

DEXMETHSONE®

dexamethasone

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about DEXMETHSONE. 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 taking DEXMETHSONE against the benefits they expect it will have for you.

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.

What DEXMETHSONE is used for

DEXMETHSONE contains dexamethasone as the active ingredient. It 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 purpose.

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take DEXMETHSONE if you have ever had an allergic reaction to:

- dexamethasone
- any of the ingredients listed at the end of this leaflet.

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

Do not take it if you have a serious or uncontrolled infection.

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

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

Do not take DEXMETHSONE after the expiry date (EXP) printed on the label.

Do not take it if the bottle shows signs of having been tampered with.

Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any 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.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor can discuss the possible risks and benefits of taking high doses of DEXMETHSONE during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is not recommended for use while breastfeeding as it is found in breast milk.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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
- fluid or 'water' tablets
- rifampicin, an antibiotic used to treat tuberculosis
- oral contraceptives
- immunisations or vaccines.

These medicines may be affected by DEXMETHSONE or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will advise you.

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 elderly

Elderly patients may be more sensitive to the effects or side effects of this medicine.

How to take it

How much to take

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

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.

When to take it

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

Do not miss any doses and do not stop taking this medicine 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.

This will depend on your condition and your response to the treatment. Some people will need to take DEXMETHSONE for short periods of time, whereas, other people may require long term therapy.

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.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much DEXMETHSONE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must 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 must not do

Do not stop taking DEXMETHSONE 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.

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.

Tell your doctor immediately if you think you have been exposed to chickenpox or measles.

Things to be aware of

As with any new medicine, you should take care when driving,

operating machinery or drinking alcohol until you know how DEXMETHSONE affects you.

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of DEXMETHSONE. You should see your doctor for medical advice for any but the most minor infections.

Side effects

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

DEXMETHSONE helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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.

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

general changes to your body:

- 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.

changes to the immune system:

- an increased seriousness or frequency of infections.

changes in behaviour:

- mood changes
- anxiety or nervousness
- restlessness
- difficulty sleeping (insomnia).

changes to the skin:

- poor wound healing
- red or flushed face
- increased sweating
- extra hair growth
- acne
- red or purple streaks on skin
- skin thinning
- itchy rash
- unusual bleeding or bruising under the skin.

changes in eyes:

- cataracts
- eyes sticking out too far
- decreased or blurred vision.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- 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 heart beat

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check-ups when DEXMETHSONE is taken for long periods of time.

Such side effects can include changes in:

- 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.

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

Some people may get other side effects while using DEXMETHSONE.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

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

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a

windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

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.

Disposal

Dispose of the tablets where children cannot reach them.

If your doctor or pharmacist tells you to stop taking DEXMETHSONE or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you may have left.

Product description

What it looks like

DEXMETHSONE tablets are available in two strengths; 0.5 mg or 4 mg.

The 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.

The 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.

Ingredients

Active ingredient:

DEXMETHSONE 0.5 mg - 0.5 mg dexamethasone per tablet.

DEXMETHSONE 4 mg - 4 mg dexamethasone per tablet.

Inactive ingredients:

- lactose
- povidone
- magnesium stearate
- starch- wheat (0.5 mg only)
- starch-maize (4 mg only).

DEXMETHSONE tablets do not contain gluten (4 mg only), sucrose, tartrazine or any other azo dyes.

Sponsor

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

Australian Registration Numbers:

0.5 mg tablet: AUST R 27917

4 mg tablet: AUST R 27915

This leaflet was prepared in August 2010.