

DBL™ Dexamethasone Sodium Phosphate Injection

Dexamethasone Phosphate (as sodium) (dex-a-METH-a-sona so-dee-um FOS-fate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Dexamethasone Sodium Phosphate Injection.

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 being given DBL™ Dexamethasone Sodium Phosphate Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

You may need to read it again.

What DBL™ Dexamethasone Sodium Phosphate Injection is used for

Dexamethasone phosphate (as sodium) is a glucocorticoid and belongs to a group of medicines called corticosteroids. It may be used to treat an inactive or underactive adrenal gland or to treat a number of different diseases such as certain immune disorders and 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 phosphate (as sodium) does not cure disease; 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.

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

Before you are given DBL™ Dexamethasone Sodium Phosphate Injection

When you must not be given it

You should not be given DBL™ Dexamethasone Sodium Phosphate Injection if you have an allergy to dexamethasone phosphate (as sodium) or any of the ingredients listed at the end of this leaflet.

The 8 mg/2mL vial formulation is contraindicated in patients with a known hypersensitivity to sulfites.

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.

You should not be given DBL™ Dexamethasone Sodium Phosphate Injection if you have an internal fungal infection.

You should not be given DBL™

Dexamethasone Sodium Phosphate Injection if you have recently been given a live vaccine such as smallpox or polio/sabin, unless you are being given the dexamethasone phosphate (as sodium) for replacement therapy.

If you are not sure whether you should be given DBL™ Dexamethasone Sodium Phosphate Injection, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

Like most corticosteroid medicines, dexamethasone phosphate (as sodium) 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.

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

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.

Tell your doctor or pharmacist if you have been given any vaccines recently.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- diabetes, a disorder of sugar metabolism or control
- current of recent infections
- heart failure or 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 infections, ulcers or allergies
- epilepsy, seizures or convulsions
- a stomach ulcer
- intestinal disease
- weak or brittle bones
- myasthenia gravis, a muscle wasting disease.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL™ Dexamethasone Sodium Phosphate Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and DBL™ Dexamethasone Sodium Phosphate Injection may interfere with each other. These include:

- barbiturates 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
- oestrogens and other oral contraceptives
- anti-thyroid medicines used to treat an over active 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
- cyclosporin, a medicine used to prevent transplant rejection
- rifampicin or amphotericin, medicines used to treat infections
- digoxin, a medicine used to treat heart conditions
- aminoglutethimide, a hormone used treat breast cancer.

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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given DBL™ Dexamethasone Sodium Phosphate Injection.

How DBL™ Dexamethasone Sodium Phosphate Injection is 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 (intravenous drip) into the veins. It may also be given as an injection into an injured muscle or joint.

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

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, go to the Accident & Emergency Department at your nearest hospital or immediately contact the Poisons Information Centre for advice on overdose (In Australia, call 13 11 26. In New Zealand, call 0800 764 766).

Symptoms of a DBL™ Dexamethasone Sodium Phosphate Injection overdose may include the side effects listed below in the 'Side effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL™ Dexamethasone Sodium Phosphate Injection

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DBL™ Dexamethasone Sodium Phosphate Injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL™ Dexamethasone Sodium Phosphate Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given DBL™ Dexamethasone Sodium Phosphate Injection.

If you become pregnant while you are being treated with DBL™ Dexamethasone Sodium Phosphate Injection, tell your doctor immediately.

If you get an infection while you are being given DBL™ Dexamethasone Sodium Phosphate Injection, you must tell your doctor immediately.

Like most corticosteroid medicines, dexamethasone phosphate (as sodium) may mask or hide the symptoms of an infection.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Dexamethasone Sodium Phosphate Injection affects you.

As with other corticosteroid medicines, DBL™ Dexamethasone Sodium Phosphate Injection may cause dizziness 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 you are dizzy.

If this occurs do not drive. If you drink alcohol, dizziness may be worse.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with DBL™ Dexamethasone Sodium Phosphate Injection.

Dexamethasone phosphate (as sodium) helps most people with immune disorders or inflammation, 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 treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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.

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

- nausea and vomiting
- 'gas' or abdominal bloating
- bad taste in the mouth
- menstrual irregularity
- weight gain
- fluid retention
- increased body hair
- easy bruising
- slow wound healing
- muscular weakness
- headache
- dizziness
- thin, fragile skin
- acne
- reduced growth in children.

Tell your doctor or nurse immediately if you notice any of the following:

- 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
- severe stomach pain
- blood in the faeces
- irregular heartbeat
- changes in vision
- changes in mood
- joint pain or broken bones
- seizures or convulsions.

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

Other side effects not listed above may occur in some patients.

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

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

You may not experience any of them.

After using DBL™ Dexamethasone Sodium Phosphate Injection

Storage

DBL™ Dexamethasone Sodium Phosphate Injection will usually be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product description

What it looks like

DBL™ Dexamethasone Sodium Phosphate Injection is a clear, colourless solution. It is available in an ampoule or in a vial.

Ingredients

Active ingredient:

- dexamethasone phosphate (as sodium)

Other ingredients (ampoule):

- sodium citrate
- creatinine
- water for injections

Other ingredients (vial):

- sodium citrate
- disodium edetate
- sodium sulfite, anhydrous
- water for injections

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

DBL™ Dexamethasone Sodium Phosphate Injection is available in the following strengths and packs:

- 4 mg/mL, 5 x 1 mL ampoules
AUST R 16374
- 8 mg/2 mL, 5 x 2 mL vials and 50 x 2 mL vials
AUST R 17774

Supplier

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street
Te Aro
Wellington
New Zealand

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