

DBL™ Dexamethasone Sodium Phosphate Injection

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 treated with DBL Dexamethasone Sodium Phosphate Injection?

DBL Dexamethasone Sodium Phosphate Injection contains the active ingredient dexamethasone sodium phosphate and may be used to treat an inactive or underactive adrenal gland or to treat a number of different conditions. For more information, see Section [1. Why am I being treated with DBL Dexamethasone Sodium Phosphate Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Dexamethasone Sodium Phosphate Injection?

Do not use if you have ever had an allergic reaction to DBL Dexamethasone Sodium Phosphate Injection, sulfites 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 use DBL Dexamethasone Sodium Phosphate Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Dexamethasone Sodium Phosphate 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 is DBL Dexamethasone Sodium Phosphate Injection given?

Your doctor will decide how much DBL Dexamethasone Sodium Phosphate Injection you will receive. DBL Dexamethasone Sodium Phosphate Injection should only be given by a doctor, nurse, or other trained person. More instructions can be found in Section [4. How do I use DBL Dexamethasone Sodium Phosphate Injection?](#) in the full CMI.

5. What should I know during treatment DBL Dexamethasone Sodium Phosphate Injection?

Things you should do	• Call your doctor straight away if you become pregnant and/or get an infection. • Remind any doctor, dentist or pharmacist you visit that you are being treated with this injection.
Things you should not do	• Do not abruptly stop treatment with this injection if you have been given high doses of this medicine or repeated doses for more than three weeks. • If you have been given DBL Dexamethasone Sodium Phosphate 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 DBL Dexamethasone Sodium Phosphate Injection affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. Alcohol may make dizziness worse increase the risk of stomach-related side effects.

For more information, see Section [5. What should I know during treatment DBL Dexamethasone Sodium Phosphate Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects include: nausea, vomiting; gas, abdominal bloating; bad taste in mouth; diarrhoea, nose bleeds; burning/tingling; menstrual irregularity; increased appetite, weight gain, fluid retention; increased body hair; sweating; bruising; slow wound healing; thin, fragile skin acne painful or tender bumps under the skin; dermatitis; redness or spots under skin; altered pigmentation; fatigue, feeling unwell; hiccups; fungal infection; muscle weakness, pain, cramps, stiffness or rigidity; headache; dizziness, spinning; fainting; carbohydrate intolerance,. If you experience the following serious side effects tell your doctor immediately or go to Accident and Emergency at your nearest hospital: allergic reaction; infection; severe muscle pain/weakness, dark wee; joint, tendon or bone degeneration or fracture; severe stomach pain, blood in poo; rapid/ irregular heartbeat; changes in vision; changes in mood/thinking/behaviour/sleep patterns; seizures/convulsions; reduced growth in children; Cushing syndrome; heart rupture, heart failure; blood clot; numbness/weakness of arms or legs; release of immune cells; increased blood sugar, diabetes. 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.

DBL™ Dexamethasone Sodium Phosphate Injection

Active ingredient(s): dexamethasone sodium phosphate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Dexamethasone Sodium Phosphate 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 using DBL Dexamethasone Sodium Phosphate Injection.**

Where to find information in this leaflet:

1. [Why am I being treated with DBL Dexamethasone Sodium Phosphate Injection?](#)
2. [What should I know before treatment with DBL Dexamethasone Sodium Phosphate Injection?](#)
3. [What if I am taking other medicines?](#)
4. [How is DBL Dexamethasone Sodium Phosphate Injection given?](#)
5. [What should I know during treatment with DBL Dexamethasone Sodium Phosphate Injection?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being treated with DBL Dexamethasone Sodium Phosphate Injection?

DBL Dexamethasone Sodium Phosphate Injection contains the active ingredient dexamethasone sodium phosphate. DBL Dexamethasone Sodium Phosphate Injection is a glucocorticoid and belongs to a group of medicines called corticosteroids.

DBL Dexamethasone Sodium Phosphate Injection may be used to treat an inactive or underactive adrenal gland or to treat a number of different conditions such as certain immune disorders; skin, lung, gastrointestinal, eye and blood problems; asthma; arthritis; or certain cancers or conditions associated with cancers. It may also be used to treat a buildup of fluid and before or after surgery to assist with the treatment of shock.

Corticosteroids reduce inflammation, one of the body's reactions to injury. Except for its use in the treatment of underactive adrenal glands, dexamethasone phosphate (as sodium) does not cure the condition, it treats the symptoms.

Your doctor may have prescribed DBL Dexamethasone Sodium Phosphate Injection for another reason. Ask your doctor if you have any questions about why DBL Dexamethasone Sodium Phosphate Injection has been prescribed for you.

DBL Dexamethasone Sodium Phosphate Injection is not addictive.

2. What should I know before treatment with DBL Dexamethasone Sodium Phosphate Injection?

Warnings

You should not be given DBL Dexamethasone Sodium Phosphate Injection if:

- you are allergic to dexamethasone sodium phosphate, or any of the ingredients listed at the end of this leaflet.
You should not be given DBL Dexamethasone Sodium Phosphate Injection (8mg/2mL vial) if you have a known allergy to sulfites or 'sulfur' products. Tell your doctor or nurse if you have this type of allergy. Symptoms of an allergic reaction may include:
 - o shortness of breath, wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- you have:
 - o an internal fungal infection or an internal infection that is not being treated
 - o recently been given a live vaccine such as polio/sabin, unless you are being given the dexamethasone phosphate (as sodium) for replacement therapy
 - o a stomach ulcer
 - o weak or brittle bones
 - o myasthenia gravis, a muscle wasting disease
 - o a severe mental health illness

You should not be given DBL Dexamethasone Sodium Phosphate Injection in a local area of the body if you have:

- a bloodstream infection
- unstable joints
- infection at the injection site

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - o diabetes, a disorder of sugar metabolism or control or family history of diabetes
 - o current or recent infections
 - o heart failure or a recent heart attack
 - o kidney problems
 - o liver problems

- o adrenal gland problems
- o thyroid problems
- o herpes infection in the eye
- o inflammation of the bowel wall or other bowel problems or diarrhoea
- o stomach ulcer(s)
- o high blood pressure
- o eye diseases, including glaucoma, infections, ulcers or allergies
- o epilepsy, seizures or convulsions, migraine
- o weak or brittle bones
- o myasthenia gravis, a muscle wasting disease
- o severe mental health illness
- o blood cancers
- take any medicines for any other condition
- have been given any vaccines recently
- have allergies to:
 - o any other medicines
 - o any other substances, such as foods, latex preservatives or dyes.

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?](#)

Use in children

Long term treatment with corticosteroids can affect growth and development in children. Your doctor will monitor your child closely if your child needs long term treatment with DBL Dexamethasone Sodium Phosphate Injection.

Thickening of the heart muscle may develop if dexamethasone is given to a prematurely born baby. Your doctor will monitor your baby's heart function and structure.

Use in the elderly

Long term treatment with corticosteroids in the elderly can result in a greater chance of osteoporosis, diabetes, high blood pressure, lack of potassium in the blood, a greater chance of infection and thinning of the skin. Your doctor will monitor for these closely if you need long term treatment with DBL Dexamethasone Sodium Phosphate Injection.

Pregnancy and breastfeeding

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

DBL Dexamethasone Sodium Phosphate Injection is not generally recommended for use during pregnancy. Your doctor will discuss with you the possible benefits and risks of using DBL Dexamethasone Sodium Phosphate Injection during pregnancy.

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

DBL Dexamethasone Sodium Phosphate Injection may pass into breast milk, and there is a possibility that the breast-fed baby may be affected. Therefore, DBL Dexamethasone

Sodium Phosphate Injection is not recommended for use during breast-feeding.

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 DBL Dexamethasone Sodium Phosphate Injection and affect how it works. These include:

- barbiturates or phenytoin, medicines used to treat epilepsy
- aspirin, and other non-steroidal anti-inflammatory medicines
- insulin or other medicines for the control of sugar in the blood
- oestrogens and other oral contraceptives
- anti-thyroid medicines used to treat an overactive thyroid gland
- fluid tablets, particularly 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
- rifampicin or amphotericin, medicines used to treat infections
- digoxin, a medicine used to treat heart condition
- anticholinergics such as glycopyrrolate, used to dry up secretions or saliva.
- pancuronium bromide and vecuronium bromide used to relax muscles

These medicines may be affected by DBL Dexamethasone Sodium Phosphate Injection or may affect how well it works. You may need different amounts of your medicine, or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Dexamethasone Sodium Phosphate Injection.

4. How is DBL Dexamethasone Sodium Phosphate Injection given?

How much is given

The dose of DBL Dexamethasone Sodium Phosphate 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 it is given

DBL Dexamethasone Sodium Phosphate Injection is given as a slow injection or infusion (slow drip) into a vein. It may also be given as an injection into an muscle or injured joint.

DBL Dexamethasone Sodium Phosphate Injection should only be given by a doctor or nurse.

If you are given too much DBL Dexamethasone Sodium Phosphate Injection (Overdose)

As DBL Dexamethasone Sodium Phosphate 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, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26),
- 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.

Symptoms of a DBL Dexamethasone Sodium Phosphate Injection overdose may include the side effects listed below in 6. Are there any side effects? section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

5. What should I know during treatment with DBL Dexamethasone Sodium Phosphate Injection?

Things you should do

- Remind any doctor, surgeon, dentist or pharmacist you visit that you are being given DBL Dexamethasone Sodium Phosphate Injection. In particular if you:
 - o are about to start on any new medicine
 - o plan to have surgery that needs a general anaesthetic

Call your doctor straight away if you:

- become pregnant
- get an infection. DBL Dexamethasone Sodium Phosphate Injection may mask or hide the symptoms of an infection.

Things you should not do

- **Do not abruptly stop treatment with DBL Dexamethasone Sodium Phosphate Injection if you have been given high doses of this medicine or repeated doses for more than three weeks.** A gradual dose reduction may be required to prevent withdrawal symptoms.

- **If you have been given DBL Dexamethasone Sodium Phosphate 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 DBL Dexamethasone Sodium Phosphate Injection affects you.

DBL Dexamethasone Sodium Phosphate Injection may cause dizziness, spinning sensation, inability to sleep or convulsions (fits) in some people. Make sure you know how you react to DBL Dexamethasone Sodium Phosphate Injection before you drive a car, operate machinery, or do anything else that could be dangerous if these occur.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make dizziness worse and increase the risk of stomach-related side effects such as stomach ulcers and bleeding.

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.

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

Thickening of the heart muscle may develop if dexamethasone is given to a prematurely born baby. Your doctor will monitor your baby's heart function and structure.

If you only receive one or two doses of DBL Dexamethasone Sodium Phosphate Injection, side effects are rare. With higher doses, or longer-term therapy, side effects become more common.

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

Side effects

Side effects	What to do
Stomach-related • nausea and vomiting • 'gas' or abdominal bloating • bad taste in the mouth • weight gain • diarrhoea	Speak to your doctor or nurse if you have any of these side effects and they worry you.
Skin and hair-related • increased body hair • easy bruising • slow wound healing • thin, fragile skin • acne • redness of the skin, or reddish flat spots under the skin	

Side effects	What to do
• painful or tender bumps under the skin • dermatitis • fungal infection including candida (thrush infection in the mouth or vagina) • changes to skin pigmentation Muscle and movement-related • muscular weakness, pain or cramps • stiffness or rigidity Head and brain-related • headache • dizziness or fainting Other • nose bleeds • worsening of the problem immediately after treatment • spinning sensation • menstrual irregularity • fatigue or generally feeling unwell • hiccups • increased appetite • decreased tolerance to carbohydrates • burning or tingling feeling • increased sweating • fluid retention and swelling	

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction • 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 Signs of infection • fever or chills • unexplained fatigue or weakness • increased susceptibility to infections and recurrence of tuberculosis if you have had it previously Muscle and bone-related • severe muscle pain or weakness often along with passing of dark red or brown urine (wee), or only passing small amounts of wee • joint pain, ruptured tendons, collapsed vertebrae,	Call your doctor or nurse straight away. If you are not already in hospital, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention. Serious side effects are rare.

Serious side effects	What to do
degeneration of the jaw bone or broken bones Stomach-related • severe stomach pain • blood in the faeces (poo) Heart-related • rapid and/or irregular heartbeat Eye-related • changes in vision Head and brain-related • changes in mood, thinking or behaviour, for example: - o irritability, over-excitement, depression, suicidal thoughts, mania, delusions, hallucinations, anxiety, confusion, memory loss, and aggravation of schizophrenia • changes in sleep patterns • seizures or convulsions; aggravation of epilepsy Other • reduced growth in children • Cushing syndrome (weight gain, rounded (moon-shaped) face and high blood pressure) • heart rupture (trouble breathing, chest pain, cold extremities, confusion or change in thinking) • congestive heart failure (shortness of breath, swelling of the feet or legs due to fluid build-up) • blood clot (sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling in the arms and legs) • numbness or weakness of the arms or legs • release of immune cells (fever, fatigue, pain, difficulty breathing, night sweats, weight loss and rash) • high blood sugar; development of diabetes; increase in need of medicine to control diabetes	

A 'withdrawal syndrome' may also occur including fever, aching, sore muscles; swollen, painful joints; runny or

blocked nose; itchy runny eyes; painful itchy skin nodules; and loss of weight. Too fast a reduction in treatment after prolonged treatment may result in adrenal insufficiency, low blood pressure and death.

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/safety/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 DBL Dexamethasone Sodium Phosphate Injection contains

Active ingredient (main ingredient)	dexamethasone sodium phosphate
Other ingredients (inactive ingredients)	sodium citrate dihydrate disodium edetate hydrochloric acid sodium hydroxide sodium sulfite water for injections

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

DBL Dexamethasone Sodium Phosphate Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Dexamethasone Sodium Phosphate Injection looks like

DBL Dexamethasone Sodium Phosphate Injection is a clear, colourless solution in a vial, available in the strength 8 mg/2 mL (AUST R 178774).

How is DBL Dexamethasone Sodium Phosphate stored

DBL Dexamethasone Sodium Phosphate Injection will be stored correctly in the pharmacy or on the ward.

Who distributes DBL Dexamethasone Sodium Phosphate Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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