

DEXAMETHASONE MYLAN

dexamethasone sodium phosphate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEXAMETHASONE MYLAN. 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 DEXAMETHASONE MYLAN 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 DEXAMETHASONE MYLAN is used for

DEXAMETHASONE MYLAN 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, skin problems, asthma or arthritis.

Corticosteroids reduce inflammation, one of the body's reactions to injury. Except for its use in the treatment of an underactive adrenal gland, DEXAMETHASONE MYLAN does

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

Before you are given DEXAMETHASONE MYLAN

When you must not be given it

You should not be given DEXAMETHASONE MYLAN if you have an allergy to:

- any medicine containing dexamethasone sodium phosphate
- any of the ingredients listed at the end of this leaflet

Some of the 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 if you have an internal fungal infection or any other infection.

You should not be given DEXAMETHASONE MYLAN if you have recently been given a live vaccine unless you are being given this medicine for replacement therapy.

You should not be given this medicine if you have:

- myasthenia gravis, a muscle wasting disease
- a stomach (peptic) ulcer
- osteoporosis (weak or brittle bones)
- have a severe mental health condition

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes, a condition in which the level of sugar in the blood is too high
- 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
- muscle disease or injury
- mental illness
- epilepsy, seizures or convulsions
- Cushing's disease, a condition where there is too much cortisol

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

Like most corticosteroid medicines, dexamethasone is not generally recommended for use during pregnancy.

The active ingredient in DEXAMETHASONE MYLAN may pass into breast milk and there is a possibility that your baby may be affected. Therefore, this medicine is not recommended for use when breast feeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor or pharmacist if you have received any vaccinations recently.

If you have not told your doctor about any of the above, tell them before you are given DEXAMETHASONE MYLAN.

Taking other medicines

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

Some medicines and DEXAMETHASONE MYLAN 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 blood sugar
- estrogens and other oral contraceptives
- anti-thyroid medicines used to treat an over active thyroid gland
- fluid tablets (known as diuretics), 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, 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 to treat breast cancer
- salbutamol, salmeterol, medicines used to treat asthma
- some medicines used in the treatment of heartburn and indigestion

These medicines may be affected by DEXAMETHASONE MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and nurse have more information on medicines to be careful with or avoid while taking this medicine.

How DEXAMETHASONE MYLAN is given

DEXAMETHASONE MYLAN is an injection which is given to you by a doctor or nurse.

How much is given

The dose of DEXAMETHASONE MYLAN is variable, depending on the condition being treated. It may be given as a course of injections or as a single dose.

Your doctor will determine the dose you will receive.

The dose 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 your symptoms.

How it is given

DEXAMETHASONE MYLAN 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.

When it is given

As your doctor will give you the injection they will determine when it is given to you.

How long to take it

Your doctor will determine how long you will take this medicine for.

If you are given too much (overdose)

As DEXAMETHASONE MYLAN will most likely 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 Accident and Emergency at the nearest hospital.

Symptoms of an overdose may include some of the side effects listed below including swelling of the limbs, sore stomach or altered mental state.

You may need urgent medical attention.

While you are receiving DEXAMETHASONE MYLAN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given DEXAMETHASONE MYLAN.

Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while you are being given this medicine, tell your doctor immediately.

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

Like most corticosteroid medicine, dexamethasone may hide the symptoms of an infection.

Things to be careful of

Be careful driving or operating machinery until you know how DEXAMETHASONE MYLAN has affected you.

As with other corticosteroid medicines, dexamethasone 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.

If you drink alcohol, dizziness may be worse.

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

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given DEXAMETHASONE MYLAN.

This medicine 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 attention 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.

If you only receive one or two doses of this medicine, side effects are rarer.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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
- bruising easily
- wounds that take a long time to heal
- 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 a 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
- changes in vision
- changes in mood
- joint pain or broken
- seizures or convulsions
- signs of infection

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

Other side effects not listed above may also occur in some people.

Product description

What it looks like

DEXAMETHASONE MYLAN is a clear, colourless solution in a vial.

This medicine is available in packs of 5 vials.

Storage

This medicine will usually be stored in the hospital pharmacy or on the ward.

The medicine should be kept in a cool, dry place protected from light where the temperature stays below 25°C.

Ingredients

DEXAMETHASONE MYLAN vials contain either 4 mg or 8 mg of dexamethasone phosphate (as sodium) as the active ingredient.

The vials also contain the following inactive ingredients:

- sodium citrate
- creatine
- water for injections

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

Supplier

Alphapharm Pty Limited

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

This leaflet was prepared in April 2019.

AUST R 163200 - 4 mg/1 mL

AUST R 163199 - 8 mg/2 mL

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