

# Dexamfetamine Tablets

## *Dexamfetamine sulfate*

Tablet, uncoated 5 mg

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## What is in this leaflet

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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.

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## What Dexamfetamine Tablets is used for

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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.

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## Before you use Dexamfetamine Tablets

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### *When you must not use it*

Do not use Dexamfetamine Tablets if you:

- are allergic to dexamphetamine sulfate or any of the other ingredients of this medicine
- 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 'Taking other medicines' Section).
- 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 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 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 'When you must not use it' section above
- 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.

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 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 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.

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## How to use Dexamfetamine Tablets

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### ***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 5mg a day, given in divided doses. Doses 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 maybe 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.

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.

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## **While you are using Dexamfetamine Tablets**

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### ***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 being given 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 characterized 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.

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## In case of overdose

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### *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 excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat and reduced breathing.

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## Side Effects

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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 (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 heartbeat 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).

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.

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## After using Dexamfetamine Tablets

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### ***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.

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## Product description

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### ***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,  
Maize starch  
Purified talc  
Magnesium stearate  
Silicon dioxide  
Acacia gum

## Sponsor Details

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Dexamfetamine Tablets are supplied in New Zealand by:

Noumed Pharmaceuticals Ltd  
Level 2, Fidelity House,  
81 Carlton Gore Road, Newmarket  
Auckland 1023,  
New Zealand

Freephone: 0800 527 545

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## Date of Preparation

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This leaflet was prepared on 18<sup>th</sup> July 2022.  
(based on data sheet prepared 17<sup>th</sup> May 2022)