delirium), hallucinations, panic attacks, suicidal or homicidal thoughts. Cardiovascular symptoms include chest pain (angina), irregular heartbeat, headache, high or low blood pressure, headache and flushing. Gastrointestinal symptoms include nausea, vomiting, diarrhoea, abdominal cramps, convulsion, coma.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Dexamfetamine Tablets.

- 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 (characterised 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 (chest discomfort, irregular heartbeat and fainting) which may lead to fatal outcome
- 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 (characterised 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
- Depression
- Difficulty concentrating
- Obsessive-compulsive behaviour
- Dizziness
- Fatigue
- 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
- Sleepiness
- Increased appetite
- Inability to feel pleasure
- Drug dependence/ craving

Other (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).

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Dexamfetamine Tablets

Storage

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 bottle label. The expiry date refers to the last day of that month.

Store below 25°C in an airtight container. Protect from light. Do not refrigerate.

Disposal

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.

Product description

What it looks like

Dexamfetamine Tablets are white, 8 mm, normal, convex tablets.

Ingredients

Active ingredient:

Dexamfetamine Tablets contain 5 mg of Dexamfetamine sulfate active ingredient.

Inactive ingredients:

This medicine contains lactose.

Also contains:

- Acacia
- Colloidal silicon dioxide
- Lactose monohydrate
- Magnesium stearate
- Maize starch
- Purified talc

Sponsor Details

Dexamfetamine Tablets are supplied in New Zealand by:

Noumed Pharmaceuticals Ltd
Suite 3, 27 Bath Street
Parnell
Auckland 1052
New Zealand

Freephone: 0800 527 545

Date of Preparation

This leaflet was prepared on 24th July 2023.
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