

ASPEN DEXAMFETAMINE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ASPEN DEXAMFETAMINE?

ASPEN DEXAMFETAMINE contains the active ingredient dexamfetamine sulfate. ASPEN DEXAMFETAMINE is used to treat a number of medical conditions such as attention deficit hyperactivity disorder (ADHD) and narcolepsy.

For more information, see Section [1. Why am I using ASPEN DEXAMFETAMINE?](#) in the full CMI.

2. What should I know before I use ASPEN DEXAMFETAMINE?

Do not use if you have ever had an allergic reaction to dexamfetamine, other amfetamine type medicines or any of the ingredients listed at the end of the CMI.

This medicine is potentially habit forming or addictive.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ASPEN DEXAMFETAMINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ASPEN DEXAMFETAMINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ASPEN DEXAMFETAMINE?

- Follow all directions given to you by your doctor including how many tablets to take each day.
- Swallow the tablet with water early in the day or in the morning.

More instructions can be found in Section [4. How do I use ASPEN DEXAMFETAMINE?](#) in the full CMI.

5. What should I know while using ASPEN DEXAMFETAMINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ASPEN DEXAMFETAMINE.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take any other medicines without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• 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.
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking alcohol or reduce the amount you drink as it may increase the chance of side effects.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the plastic bottle until it is time to take them.• Store in a cool dry place where the temperature stays below 25°C and keep out of reach of children.

For more information, see Section [5. What should I know while using ASPEN DEXAMFETAMINE?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ASPEN DEXAMFETAMINE. Some mild side effects include nausea, headache, dizziness, mood changes and insomnia. Some more serious side effects include irregular heart beat, vision problems, seizures, worsening aggression, weakness of limbs and severe or persistent headaches.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ASPEN DEXAMFETAMINE

Active ingredient: *dexamfetamine sulfate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ASPEN DEXAMFETAMINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ASPEN DEXAMFETAMINE.**

Where to find information in this leaflet:

- [1. Why am I using ASPEN DEXAMFETAMINE?](#)
- [2. What should I know before I use ASPEN DEXAMFETAMINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ASPEN DEXAMFETAMINE?](#)
- [5. What should I know while using ASPEN DEXAMFETAMINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ASPEN DEXAMFETAMINE?

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

ASPEN DEXAMFETAMINE 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.

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.

2. What should I know before I use ASPEN DEXAMFETAMINE?

Warnings

Because of the liability for abuse, drugs of the amphetamines type are subject to special restrictions on their availability. Prescriptions for this substance may

require validation by State or Territory Health Departments or Commissions.

Do not use ASPEN DEXAMFETAMINE if:

- You are allergic to dexamfetamine, other amphetamine type medications, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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.

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 use 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 give it to children unless your doctor has prescribed it.

It is not recommended for use in children under three years of age.

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

Check with your doctor if you:

Are allergic to any other medicines or any foods, dyes or preservatives.

Have any other medical conditions including:

- Suspicion or presence of any cardiac or heart-related abnormalities; irregular heartbeats 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.

Take any medicines for any other condition.

Drink alcohol regularly. Alcohol should not be taken with ASPEN DEXAMFETAMINE.

Your doctor should carefully check if you have any heart-related conditions or abnormalities, or a family history of sudden/cardiac (heart-related) death

Stimulant medicines such as dexamfetamine may increase the risk of sudden/heart-related death if you have certain heart conditions or abnormalities. Your doctor will tell you if dexamfetamine is appropriate for you.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ASPEN DEXAMFETAMINE should be avoided during early pregnancy as it may increase the risk of defects present at birth.

ASPEN DEXAMFETAMINE may cause unwanted effects in the newborn baby if the mother is dependent on amfetamines, such as lack of energy, agitation and distress.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

ASPEN DEXAMFETAMINE is passed into breast milk. Breastfeeding is not recommended while taking this medicine.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ASPEN DEXAMFETAMINE.

4. How do I use ASPEN DEXAMFETAMINE?

How much to use

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.

When to take it

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

How to take it

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

How long to take it

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

If you forget to use ASPEN DEXAMFETAMINE

ASPEN DEXAMFETAMINE should be used regularly at the same time each day.

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 use too much ASPEN DEXAMFETAMINE

If you think that you have used too much ASPEN DEXAMFETAMINE, you may need urgent medical attention.

The 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.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using ASPEN DEXAMFETAMINE?

Things you should do

Use this medicine exactly as your doctor has prescribed.

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

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

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

Always discuss with your doctor any problems or difficulties during or after taking ASPEN DEXAMFETAMINE.

Like all CNS stimulants, ASPEN DEXAMFETAMINE may become habit-forming and can be abused by some people. Using it strictly as your doctor prescribed will ensure that abuse or drug dependence should not be a problem.

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, 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.

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.

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 symptoms but does not cure the condition. Your doctor will check any progress to make sure the medicine is working and will discuss with you how long the treatment should continue.

During treatment for ADHD, your doctor may stop 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.

Things you should not do

- **Do not take any other medicines while you are taking ASPEN DEXAMFETAMINE without first checking with your doctor.**
- **Do not change your dose without first checking with your doctor.**
- **Do not take this medicine for a longer time than your doctor has prescribed.**
- **Do not stop using this medicine suddenly 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.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ASPEN DEXAMFETAMINE affects you.

ASPEN DEXAMFETAMINE 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may 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 coordination and increase the risk when using dangerous machinery.

Looking after your medicine

Keep your medicine in the original container where the temperature stays below 25°C and protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>mostly occur during the first</p>

The above side effects are usually mild and few days of treatment. 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.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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).	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ASPEN DEXAMFETAMINE contains

Active ingredient (main ingredient)	Dexamfetamine 5 mg (as dexamfetamine sulfate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Povidone• Lactose monohydrate• Wheat starch• Magnesium stearate
Potential allergens	<ul style="list-style-type: none">• Lactose• Gluten

ASPEN DEXAMFETAMINE tablets contain sugars (from lactose monohydrate) and gluten (from wheat starch). They do not contain tartrazine or any other azo dye.

Do not take this medicine if you are allergic to any of these ingredients.

What ASPEN DEXAMFETAMINE looks like

ASPEN DEXAMFETAMINE is a white, round, scored tablet marked with 'D5' on one side and plain on the other.

Available in bottles of 100 tablets.

(AUST R 19684)

Who distributes ASPEN DEXAMFETAMINE

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

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