

DEXAMETHASONE SXP

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 being given DEXAMETHASONE SXP?

DEXAMETHASONE SXP injection contains the active ingredient dexamethasone sodium phosphate. DEXAMETHASONE SXP injection is used to treat an underactive adrenal gland, immune disorders, skin problems, asthma, arthritis or in other situations to reduce inflammation.

For more information, see Section [1. Why am I being given DEXAMETHASONE SXP?](#) in the full CMI.

2. What should I know before I am given DEXAMETHASONE SXP?

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

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 am given DEXAMETHASONE SXP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEXAMETHASONE SXP injection 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 am I given DEXAMETHASONE SXP?

- DEXAMETHASONE SXP is given as a slow injection or infusion (intravenous drip) into the veins. It may also be given as an injection into an injured muscle or joint. It may be given as a course of injections or as a single dose.
- DEXAMETHASONE SXP injection should only be given by a doctor or nurse who will decide the correct dose depending upon the condition being treated, and other factors such as your weight.

More instructions can be found in Section [4. How am I given DEXAMETHASONE SXP?](#) in the full CMI.

5. What should I know while I am being given DEXAMETHASONE SXP?

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|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are being given this medicine.• If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DEXAMETHASONE SXP.• If you plan to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are being given this medicine.• If you become pregnant while you are being treated with DEXAMETHASONE SXP, tell your doctor immediately.• Tell your doctor immediately if you get an infection while being treated with this medicine. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery while being treated with DEXAMETHASONE SXP, as it may cause dizziness in some people. |
| Drinking alcohol | <ul style="list-style-type: none">• If you drink alcohol while being treated with DEXAMETHASONE SXP, you may experience dizziness. |
| Looking after your medicine | <ul style="list-style-type: none">• DEXAMETHASONE SXP will usually be stored in the pharmacy or on the ward, in a cool dry place, protected from light, where the temperature stays below 25°C. |

For more information, see Section [5. What should I know I am being given DEXAMETHASONE SXP?](#) in the full CMI.

6. Are there any side effects?

Common side effects of this medicine include nausea, vomiting, 'gas' or abdominal bloating, bad taste in the mouth, menstrual irregularity, weight gain, fluid retention, increased body hair, easily bruising, slow healing wounds, muscular weakness, headache, dizziness, thin or fragile skin, acne, sleep disturbances, blurred vision, fungal infection and being susceptible to other kinds of infections and reduced growth in children.

Serious side effects include signs of an allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing. Other serious side effects are severe stomach pain, blood in the faeces, irregular heartbeat, changes in vision, changes in mood or sleep patterns, joint pain or broken bones, breakdown of weight-bearing joints, tendon rupture, signs of infection, seizures or convulsions.

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.

DEXAMETHASONE SXP

Active ingredient: Dexamethasone Phosphate (as sodium)

Consumer Medicine Information (CMI)

This leaflet provides important information about being given DEXAMETHASONE SXP injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given this medicine.**

Where to find information in this leaflet:

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

1. Why am I being given DEXAMETHASONE SXP?

DEXAMETHASONE SXP contains the active ingredient dexamethasone phosphate (as sodium). DEXAMETHASONE SXP is a glucocorticoid and belongs to a group of medicines called corticosteroids.

DEXAMETHASONE SXP is used to treat an inactive or underactive adrenal gland or to treat a number of different diseases such as certain immune disorders, skin problems, asthma or arthritis.

Corticosteroids reduce inflammation, one of the body's reactions to injury.

Except for its use in the treatment of underactive adrenal glands, DEXAMETHASONE SXP does not cure disease; it treats the symptoms.

2. What should I know before I am given DEXAMETHASONE SXP?

Warnings

You should not be given DEXAMETHASONE SXP injection if you:

- are allergic to DEXAMETHASONE SXP, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
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.
- have an internal fungal infection.
- have recently been given a live vaccine such as smallpox or polio/sabin, unless you are being given the DEXAMETHASONE SXP for replacement therapy.
- have myasthenia gravis, a muscle wasting disease.
- have a stomach (peptic) ulcer.
- have osteoporosis (weak or brittle bones).
- have a severe mental health condition.

If you are not sure whether you should be given DEXAMETHASONE SXP Injection, talk to your doctor or pharmacist.

Check with your doctor if you have:

- been given any vaccines recently.
- diabetes, a disorder of blood sugar- levels
- current or recent infections
- heart failure or had a recent heart attack
- kidney disease
- liver disease
- thyroid disease
- inflammation of the bowel wall or other bowel problems
- high blood pressure
- eye diseases, including glaucoma or a family history of glaucoma, including infections, ulcers or allergies
- muscle disease or injury
- mental illness
- Cushing's disease, a condition where there is too much cortisol
- epilepsy, seizures or convulsions, migraine
- a stomach ulcer
- intestinal disease
- osteoporosis (weak or brittle bones)
- myasthenia gravis, a muscle wasting disease
- presence of bacteria in the bloodstream
- unstable joints
- infection at the injection site
- latent tuberculosis, where you have tuberculosis bacteria in your body but do not feel sick
- chicken pox or measles, or have been exposed to these recently
- suspected or identified pheochromocytoma, which are tumours growing on part of your kidneys
- been diagnosed with Acute Respiratory Disease Syndrome (ARDS) for over 2 weeks
- you have suffered a head injury or stroke
- pre-eclampsia or fluid retention
- any other medical conditions or take any medicines for any other condition

Tell your doctor if take any medicines for any other conditions.

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.

Like most corticosteroid medicines, DEXAMETHASONE SXP injection is not generally recommended for use during pregnancy. Your doctor will discuss with you the possible

benefits and risks of this medicine being given to you during pregnancy.

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

DEXAMETHASONE SXP injection may pass into breast milk, and there is a possibility that the breast-fed baby may be affected.

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 and DEXAMETHASONE SXP injection may interfere with each other. These include:

- barbiturates, carbamazepine or phenytoin, medicines used to treat epilepsy
- aspirin, and other non-steroidal anti-inflammatory medicines, especially phenylbutazone
- insulin or other medicines for the control of sugar in the blood
- estrogens and other oral contraceptives
- anti-thyroid medicines used to treat an over active thyroid gland
- fluid tablets, particularly furosemide (frusemide) and thiazides or other medicines affecting the kidneys
- anticoagulant medicines (medicines to prevent blood clots), such as warfarin or heparin
- any recent vaccinations or immunisations
- ciclosporin, a medicine used to prevent transplant rejection
- rifabutin, rifampicin or amphotericin or vancomycin, medicines used to treat infections
- ritonavir, a medicine used in the treatment of HIV/AIDS
- ketoconazole, a medicine used to treat fungal infections
- digoxin, a medicine used to treat heart conditions
- aminoglutethimide, a hormone used treat breast cancer
- daunorubicin or doxorubicin, a medicine used to treat cancer
- salbutamol, salmeterol, medicines used to treat asthma
- some medicines used in the treatment of heartburn and indigestion
- doxapram, a medicine used to treat chronic obstructive pulmonary disease
- glycopyrrolate, a medicine used to dry up secretions or saliva.

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

3. How am I given DEXAMETHASONE SXP?

How much DEXAMETHASONE SXP is given

- The dose of DEXAMETHASONE SXP injection is variable, depending upon the condition being treated. It may be given as a course of injections or as a single dose. Your doctor will decide what dose will

receive. This depends on your condition and other factors, such as your weight.

- As soon as an improvement in your condition is noticed, the dosage should be adjusted to the minimum required to control the symptoms.

How DEXAMETHASONE SXP is given

- DEXAMETHASONE SXP is given as a slow injection or infusion (intravenous drip) into the veins. It may also be given as an injection into an injured muscle or joint.
- DEXAMETHASONE SXP injection should only be given by a doctor or nurse.

If you are given too much DEXAMETHASONE SXP

As DEXAMETHASONE SXP Injection is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects tell your doctor or nurse immediately. If you are not already in hospital, go to the Accident & Emergency Department at your nearest hospital or immediately contact the Poisons Information Centre for advice on overdose (Call 13 11 26).

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

4. What should I know while I am being given DEXAMETHASONE SXP?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DEXAMETHASONE SXP injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DEXAMETHASONE SXP injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given DEXAMETHASONE SXP injection.

If you become pregnant while you are being treated with DEXAMETHASONE SXP injection, tell your doctor immediately.

If you get an infection while you are being given DEXAMETHASONE SXP, you must tell your doctor immediately. Like most corticosteroid medicines, dexamethasone phosphate (as sodium) may hide the symptoms of an infection.

Things you should not do

If you have been given DEXAMETHASONE SXP Injection for a painful or inflamed joint, you should be careful not to overuse the joint as long as the inflammation is still present.

Driving or using machines

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

As with other corticosteroid medicines, DEXAMETHASONE SXP injection may cause dizziness and blurred vision in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while being treated with DEXAMETHASONE SXP injection, you may experience dizziness.

Looking after your medicine

DEXAMETHASONE SXP injection will usually be stored in the pharmacy or on the ward, in a cool dry place, protected from light, where the temperature stays below 25°C.

5. 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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 and vomiting'gas' or abdominal bloatingbad taste in the mouthmenstrual irregularityweight gainfluid retentionincreased body hairbruising easilyslow wound healingmuscular weaknessheadachedizzinessthin, fragile skinacnesleep disturbances | Speak to your doctor if you have any of these less serious side effects and they worry you. |

| | |
|---|--|
| <ul style="list-style-type: none">reduced growth in childrenblurred visionfungal infection and being susceptible to other kinds of infections | |
|---|--|

Serious side effects

| Serious side effects | What to do |
|--|---|
| <ul style="list-style-type: none">signs of an allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathingsevere stomach painblood in the faecesirregular heartbeatchanges in visionchanges in mood or sleep patternsjoint pain or broken bonesbreakdown of weight-bearing joints (Charcot-like arthropathy)tendon ruptureseizures or convulsionssigns of infection | 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. |

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.

6. Product details

This medicine is only available with a doctor's prescription. DEXAMETHASONE SXP is not addictive.

What DEXAMETHASONE SXP contains

| | |
|---|---|
| Active ingredient (main ingredient) | Dexamethasone phosphate (as dexamethasone sodium phosphate) |
| Other ingredients (inactive ingredients) | Sodium citrate Disodium edetate Creatinine Sodium hydroxide Hydrochloric acid Water for injections |

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

What DEXAMETHASONE SXP looks like

DEXAMETHASONE SXP injection is a clear, colourless to slightly yellowish solution in an amber glass ampoule. Each carton of DEXAMETHASONE SXP includes 5 or 10 ampoules.

DEXAMETHASONE SXP is available as two strengths:

4 mg dexamethasone phosphate/ 1 mL (AUST R 387934)

8 mg dexamethasone phosphate/ 2 mL (AUST R 387937)

Who distributes DEXAMETHASONE SXP?

Southern XP Pty Ltd
Unit 5/118 Church St
Hawthorn, VIC, 3122
Australia

Sponsor:

Southern XP IP Pty Ltd
Unit 5/118 Church Street
Hawthorn, 3122, Victoria
Australia

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