

ASPEN DEXAMFETAMINE™

dexamfetamine sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ASPEN DEXAMFETAMINE tablets.

It does not contain all of 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 or your child taking ASPEN DEXAMFETAMINE tablets against the benefits they expect it will have.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What is ASPEN DEXAMFETAMINE

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

It is used to treat a 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. ASPEN DEXAMFETAMINE 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.

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

Your doctor may have prescribed this medicine for another purpose.

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

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

Before you take it

When you must not take it

Do not take ASPEN DEXAMFETAMINE if you are allergic to:

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

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 ASPEN DEXAMFETAMINE 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 it 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 it if you are breastfeeding or plan to breast feed.

Do not use it 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 ASPEN DEXAMFETAMINE.

4. you are pregnant or plan to become pregnant.

Like all medicines, it should not be used during pregnancy, unless your doctor tells you.

5. you are breastfeeding or plan to breastfeed.

ASPEN DEXAMFETAMINE 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 ASPEN DEXAMFETAMINE.

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
- 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 ASPEN DEXAMFETAMINE 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
- ethosuximide e.g. Zarontin
- some opioid type analgesics e.g. pethidine
- barbiturates e.g. phenobarbitone.

The above medicines may either reduce the effectiveness of ASPEN DEXAMFETAMINE, reduce its own effectiveness and/or react with this medicine 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 this medicine.

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

How to take it

How much to take

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

The recommended doses for:

Narcolepsy

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

For patients 12 years or older your doctor may start treatment with two tablets (10 mg) daily. The dose may be increased by 10 mg 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 (2.5 mg) daily. The dose may be increased by 2.5 mg 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

ASPEN DEXAMFETAMINE should be taken either early in the day or in the morning.

How long to take it

Continue taking your medicine as long as your doctor recommends it.

If you forget to take it

If you forget to take a dose of ASPEN DEXAMFETAMINE, 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 ASPEN DEXAMFETAMINE. Do this even if there are no signs of discomfort or poisoning. Be sure

to report any other medicine or alcohol which has been taken.

You may need urgent medical attention.

Symptoms of overdose include nausea, vomiting, diarrhoea, chills, sweating, restlessness, hallucinations, panic, headache, convulsions and symptoms associated with severe high blood pressure or manifestations of acute psychosis.

While you are taking it

Things you must do:

Use ASPEN DEXAMFETAMINE exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

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

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

Tell your doctor if you feel this medicine is not helping your condition.

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

Regularly check the height and weight of your child. If your child is not growing or gaining height or weight as expected, treatment with ASPEN DEXAMFETAMINE 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 your treatment 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 ASPEN DEXAMFETAMINE.

Like all CNS stimulants, it may become habit-forming and can be abused by some people. Using this medicine 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 medicine to last weekends and holidays.

Things you must not do

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

Do not take this medicine 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 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 ASPEN DEXAMFETAMINE affects you.

It may cause dizziness in some people and therefore may affect alertness.

Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or overstimulated.

Be careful when doing strenuous exercise or activity and drinking alcohol while taking ASPEN DEXAMFETAMINE.

If you drink alcohol, it could make some of the unwanted side effects worse.

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

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.

Side effects

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

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.

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

- nausea (feeling sick)
- vomiting or abdominal pain
- headache

- dizziness
- mood changes such as depression or irritability
- fast heart beat or pulse
- palpitations
- restlessness, nervousness, tremor
- insomnia. This might be improved by taking the dose well before bedtime
- loss of appetite, weight loss or slower growth in children.

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 – a condition where there is decreased blood supply to extremities (e.g. fingers or toes) which may feel cold, numb or painful.

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 uninhibited 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 ASPEN DEXAMFETAMINE 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 ASPEN DEXAMFETAMINE even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

After taking it

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 your medicine 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.

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.

Product description

What it looks like

ASPEN DEXAMFETAMINE 5 mg tablet is a white round scored tablet marked with 'D5' on one side and plain on the other. Available in bottles of 100 tablets.

Ingredients

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

The non-active ingredients are povidone, lactose monohydrate, wheat starch and magnesium stearate.

ASPEN DEXAMFETAMINE tablets contain lactose monohydrate and very low levels of gluten from the wheat starch. It does not contain tartrazine or any other azo dye.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

The Australian registration number is AUST R 19684.

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