

DEXMETHSONE tablets

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 DEXMETHSONE?

DEXMETHSONE contains the active ingredient dexamethasone. DEXMETHSONE is used to in the treatment of many different conditions including severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, some types of cancer and “auto-immune” diseases. It is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body.

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

2. What should I know before I use DEXMETHSONE?

Do not use if you have ever had an allergic reaction to dexamethasone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions (such as an uncontrolled infection or an infection in your blood) 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 DEXMETHSONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEXMETHSONE 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 DEXMETHSONE?

The dosage varies depending on your condition. Your doctor will advise you.

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

5. What should I know while using DEXMETHSONE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, surgeon, dentist or pharmacist you visit that you are using DEXMETHSONE.• Tell your doctor if you get a serious infection or injury whilst taking DEXMETHSONE.• Tell your doctor immediately if you are diabetic and if you notice any change in your blood or urine sugar readings.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not have any ‘live’ immunisations without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how this medicine affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tables in the bottle until it is time to take them.• Store in a cool dry place where the temperature stays below 30°C and keep out of reach of children.

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

6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. When DEXMETHSONE is taken for short periods of time, even at high doses, it is unlikely to cause any problems. However, the risk of side effects is greater when DEXMETHSONE is taken for long periods of time and in high doses.

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.

DEXMETHSONE tablets

Active ingredient: *dexamethasone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DEXMETHSONE.

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 DEXMETHSONE.

Where to find information in this leaflet:

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

1. Why am I using DEXMETHSONE?

DEXMETHSONE contains the active ingredient dexamethasone. DEXMETHSONE belongs to a group of medicines called corticosteroids which are a synthetic version of a naturally occurring body hormone called cortisol.

DEXMETHSONE is used in the treatment of many different conditions including severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, some types of cancer and “auto-immune” diseases.

It is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body. These symptoms can occur in response to injury or can be caused by many different conditions.

DEXMETHSONE works by acting on the immune system and blocking the production of substances that trigger allergic and inflammatory actions.

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

Your doctor may have prescribed it for another reason.

2. What should I know before I use DEXMETHSONE?

Warnings

Do not use DEXMETHSONE if:

- you are allergic to dexamethasone or any of the ingredients listed at the end of this leaflet.
- you have a serious or uncontrolled infection.
- you have an infection in your blood
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - recent surgery or serious injury
 - a current serious or uncontrolled infection
 - eye problems, such as glaucoma or cataracts
 - liver or kidney disease
 - diabetes mellitus, sugar diabetes
 - osteoporosis, softening of the bone
 - tuberculosis
 - adrenal gland tumour.
- take any medicines for any other condition.

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.

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

It is not recommended for use while breastfeeding as the active ingredient is found in breast milk. Your doctor can discuss with you the risks and benefits involved.

Use in children

Take special care when giving DEXMETHSONE to children. It should only be given under your doctor’s supervision. If possible, children should not be exposed to common childhood illnesses such as chicken pox or measles while they are taking DEXMETHSONE. They may suffer from more serious attacks of these illnesses if such exposure occurs.

Children should not be vaccinated with ‘live’ vaccines against common childhood illnesses while they are taking DEXMETHSONE, as this may result in severe attacks of these illnesses.

Potentially serious side effects may occur in children and growing teenagers who are on long-term treatment of corticosteroids. Some of these include obesity, slowed growth, osteoporosis (softening of the bone) and changes to the adrenal glands.

Use in the elderly

Elderly patients may be more sensitive to the effects or side effects of 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 DEXMETHSONE. These include:

- barbiturates, drugs which cause relaxation and sleepiness
- phenytoin, a drug used to treat epilepsy
- phenobarbitone, a drug used to treat epilepsy and also used for sedation
- fluid or 'water' tablets
- hypoglycaemic medicines, used to treat diabetes
- heart medication
- rifampicin, an antibiotic used to treat tuberculosis
- oral contraceptives
- immunisations or vaccines.

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

4. How do I use DEXMETHSONE?

How much to take

The dose will depend on the condition being treated and your response to the treatment. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

Your doctor will tell you how many tablets you will need to take each day.

When to take it

How often you take DEXMETHSONE depends on what condition is being treated.

Do not miss any doses even if you feel better.

Missing doses may make your symptoms worse.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Some people will need to take DEXMETHSONE for short periods of time, whereas other people may require long term therapy.

If you have been taking it for a long time, your doctor may gradually reduce the amount you are taking over a period of several days, weeks or months before stopping completely.

If you have been taking it for a short period of time, this may not apply.

If you forget to use DEXMETHSONE

If you miss a dose of this medicine, the decision of whether you should take it or not will depend on how many times a day your doctor has told you to take DEXMETHSONE.

If you are taking DEXMETHSONE:

Once a day -

Take the missed dose as soon as possible, then go back to your regular dosing schedule. If you do not remember until the next day, skip the missed dose and do not double the next one.

Several times a day -

Take the missed dose as soon as possible, then go back to your regular dosing schedule.

On alternate days -

If you miss a dose and remember it the same morning, take it straight away, then continue as you normally would. If you do not remember the missed dose until later in the day, wait and take it the following morning. Then skip a day before continuing your regular dosage schedule.

Do not take a double dose to make up for any missed dose.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much DEXMETHSONE

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

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.

5. What should I know while using DEXMETHSONE?

Things you should do

Take DEXMETHSONE exactly as directed by your doctor.

If you do not follow your doctor's instructions, you may not get improvement in the symptoms of your condition. Try not to miss any doses and take the medicine even if you feel well.

Ask your doctor when and how you should stop taking DEXMETHSONE.

If you have been taking it for a long time, your doctor may gradually reduce the amount you are taking over a period of several days, weeks or months before stopping completely.

If you have been taking it for a short period of time, this may not apply.

Keep all of your doctor's appointments.

If you are taking DEXMETHSONE for a long period of time, you must have regular checkups with your doctor. This is especially important for children who are taking DEXMETHSONE.

Tell your doctor if you get a serious infection or injury whilst taking DEXMETHSONE.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking DEXMETHSONE, especially if you are being started on any new medicines.

If you plan to have surgery that needs a general anaesthetic, tell your doctor, surgeon or dentist that you are taking DEXMETHSONE.

The trauma of the operation or surgery may mean that your dose of this medicine needs to be adjusted to cover this stressful time.

Tell your doctor immediately if you are diabetic and if you notice any change in your blood or urine sugar readings.

DEXMETHSONE may affect your blood sugar levels as it can affect the body's ability to handle glucose. For diabetics, this means that your diabetes may become more severe.

For others, diabetes may develop for the first time while taking corticosteroids such as DEXMETHSONE.

Tell your doctor if you become pregnant while taking DEXMETHSONE.

Things you should not do

- **Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, the symptoms of your condition may return or you may develop symptoms of certain hormone deficiencies such as fainting, weakness, restlessness, nausea, vomiting, headache, dizziness, muscle weakness or joint pain.

- **Do not have any immunisations while you are taking DEXMETHSONE.**

Immunisation with 'live' vaccines may interfere with DEXMETHSONE or not work at all.

Things to be careful of

- **Avoid close contact with anyone who has a contagious disease such as chicken pox or measles.**
- **Tell your doctor immediately if you think you have been exposed to chickenpox or measles.**

Exposure to such diseases while you are taking DEXMETHSONE can put you at greater risk of developing these diseases if you have not had them before.

Driving or using machines

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

Infections

You should see your doctor for medical advice for any but the most minor infections.

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of DEXMETHSONE.

Looking after your medicine

Keep DEXMETHSONE tablets in a cool dry place where the temperature stays below 30°C.

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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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.

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.

If you are elderly, you may have an increased chance of getting side effects.

Short term use

When DEXMETHSONE is taken for short periods of time, even at high doses, it is unlikely to cause any problems.

Long term use

When DEXMETHSONE is taken for long periods of time and in high doses the risk of side effects is greater.

Less serious side effects

Less serious side effects	What to do
<p><i>General changes to your body:</i></p> <ul style="list-style-type: none"> • headache • nausea, feeling sick • vomiting • dizziness • indigestion, stomach pain or discomfort • diarrhoea or constipation • increased or reduced appetite • weight gain • slowed growth in children • bloating or rounding of the face • cramps or weakness in the muscles of the arms and legs • water retention leading to swollen legs and feet • irregular heart beat • irregular menstrual periods • hiccups (cases have been reported immediately after starting therapy). <p><i>Changes to the immune system:</i></p> <ul style="list-style-type: none"> • an increased seriousness or frequency of infections. <p><i>Changes in behaviour:</i></p> <ul style="list-style-type: none"> • mood changes, confusion, forgetfulness • anxiety or nervousness • restlessness • difficulty sleeping (insomnia). <p><i>Changes to the skin:</i></p> <ul style="list-style-type: none"> • poor wound healing • red or flushed face • increased sweating • extra hair growth • acne 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • red or purple streaks on skin • skin thinning • itchy rash • unusual bleeding or bruising under the skin. <p><i>Changes in eyes:</i></p> <ul style="list-style-type: none"> • cataracts • eyes sticking out too far • decreased or blurred vision. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • severe stomach or intestinal pain • sudden changes in your vision • fits • major psychiatric or personality changes • symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heartbeat • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. <p>Serious side effects are rare.</p>	<p>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention.</p>

Other side effects

Some side effects can only be detected by your doctor.

Side effects	What to do
<ul style="list-style-type: none"> • osteoporosis, softening of the bone • blood sugar level (diabetes) • eye pressure (glaucoma) • cholesterol levels • hormone levels • sperm count • high blood pressure (hypertension) • certain blood cells • the way nerves work • heart beat and rhythm. 	<p>It is important to visit your doctor for regular check-ups when DEXMETHSONE is taken for long periods of time.</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.

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.

DEXMETHSONE tablets are available in two strengths.

What DEXMETHSONE 0.5 mg tablets contain

Active ingredient (main ingredient)	<ul style="list-style-type: none">dexamethasone 0.5 mg/tablet.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactose monohydratepovidonemagnesium stearatewheat starch.
Potential allergens	<ul style="list-style-type: none">sugars as lactosegluten.

What DEXMETHSONE 4 mg tablets contain

Active ingredient (main ingredient)	<ul style="list-style-type: none">dexamethasone 4 mg/tablet.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactose monohydratepovidonemagnesium stearatemaize starch.
Potential allergens	<ul style="list-style-type: none">sugars as lactose.

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

What DEXMETHSONE tablets look like

- DEXMETHSONE 0.5 mg tablets are round, slightly biconvex and white with a breakline and "DS/0.5" on one side and plain on the other side. Available in bottles of 30 tablets.
- DEXMETHSONE 4 mg tablets are round and white with a breakline and "DS/4" on one side and plain on the other side. Available in bottles of 30 tablets.

Australian Registration numbers:

BETNOVATE 0.5 mg tablet: AUST R 27917

BETNOVATE 4 mg tablet: AUST R 27915

Who distributes DEXMETHSONE

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

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