

DEXAMETHASONE MYLAN

Injection

dexamethasone sodium phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine.

It does not contain all the available information and does not take the place of talking with your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has more information about this medicine than is contained in this leaflet. Also, your doctor has had the benefit of taking a full and detailed history from you and is in the best position to make an expert judgement to meet your individual needs.

If you have any concerns about being given this medicine, talk to your doctor or health care professional.

Keep this leaflet with this medicine.

You may need to read it again.

What DEXAMETHASONE MYLAN 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 MYLAN injection does not cure disease; it treats the symptoms.

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

Your doctor may have prescribed it for another reason.

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

DEXAMETHASONE MYLAN injection is not addictive.

Before you are given it

Tell your doctor or health care professional if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not take it

You should not be given DEXAMETHASONE MYLAN injection if you have an allergy to dexamethasone or any of the ingredients listed at the end of this leaflet.

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 DEXAMETHASONE MYLAN injection if you have an internal fungal infection.

You should not be given this medicine if you have recently been given a live vaccine such as smallpox or polio/sabin, unless you are being given it for replacement therapy.

You must not be given DEXAMETHASONE MYLAN injection if the packaging is torn or shows signs of tampering.

You must not be given DEXAMETHASONE MYLAN injection after the expiry date printed on the pack.

Talk to your doctor or health care professional if you are not sure whether you should be given DEXAMETHASONE MYLAN injection.

Before you start to take it

Tell your doctor 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 plan to become pregnant.

Like most corticosteroid medicines, dexamethasone is not generally recommended for use during pregnancy. Your doctor will discuss with you the possible benefits and

risks of using dexamethasone during pregnancy.

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

Dexamethasone may pass into breast milk and there is a possibility that the breast-fed baby may be affected. Therefore, this medicine 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
- any 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 about any of the above, tell them before you are given this medicine.

Use in children

Your child's doctor will discuss the risks and benefits of your child using this medicine.

Taking other medicines

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

Some medicines may be affected by DEXAMETHASONE MYLAN injection or may affect how it works. 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 immunizations
- cyclosporin, a medicine used to prevent transplant rejection
- rifampicin or amphotericin, medicines used to treat infections
- digoxin, a medicine used to treat heart conditions
- amino glutethimide, a hormone used treat breast cancer.

These medicines may be affected by dexamethasone 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 DEXAMETHASONE MYLAN injection.

How it is given

DEXMETHSONE injection must only be given by a doctor or nurse.

How much is given

The dose 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 you 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

DEXAMETHASONE MYLAN 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.

Overdose

As DEXAMETHASONE MYLAN 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, or if you are not already in hospital, go to the Accident & Emergency Department at your nearest hospital.

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

While you are receiving it

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you 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 MYLAN injection.

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

Tell your doctor immediately if you become pregnant while you are being treated with DEXAMETHASONE MYLAN injection.

Tell your doctor immediately if you get an infection while you are being given this medicine.

Like most corticosteroid medicines, dexamethasone may mask or hide the symptoms of an infection.

Things to be careful of

Be careful driving or operating machinery until you know how DEXAMETHASONE MYLAN injection affects you.

As with other corticosteroid medicines, dexamethasone may cause dizziness in some people.

Make sure you know how you react to it 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 DEXAMETHASONE MYLAN 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 this medicine.

Dexamethasone 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 dexamethasone, 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.

Do not be alarmed by the above list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Product description

What it looks like

DEXAMETHASONE MYLAN injection is a clear, colourless solution in a vial. It is available in two vial sizes in packs of 5.

Storage

This medicine 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.

Ingredients

Active ingredient:

Each vial contains either 4 mg or 8 mg of dexamethasone phosphate (as sodium).

Other ingredients:

- creatinine
- sodium citrate anhydrous
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Australian Registration Numbers:

4 mg/1 mL: AUST R 163200

8 mg/2 mL: AUST R 163199

This leaflet was prepared in March
2015.

Dexamethasone

Mylan_cmi\0315/00