

# DEXAMETHASONE VIATRIS

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## 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.

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### 1. Why am I being given DEXAMETHASONE VIATRIS?

DEXAMETHASONE VIATRIS contains the active ingredient dexamethasone phosphate (as sodium). 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.

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

### 2. What should I know before I am given DEXAMETHASONE VIATRIS?

Do not use if you have ever had an allergic reaction to DEXAMETHASONE VIATRIS 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, are pregnant or breastfeeding or plan to become pregnant or breastfeed.**

For more information, see Section [2. What should I know before I am given DEXAMETHASONE VIATRIS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with DEXAMETHASONE VIATRIS 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 VIATRIS?**

DEXAMETHASONE VIATRIS 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 VIATRIS 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 VIATRIS?](#) in the full CMI.

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

<b>Things you must do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or pharmacist you visit that you have been given DEXAMETHASONE VIATRIS.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery while being treated with DEXAMETHASONE VIATRIS, as it may cause dizziness and blurred vision in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• If you drink alcohol while being treated with DEXAMETHASONE VIATRIS, you may experience dizziness</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• DEXAMETHASONE VIATRIS will usually be stored in the pharmacy or on the ward, in a cool dry place, protected from light, where the</li></ul>

temperature stays below 25°C.

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

## 6. Are there any side effects?

Dexamethasone phosphate (as sodium) may cause 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. If you only receive one or two doses of DEXAMETHASONE VIATRIS, side effects are rare. With higher doses, or longer-term therapy, side effects become more common. 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 VIATRIS

**Active ingredient(s):** *Dexamethasone Phosphate (as sodium)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about given DEXAMETHASONE VIATRIS injection. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given DEXAMETHASONE VIATRIS.**

### Where to find information in this leaflet:

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

## **1. Why am I being given DEXAMETHASONE VIATRIS?**

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

**DEXAMETHASONE VIATRIS 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 an underactive adrenal gland, DEXAMETHASONE VIATRIS does not cure disease; it treats the symptoms.

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.

## 2. What should I know before I am given DEXAMETHASONE VIATRIS?

### Warnings

#### Do not use DEXAMETHASONE VIATRIS if:

- you are allergic to dexamethasone sodium phosphate, or 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.

Always check the ingredients to make sure you can use DEXAMETHASONE VIATRIS.

- you have an internal fungal infection or infection at the injection site
- you have recently been given a live vaccine unless you are being given DEXAMETHASONE VIATRIS for replacement therapy
- you have myasthenia gravis, a muscle wasting disease
- you have a stomach (peptic) ulcer
- you have osteoporosis (weak or brittle bones)
- you have a severe mental health condition.

## **Do not use DEXAMETHASONE VIATRIS injection in a local area of the body if:**

- **you have a bloodstream infection**
- **you have unstable joints.**

## **Check with your doctor if you:**

- have allergies to any other medicines, foods, dyes or preservatives
- take any medicines for any other condition
- 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 current or recent infections
  - heart failure or a recent heart attack
  - kidney disease
  - liver disease
  - adrenal gland 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
  - epilepsy, seizures or convulsions, migraine
  - Cushing's disease, a condition where there is too much cortisol

- a stomach ulcer
- intestinal disease
- osteoporosis (weak or brittle bones)
- 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
- chickenpox 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
- suffered a head injury or stroke
- pre-eclampsia or fluid retention
- myasthenia gravis, a muscle wasting disease
- severe mental illness.

If you have not told your doctor about any of the above, tell them before you start taking DEXAMETHASONE VIATRIS.

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**

**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 the risks and benefits of taking DEXAMETHASONE VIATRIS during pregnancy.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

The active ingredient in DEXAMETHASONE VIATRIS may pass into breast milk and there is a possibility that your baby may be affected. Therefore, DEXAMETHASONE VIATRIS is not recommended for use during breastfeeding.

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

### **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 DEXAMETHASONE VIATRIS and affect how it works. 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 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, amphotericin B 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 to 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
- 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 DEXAMETHASONE VIATRIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**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 VIATRIS.**

## **4. How am I given DEXAMETHASONE VIATRIS?**

### **How much DEXAMETHASONE VIATRIS is given**

The dose of DEXAMETHASONE VIATRIS 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.

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

Your doctor will determine how long you will take DEXAMETHASONE VIATRIS for.

## **How is DEXAMETHASONE VIATRIS given**

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

## **If you are given too much DEXAMETHASONE VIATRIS**

As DEXAMETHASONE VIATRIS 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 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 some of the side effects listed below [6. Are there any side effects](#) including swelling of the limbs, sore stomach or altered mental state.

You may need urgent medical attention.

## **5. What should I know while being given DEXAMETHASONE VIATRIS?**

### **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 VIATRIS.
- **Tell any other doctors, dentists and pharmacists who treat you that you are being given DEXAMETHASONE VIATRIS.**
- If you are going to have surgery, tell the surgeon or anaesthetist that you are being given DEXAMETHASONE VIATRIS. It may affect other medicines used during surgery.
- If you become pregnant while you are being given DEXAMETHASONE VIATRIS, tell your doctor immediately.
- Tell your doctor immediately if you get an infection whilst you are being given DEXAMETHASONE VIATRIS.

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

## **Things you should not do**

Do not abruptly stop treatment with DEXAMETHASONE VIATRIS 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. These withdrawal symptoms may include fever, aches and pains, itchy skin, weight loss, conjunctivitis or blocked sinuses.

## **Things to be careful of**

If you have been given DEXAMETHASONE VIATRIS for a painful or inflamed joint, you should be careful not to overuse the joint if 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 VIATRIS affects you.**

As with other corticosteroid medicines, DEXAMETHASONE VIATRIS may cause dizziness in some people. Make sure you know how you react to DEXAMETHASONE VIATRIS before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

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

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

If you drink alcohol, dizziness may be worse.

## **Looking after your medicine**

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

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

**DEXAMETHASONE VIATRIS** will be opened for use on you. It will be used only once and then it will be discarded. It will never be stored after it is opened nor used for more than one person.

## **Getting rid of any unwanted medicine**

Any unwanted medicine will be disposed of in safe manner by our doctor, nurse or pharmacist.

## **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.

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

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

Thickening of the heart muscle (hypertrophic cardiomyopathy) 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 DEXAMETHASONE VIATRIS, side effects are rarer. With higher doses, or longer-term therapy, side effects become more common.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• nausea and vomiting</li><li>• 'gas' or abdominal bloating</li><li>• bad taste in the mouth</li><li>• menstrual irregularity</li><li>• weight gain</li><li>• fluid retention and swelling</li><li>• increased body hair</li><li>• easy bruising</li><li>• wounds that take a long time to heal</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Muscle pain or cramps</li> <li>• stiffness or rigidity</li> <li>• headache</li> <li>• dizziness or fainting</li> <li>• thin, fragile skin</li> <li>• acne</li> <li>• painful or tender bumps under the skin</li> <li>• sleep disturbances</li> <li>• reduced growth in children</li> <li>• blurred vision</li> <li>• fungal infection and being susceptible to other kinds of infections.</li> </ul>	

## Serious side effects

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• 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</li> </ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● severe stomach pain</li> <li>● severe muscle pain or weakness often along with passing of dark red or brown urine (wee), or only passing small amounts of wee</li> <li>● signs of infection</li> <li>● severe stomach pain</li> <li>● blood in the faeces (poo)</li> <li>● irregular heartbeat</li> <li>● changes in vision</li> <li>● changes in mood or other mental disorders e.g. irritability, over excitement, depression, suicidal thoughts, hallucinations, anxiety, confusion, memory loss, insomnia</li> <li>● changes in sleep patterns</li> <li>● joint pain or broken bones</li> <li>● breakdown of weight-bearing joints (Charcot-like arthropathy)</li> <li>● tendon rupture</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
• seizures or convulsions	

**Tell your doctor or nurse if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

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

## **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](http://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.**

## **7. Product details**

DEXAMETHASONE VIATRIS is only available with a doctor's prescription.

## What DEXAMETHASONE VIATRIS contains

<b>Active ingredient (main ingredient)</b>	Dexamethasone phosphate (as sodium)
<b>Other ingredients (inactive ingredients)</b>	sodium citrate creatinine sodium hydroxide hydrochloric acid water for injections

**Do not take DEXAMETHASONE VIATRIS if you are allergic to any of these ingredients.**

## What DEXAMETHASONE VIATRIS looks like

DEXAMETHASONE VIATRIS is a clear, colourless solution, free from visible particulate matter and packaged in a 2 mL amber vial with rubber stopper and aluminium seal.

This medicine is available in packs of 10 vials.

Some pack sizes may not be marketed.

DEXAMETHASONE VIATRIS 4 mg/1 mL ampoule -  
AUST R 163200

DEXAMETHASONE VIATRIS 8 mg/2 mL ampoule -  
AUST R 163199

## **Who distributes DEXAMETHASONE VIATRIS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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