

# DEXAMPHETAMINE

Contains active ingredient *Dexamphetamine Sulfate*



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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about DEXAMPHETAMINE

It does not contain all of the available information about DEXAMPHETAMINE.

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 or your child taking DEXAMPHETAMINE against the benefits he/she expect it will have.

**If you have any concerns about taking 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 is DEXAMPHETAMINE

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The name of your medicine is DEXAMPHETAMINE.

The active ingredient is called dexamphetamine sulfate. Dexamphetamine sulfate belongs to a group of medicines called central nervous system stimulants and is a sympathomimetic amine of the amphetamine group.

Dexamphetamine is available as a 5.0mg tablet.

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### What DEXAMPHETAMINE is used for

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DEXAMPHETAMINE is used to treat number of medical conditions.

- Hyperkinetic behaviour disorders in children. This behavioural disorder is also known as Attention-deficit Hyperactivity Disorder (ADHD). Not all people with this disorder are hyperactive, which affects the ability to concentrate on tasks for any length of time. Children suffering from ADHD may have trouble learning or doing school work, and may become aggressive or unmanageable at school or at home. Dexamphetamine helps focus attention and shuts out distraction, allowing the child to concentrate.

- Narcolepsy (a sleep disorder). People with narcolepsy have recurring attacks of irresistible day-time sleepiness in spite of a good night's sleep.

#### Note:

Because of the liability for abuse, drugs of the amphetamine type are subject to special restrictions on their availability. Prescriptions for this substance may require validation by State or Territory Health Departments or Commissions.

Your doctor, however, may have prescribed DEXAMPHETAMINE for another purpose.

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

If you have any concerns, you should discuss this with your

doctor.

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

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### Before you take DEXAMPHETAMINE

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#### When you must not take it

**Do not take DEXAMPHETAMINE if you are allergic to:**

DEXAMPHETAMINE or other amphetamine type medications including other sympathomimetic amines or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take DEXAMPHETAMINE if you have any of the following medical conditions:**

- heart disease or severe blood vessel disease
- moderate to severe high blood pressure
- heart attack or angina
- glaucoma
- hyperthyroidism (overactive thyroid)
- tics (muscle twitching usually in the face or shoulders)
- degenerative diseases of the nervous system or suffer from epilepsy
- Tourette's syndrome or you have a family history of this disorder
- severe depression, suicidal ideation or behaviour, thoughts

- or acts of self-harm or other mental illness
- periods of severe anxiety, tension or agitation
- drug dependence
- alcohol abuse

**Do not take DEXAMPHETAMINE if you are taking Mono Amine Oxidase Inhibitors (MAOI drugs) or it is not yet 14 days since MAOI therapy was discontinued.**

**Do not take DEXAMPHETAMINE if you are breastfeeding or plan to breast feed.**

**Do not use DEXAMPHETAMINE after the expiry date (EXP.) printed on the pack.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

**Do not give it to children unless your doctor has prescribed it. It is not recommended for use in children under three years of age.**

**Before you start to take it**

**You must tell your doctor if :**

**1. you are allergic to any other medicines, or any foods, dyes or preservatives.**

**2. you have any other medical conditions or health problems, including:**

- suspicion or presence of any cardiac or heart-related abnormalities; irregular heart beats or rate; family history of sudden/cardiac death
- suffer from blood pressure and/or take any medications to treat blood pressure.
- angina (chest pain)
- disease of the arteries due to cholesterol deposits

- disorders of the blood vessels in the brain
- epilepsy
- drug dependence or addiction including alcoholism
- suffer from insomnia (an inability to sleep).
- suffer from depression or schizophrenia or another mental illness.
- suffer from motor tic or Tourette syndrome (or a family member does)
- kidney problems

**3. You drink alcohol regularly.**

Alcohol should not be taken with DEXAMPHETAMINE.

**4. You are pregnant or plan to become pregnant.**

DEXAMPHETAMINE like all medicines should not be used during pregnancy, unless your doctor tells you.

**5. You are breastfeeding or plan to breastfeed.**

DEXAMPHETAMINE is passed into breast milk. Breast-feeding is not recommended while taking this medicine.

**Taking other medicines**

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

Some medicines may interfere with DEXAMPHETAMINE. These include:

- drugs which are used to treat depression (e.g. tricyclic antidepressants and MAO inhibitors).
- drugs used to treat other types of mental illnesses such as schizophrenia (e.g. chlorpromazine) or manic depressive psychosis (e.g.

- Lithium Carbonate)
- medicines used to treat mental illnesses such as psychotic disorders (e.g. haloperidol (Haldol))
- some medicines including Vitamin C and fruit juices which can affect the gastric or urine pH (that is make it acidic or alkaline) may alter the rate of absorption or urinary excretion of dexamphetamine e.g. (guanethidine, reserpine, glutamic acid, ammonium chloride, sodium bicarbonate, acetazolamide, some thiazide diuretics).
- blood pressure medicines
- some antihistamines
- anti-epileptic medicines e.g. phenytoin (Dilantin), ethosuximide (Zarontin)
- some opioid type analgesics e.g. Pethidine
- barbiturates e.g. phenobarbitone

The above medicines may either reduce the effectiveness of DEXAMPHETAMINE, reduce its own effectiveness and/ or react with DEXAMPHETAMINE resulting in untoward or sometimes dangerous side effects.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DEXAMPHETAMINE.

**If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.**

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**How to take DEXAMPHETAMINE**

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**How much to take**

The dose of DEXAMPHETAMINE may be different for each person and their medical condition. Your doctor will decide the right dose for you.

**The recommended doses are**

**for:**

Narcolepsy

For children 6 to 12 years one tablet (5mg) is given daily. The dose may be increased by 5mg each week until the required response is obtained.

For patients 12 years or older your doctor may start treatment with two tablets (10mg) daily. The dose may be increased by 10mg each week until the required response is obtained.

Attention Deficit Disorder

For children over 3 years, your doctor may start treatment with half a tablet (2.5mg) daily. The dose may be increased by 2.5mg every week until the required response is obtained up to a maximum of 40 mg (8 tablets) each day taken in two divided doses.

**How to take it**

Swallow the medicine with water. If the dose is one-half tablet, there is a breakline on the tablet to help you divide it.

**When to take it**

DEXAMPHETAMINE should be taken either early in the day or in the morning.

**How long to take it**

Continue taking DEXAMPHETAMINE as long as your doctor recommends it.

**If you forget to take it**

**If you forget to take a dose of DEXAMPHETAMINE, take the missed dose as soon as you remember, but not later than 6 hours before bedtime.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.**

**Do not try to make up for missed doses by taking more than one dose at a time.**

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

***If you take too much (Overdose):***

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much DEXAMPHETAMINE. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol which has been taken. You may need urgent medical attention.**

**Keep telephone numbers for these places handy.**

If you take too much DEXAMPHETAMINE you may have symptoms of nausea, vomiting, diarrhoea, chills, sweating, restlessness, hallucinations, panic, headache, convulsions and symptoms associated with severe high blood pressure or manifestations of acute psychosis.

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**While you are using DEXAMPHETAMINE**

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***Things you must do:***

**Use DEXAMPHETAMINE exactly as your doctor has prescribed.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking DEXAMPHETAMINE.**

**Tell your doctor (immediately) if you become pregnant while you are taking DEXAMPHETAMINE.**

Your doctor can discuss with you the risks and benefits of taking it while you are pregnant.

**Tell your doctor if you feel DEXAMPHETAMINE is not helping your condition.**

**Visit your doctor regularly** for checking on your blood pressure and pulse.

Regularly checking the height and weight of your child. If your child is not growing or gaining height or weight as expected, treatment with DEXAMPHETAMINE may need to be interrupted.

This medicine helps to control your or your child's symptoms but does not cure your condition. Your doctor will check your or your child's progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

During treatment for ADHD, your doctor may stop DEXAMPHETAMINE every so often (e.g. over weekends or school holidays) to see whether it is still needed. Breaks from treatment also help to prevent a slow-down in growth that sometimes happens when children take this medicine for a long time.

**Always discuss with your doctor any problems or difficulties during or after taking DEXAMPHETAMINE.**

**Like all CNS stimulants, DEXAMPHETAMINE may**

become habit-forming and can be abused by some people. Use **DEXAMPHEMAMINE** strictly as your doctor prescribed will ensure that abuse or drug dependence should not be a problem.

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

**Keep enough DEXAMPHEMAMINE to last weekends and holidays.**

*Things you must not do:*

**Do not take any other medicines while you are taking DEXAMPHEMAMINE without first checking with your doctor.**

**Do not take DEXAMPHEMAMINE for a longer time than your doctor has prescribed.**

**Do not change your dose without first checking with your doctor.**

**Do not stop your treatment without first checking with your doctor.**

If you suddenly stop taking this medicine, your conditions may reappear or you may get unwanted effects such as depression or extreme tiredness. To prevent this, your doctor may want to gradually reduce the amount of medicine you take each day before stopping you take each day before stopping it completely.

**Do not use this medicine to treat any other complaints unless your doctor says to.**

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

*Things to be careful of:*

**Do not drive or operate machinery until you know how DEXAMPHEMAMINE affects you.**

DEXAMPHEMAMINE may cause dizziness in some people and therefore may affect alertness. Make sure you know how you react to DEXAMPHEMAMINE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or overstimulated.

**Strenuous exercise or activity and drinking alcohol while taking DEXAMPHEMAMINE. If you drink alcohol, it could make some of the unwanted side effects of DEXAMPHEMAMINE worse.**

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking DEXAMPHEMAMINE.

Some people may experience side effects such as nausea, headache and dizziness which may affect co-ordination and increase the risk when using dangerous machinery.

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**Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DEXAMPHEMAMINE.**

All medicines 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 side effects.

**Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.**

**Ask your doctor or pharmacist any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- **nausea (feeling sick)**
- **vomiting or abdominal pain.** This can usually be relieved by taking the medicine with food.
- **headache**
- **dizziness**
- **mood changes such as depression or irritability**
- **tremor or palpitations**
- **restlessness, nervousness or insomnia.** This can usually be relieved by taking the dose no later than 4 hours before bedtime.
- **loss of appetite, weight loss or slower growth in children.** Your doctor may consider breaks from treatment in order to avoid this.

The above side effects are usually mild and mostly occur during the first few days of treatment and some may disappear as your body adjusts to the treatment.

There are other side effects which occur less often, for example stomach pain or other stomach problems that won't go away, dry mouth, metallic taste, uncontrolled movements, impotence, skin rash or itchiness, Raynaud's phenomenon.

**Tell your doctor or go to Accident and Emergency at your nearest hospital if you /your child develop**

- chest pain or tightness in the chest
- shortness of breath
- irregular heart beat
- seizures (fits)

- vision problems
- mood changes such as depression or irritability
- new or worsening aggressive behaviour
- excitement, overactivity and uninbited behaviour
- weakness or paralysis of limbs or face
- difficulty speaking or unexplained fainting
- severe or persistent headache
- suicidal or self-harm thoughts or behaviour
- confusion, delusion or hallucinations (seeing or feeling things that are not really there)
- abnormal thinking (psychosis)

The above side effects may be serious. You may need urgent medical attention.

Some people may get other side effects of DEXAMPHETAMINE not yet known or mentioned in this leaflet.

**Your doctor may lower the dose to help control serious side effects and decide on necessary tests to monitor any of the above problems.**

**Check with your doctor as soon as possible if you have any problems while taking DEXAMPHETAMINE even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

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#### **After using DEXAMPHETAMINE**

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#### **Storage**

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep DEXAMPHETAMINE in a cool dry place where the temperature stays below 25°C and protect from light.**

**Do not store it, or any other medicines, in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines. Do not take DEXAMPHETAMINE if the tablets do not look quite right.

**Keep your tablets in the plastic bottle they were provided in until it is time to take them.**

#### **Disposal**

**If your doctor tells you to stop taking the tablets OR they have passed their expiry date, ask your pharmacist what to do with any left over.**

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#### **Product description**

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#### **What it looks like**

*DEXAMPHETAMINE 5mg tablet* is a white round flat tablet, scored on one side with D5 on the other.

#### **Ingredients**

Each DEXAMPHETAMINE tablet contains 5mg of the active ingredient, dexamphetamine (present as dexamphetamine sulfate).

The excipients or other non-active ingredients are povidone, lactose, starch-wheat, and magnesium stearate. The tablets do not contain a colouring agent.

DEXAMPHETAMINE does contain lactose and very low levels of gluten. It does not contain tartrazine or any other azo dye.

#### **Sponsor or Supplier**

Sigma Pharmaceuticals  
(Australia) Pty Ltd (A.C.N. 004  
118 594)  
96 Merrindale Drive  
Croydon Victoria 3136

Australia

Telephone: 03 - 9839 2800

The Australian Registration Number for DEXAMPHETAMINE 5mg tablet is AUST R 19684

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