DEXAMETHASONE JUNO

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 using Dexamethasone Juno?

DEXAMETHASONE JUNO contains the active ingredient dexamethasone phosphate (as sodium). 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. For more information, see Section 1. Why am I using Dexamethasone Juno? in the full CMI.

2. What should I know before I use Dexamethasone Juno?

Do not use if you have ever had an allergic reaction to dexamethasone sodium phosphate 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 Dexamethasone Juno? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with dexamethasone phosphate (as sodium) 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 do I use Dexamethasone Juno?

- Your doctor will decide the appropriate dose for you
- A doctor or nurse will usually prepare and administer the injection, 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.
- Follow all instructions given to you by your doctor or pharmacist.

More instructions can be found in Section 4. How do I use Dexamethasone Juno? in the full CMI.

5. What should I know while using Dexamethasone Juno?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using Dexamethasone Juno
Things you should not do	Do not abruptly stop treatment if you have been given higher or repeated doses for more than three weeks.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how this medicine affects you. This medicine may cause dizziness in some people.
Drinking alcohol	If you drink alcohol, dizziness may be worse.
Looking after your medicine	This medicine will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Dexamethasone Juno? 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 Juno, 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 <u>6. Are there any side effects?</u> in the full CMI.

DEXAMETHASONE JUNO

Active ingredient(s): Dexamethasone (DEX-ah-METH-ah-sone) phosphate (as sodium)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dexamethasone Juno. 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 Dexamethasone Juno.

Where to find information in this leaflet:

- 1. Why am I using Dexamethasone Juno?
- 2. What should I know before I use Dexamethasone Juno?
- 3. What if I am taking other medicines?
- 4. How do I use Dexamethasone Juno?
- 5. What should I know while using Dexamethasone Juno?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Dexamethasone Juno?

Dexamethasone Juno 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 Juno 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.

2. What should I know before I use Dexamethasone Juno?

Warnings

Do not use DEXAMETHASONE JUNO if:

- you are allergic to dexamethasone phosphate (as sodium) or any of the ingredients listed at the end of this leaflet
 - Always check the ingredients to make sure you can use this medicine
- you have an internal fungal infection
- 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
- a stomach ulcer
- weak or brittle bones or osteoporosis

- myasthenia gravis, a muscle wasting disease
- severe mental health illness
- presence of bacteria in the bloodstream
- unstable joints
- infection at the injection site

You should not be given Dexamethasone Juno if the solution is discoloured, cloudy, turbid, or particles or a precipitate is present.

The solution is normally a clear, colourless to light yellow solution.

You should 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 this medicine is used after the expiry date it may not work as well.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes
- have been given any vaccines recently
- have or have had any of the following medical conditions:
 - diabetes, a disorder of sugar metabolism or control
 - · current or recent infections
 - heart failure or a recent heart attack
 - kidney disease
 - liver disease
 - thyroid disease
 - Cushing's disease (where your body produces too much cortisol, which is a hormone)
 - inflammation of the bowel wall or other bowel problems
 - · high blood pressure
 - eye diseases, including glaucoma or a family history of glaucoma, infections, ulcers or allergies
 - epilepsy, seizures or convulsions, migraines
 - a stomach ulcer
 - have suffered from gastro or diarrhea after travelling in a developing country
 - · intestinal disease
 - weak or brittle bones
 - myasthenia gravis, a muscle wasting disease
 - severe mental health illness
 - presence of bacteria in the bloodstream
 - unstable joints
 - infection at the injection site.
 - blood cancer such as leukemia, lymphoma or myeloma
 - a history of allergy or allergic reactions to certain medications
 - latent tuberculosis, where you have tuberculosis bacteria in your body but do not feel sick

- chicken pox 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
- you have suffered a head injury or stroke
- pre-eclampsia or fluid retention.

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with 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 Dexamethasone Juno during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Dexamethasone Juno may pass into breast milk, and there is a possibility that the breast-fed baby may be affected. Therefore, Dexamethasone Juno 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 Dexamethasone Juno and 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
- certain medications used in HIV/AIDs such as ritonavir
- anti-fungal medications such as ketoconazole or itraconazole
- certain antibiotics such as clarithromycin and erythromycin
- 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 or vancomycin, medicines used to treat infections or tuberculosis
- digoxin, a medicine used to treat heart conditions
- diltiazem, used to treat high blood pressure or certain heart conditions
- aminoglutethimide, a hormone used treat breast cancer
- daunorubicin or doxorubicin, a medicine used to treat cancer
- doxapram, a medicine used to treat chronic obstructive pulmonary disease
- glycopyrrolate, a medicine used to dry up secretions or saliva.

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 Juno.

4. How do I use Dexamethasone Juno?

How much to use

• your doctor will decide the appropriate dose for you.

When to use DEXAMETHASONE JUNO

 you will be given Dexamethasone Juno as directed by your doctor.

How to use Dexamethasone Juno

- this medicine must only be given by a doctor or nurse
- it 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.

If you use too much DEXAMETHASONE JUNO

Dexamethasone Juno must only be given by a doctor or nurse so an overdose is not likely to occur.

Overdose may include the side effects listed below in '6. Are there any side effects?' section but are usually of a more severe nature.

5. What should I know while using Dexamethasone Juno?

Things you should do

If you are about to be started on any new medicines, remind your doctor or pharmacist that you have recently been given Dexamethasone Juno.

Tell any other doctors or dentists, and pharmacists who treat you that you have been given this medicine.

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

If you plan to become pregnant, tell your doctor that you have been given this medicine. Your doctor can discuss with you the risks and benefits involved.

If you get an infection while you are being given Dexamethasone Juno, 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 /you should not do

If you have been given Dexamethasone Juno for a painful or inflamed joint, you should be careful not to overuse the joint as long as the inflammation is still present.

Do not abruptly stop treatment with Dexamethasone Juno 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how dexamethasone sodium phosphate affects you.

As with other corticosteroid medicines, Dexamethasone Juno may cause dizziness in some people. Make sure you know how you react to Dexamethasone Juno 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness may be worse.

Looking after your medicine

Dexamethasone Juno will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C. Store in the original packaging.

When to discard your medicine

Dexamethasone Juno 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 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.

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

Less serious side effects

Less serious side effects	What to do
 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 sleep disturbances reduced growth in infants, children and adolescents blurred vision fungal infections and being susceptible to other kinds of infections . 	Speak to your doctor if you start to have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 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 or feeling depressed, including thinking about suicide, or changes in sleep patterns joint pain or broken bones breakdown of weight-bearing joints (Charcot-like arthropathy) tendon rupture seizures or convulsions. 	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.

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/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 Dexamethasone Juno contains

Active ingredient (main ingredient)	Dexamethasone phosphate (as sodium)	
Other ingredients (inactive ingredients)	 Sodium citrate Disodium edetate Creatinine Sodium hydroxide Water for injections 	

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

What DEXAMETHASONE JUNO looks like

A clear, colourless to light yellow solution in amber glass ampoule.

Australian registration numbers:

Dexamethasone Juno 4 mg/1 mL ampoule - AUST R379531 Dexamethasone Juno 8 mg/2 mL ampoule - AUST R379530

Who distributes DEXAMETHASONE JUNO

Juno Pharmaceuticals Pty Ltd 42 Kelso Street, Cremorne, VIC. 3121 Australia.

www.junopharm.com.au

This leaflet was prepared in May 2023