HYDROCORTISONE 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 HYDROCORTISONE JUNO?

HYDROCORTISONE JUNO contains the active ingredient hydrocortisone sodium succinate. e. It belongs to a group of medicines called Corticosteroids. HYDROCORTISONE JUNO is used to reduce inflammation (pain, swelling, redness and heat) in certain glandular disorders, rheumatic disorders, skin diseases, allergic conditions, inflammation of the eyes, stomach or gut disorders, respiratory diseases and blood disorders.

For more information, see Section 1. Why am I using HYDROCORTISONE JUNO? in the full CMI.

2. What should I know before I use HYDROCORTISONE JUNO?

Do not use if you have ever had an allergic reaction to hydrocortisone 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 HYDROCORTISONE JUNO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYDROCORTISONE JUNO 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 HYDROCORTISONE JUNO?

- HYDROCORTISONE JUNO is given as an injection into a muscle, or slowly into a vein by a doctor or nurse
- A doctor or nurse will prepare and administer the injection.

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

5. What should I know while using HYDROCORTISONE JUNO?

Things you should do	 If you get an infection or suspect an infection during a course of treatment, tell your doctor as soon as possible. Tell your doctor if you plan to have surgery; you are about to be given a vaccine or start on any new medicine; you become pregnant during treatment, you are diabetic; or you have liver disease. 	
Things you should not do	 Do not stop using this medicine suddenly unless your doctor tells you. Avoid drinking grapefruit juice while you are being treated with HYDROCORTISONE JUNO. Do not use diluents containing benzyl alcohol with HYDROCORTISONE JUNO to treat children. 	
Driving or using machines	Be careful when driving or operating machinery until you know how HYDROCORTISONE JUNO affects you.	
Drinking alcohol	Be careful drinking alcohol, HYDROCORTISONE JUNO may cause dizziness, light headedness, visual disturbances and fatigue.	
Looking after your medicine	HYDROCORTISONE JUNO should be stored below 25°C. Keep it where young children cannot reach it.	

For more information, see Section 5. What should I know while using HYDROCOSTISONE JUNO? in the full CMI.

6. Are there any side effects?

Side effects include nausea and vomiting, changes in appetite, weight gain caused by fluid retention, muscle weakness or tenderness, increased sweating, excessive thirst, changes in mood, changes in skin, excessive hairiness, tiredness or drowsiness. Serious side effects are rare and may include sudden signs of allergy, severe stomach pain, vomiting blood, or blood in the stools, convulsions or fits, changes in vision, eye infections, pain and tenderness of the lower leg, ankle and foot, chest pain and breathlessness. Long term treatment with corticosteroids can affect growth and development in children.

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.

HYDROCORTISONE JUNO

Active ingredient(s): [hydrocortisone sodium succinate]

Consumer Medicine Information (CMI)

This leaflet provides important information about using HYDROCORTISONE 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 HYDROCORTISONE JUNO.

Where to find information in this leaflet:

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

1. Why am I using HYDROCORTISONE JUNO?

HYDROCORTISONE JUNO contains the active ingredient hydrocortisone sodium succinate. HYDROCORTISONE
JUNO is a corticosteroid and is used to reduce
inflammation (pain, swelling, redness and heat).

HYDROCORTISONE JUNO is used to treat the following

- · certain glandular disorders
- · rheumatic disorders
- skin diseases
- allergic conditions
- inflammation of the eyes
- stomach or gut disorders
- respiratory diseases
- blood disorders.

2. What should I know before I use HYDROCORTISONE JUNO?

Warnings

Do not use HYDROCORTISONE JUNO if:

- you are allergic to hydrocortisone sodium succinate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Have a severe fungal infection.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions such as
 - stomach or gut disorders e.g. stomach ulcers
 - high blood pressure or congestive heart failure
 - blood clots
 - tuberculosis (TB)
 - herpes simplex of the eye
 - chicken pox or measles
 - mental or mood disorders
 - thin or weak bones that tend to break easily
 - ongoing chronic fatigue and muscle weakness
 - underactive thyroid gland
 - condition or tumour of the adrenal and/or pituitary glands
 - kidney or liver disease
 - recent head injuries
 - fits or convulsions
 - disease of the bowel
 - diabetes or increased sugar in your blood
- take any medicines for any other condition

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?

Before you are treated with HYDROCORTISONE JUNO

Tell your doctor if you plan to have surgery. The use of HYDROCORTISONE JUNO may disguise the signs of infections due to a decrease in the body's response to the infection. Talk to your doctor if you have any concerns.

Children

Long term treatment with corticosteroids can affect growth and development in children. Other side effects may occur when HYDROCORTISONE JUNO is given to children. Talk to your doctor if you have any concerns about HYDROCORTISONE JUNO being given to your child.

Growth in children may be affected by treatment with HYDROCORTISONE JUNO so your doctor may also monitor your child's height.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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 HYDROCORTISONE JUNO and affect how it works.

- non-steroidal anti-inflammatory medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis e.g. aspirin or salicylates
- some antibiotics, e.g. erythromycin, clarithromycin, rifampicin
- medicines used to treat tuberculosis, e.g. isoniazid
- antifungal agents, e.g. ketoconazole, itraconazole
- medicines to treat HIV, e.g. indinavir, ritonavir
- medicines used to treat blood pressure and stroke, e.g. digoxin and diltiazem
- some diuretics s (a medicine to help kidneys get rid of salt and water by increasing the amount of urine produced)
- nausea medication e.g. aprepitant, fosaprepitant
- oral contraceptives
- medicines used for myasthenia gravis, glaucoma
- medicines for psychiatric disorders
- bronchodilators (a type of medicine that opens up the airways in the lungs) used to treat asthma, bronchitis, emphysema and other lung diseases e.g. salbutamol
- anticonvulsants, e.g. carbamazepine, phenytoin, phenobarbital (phenobarbitone)
- oral medicines to reduce blood clotting, e.g. warfarin
- antidiabetic medicines e.g., insulin, glibenclamide and metformin
- immunosuppressants, e.g. methotrexate or ciclosporine (a medicine used in kidney transplant patients)
- some immunisation, inoculation or vaccinations
- medicine used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease (anticholinergics)
- medicines used to treat breast cancer or hormone disorder

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HYDROCORTISONE JUNO.

4. How do I use HYDROCORTISONE JUNO?

How much to take / use

Your doctor will decide the appropriate dose for you.

When to take / use HYDROCORTISONE JUNO

 HYDROCORTISONE JUNO should be used as directed by your doctor.

If you forget to use HYDROCORTISONE JUNO

HYDROCORTISONE JUNO is administered by a doctor or nurse in a hospital. If you miss your dose at the usual time, tell your doctor.

Do not take a double dose to make up for the dose you missed.

If you use too much HYDROCORTISONE JUNO

As HYDROCORTISONE JUNO is given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. Symptoms of a hydrocortisone overdose include the effects listed below in the 'Side Effects' section but are usually of a more severe nature.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using HYDROCORTISONE JUNO?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are being treated with HYDROCORTISONE JUNO.

If you are about to be given a vaccine or started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with HYDROCORTISONE JUNO.

If you become pregnant while having treatment with HYDROCORTISONE JUNO tell your doctor.

HYDROCORTISONE JUNO may hide some of the signs of an infection. If you get an infection or suspect an infection during a course of treatment tell your doctor as soon as possible.

If you are a diabetic, your need for insulin or glucose lowering medicines may increase while being treated with HYDROCORTISONE JUNO.

Remind any doctor, dentist or pharmacist you visit that you are using HYDROCORTISONE JUNO.

Things you should not do

 Avoid drinking grapefruit juice while you are being treated with HYDROCORTISONE JUNO. Grapefruit may interact with HYDROCORTISONE JUNO and affect the way your body uses the medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how HYDROCORTISONE JUNO affects you.

HYDROCORTISONE JUNO may cause dizziness in some people, light headedness, visual disturbances, and fatigue in some people.

Looking after your medicine

HYDROCORTISONE JUNO will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, where the temperature stays below 25°C. Store below 25°C

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
 weight gain as a result of fluid retention or increased appetite muscle weakness or loss of muscle mass increased sweating headache, dizziness or light headedness effects on your menstrual periods mood changes and other mental disorders e.g. over-excitement, depression, suicidal thoughts, hallucinations, anxiety, irritability, feeling of confusion, memory loss, reduced perception and problem solving abilities, abnormal behaviour, addiction to drugs or medicines itchy skin acne thin fragile skin, bruising or change in skin colour, redness of the skin, stretch marks, pale areas of the skin excessive hairiness, particularly in women excessive thirst, the passing of an increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable, and generally unwell 	Speak to your doctor if you have any of these less serious side effects and they worry you.

- loss of appetite, weight loss, nausea, vomiting, feeling of tiredness, drowsiness or lack of energy, headache, fever, joint pain, peeling skin, aching muscle, muscle tenderness or weakness not caused by exercise
- small lumps under the skin as a result of fat deposits in the tissues
- inflammation of the food pipe. You may experience difficulty or pain when swallowing, or heartburn problems with your growth
- hiccups
- pain, redness at the injection site

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Serious side effects				
Ser	ious side effects	What to do		
•	bone fractures or muscle pain wounds that will not heal red, purple or brown patches on your skin problems with your back, including pain or weakness loss of sensation or problems with your reflexes (slow or too fast) bouts of anxiety and headaches, sweating, palpitations, dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurred vision, stomach pains, and raised blood pressure. These could be symptoms of a rare tumour of the adrenal gland, which sits near the kidney	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.		
Allergic Reactions:				
•	skin rash, itching, difficulty breathing, wheezing or coughing swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing			
•	swelling of hands, ankles or feet severe stomach pain, nausea and vomiting			
•	vomiting blood or material that looks like coffee grounds,			
•	bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea convulsions or fits blurred or distorted vision or			
	loss of vision, eye infections			

pain and tenderness in the leg, pain on extending the foot, swelling of the lower leg, ankle and foot
 chest pain and breathlessness.

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 HYDROCORTISONE JUNO contains

Active ingredient	Hydrocortisone sodium succinate	
(main ingredient)		
Other ingredients	Sodium phosphate monobasic	
(inactive ingredients)	Sodium phosphate dibasic	
	Sodium hydroxide	

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

What HYDROCORTISONE JUNO looks like

HYDROCORTISONE JUNO is presented in a clear, type I glass vial, stoppered with a (chlorobutyl elastomer) rubber stopper and capped with an aluminium capsule in extractable yellow plastic cover. (Aust R 377148).

Who distributes HYDROCORTISONE JUNO

Juno Pharmaceuticals Pty Ltd,

42 Kelso Street,

Cremorne,

VIC 3121.

For medical information enquiries please contact <u>medical-enquiries@junopharm.com.au</u>.

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