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.

▼ This medicine is new or being used differently. Please report side effects. See the <u>full CMI</u> for further details.

1. Why am I being given RAPIVAB™?

RAPIVAB™ contains the active ingredient peramivir. RAPIVAB™ is used for the treatment of influenza infection (caused by the influenza virus).

For more information, see Section 1. Why am I being given RAPIVAB™? in the full CMI.

2. What should I know before I am given RAPIVAB™?

Do not use if you have ever had an allergic reaction to RAPIVAB™ 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 am given RAPIVAB™? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RAPIVAB™ and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicine? in the full CMI.

4. How is RAPIVAB™ given?

RAPIVAB™ is given by a doctor or nurse in hospital as an infusion, that is, an injection given slowly into the vein.

More instructions can be found in Section 4. How is it given? in the full CMI.

5. What should I know while using RAPIVAB™?

Things you should do	Keep any follow-up appointments with your doctor or clinic.	
	Remind any doctor, dentist or pharmacist you visit that you have been given RAPIVAB™.	
Things you should not do	Do not stop using this medicine suddenly (if relevant).	
	• [Insert other relevant key point(s)]	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how RAPIVAB™ affects you.	
Looking after your medicine	RAPIVAB™ will be stored by your doctor under the recommended conditions.	

For more information, see Section 5. What should I know while using RAPIVAB™ in the full CMI.

6. Are there any side effects?

Common side effects include:	Serious side effects include:		
 diarrhea constipation insomnia earache hearing loss fever, nausea, vomiting headaches, fatigue, vision problems, chest pain. 	 serious skin reactions mental disorders, such as abnormal behaviour, delirium an allergic reaction: Typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body severe blistering, peeling skin, mouth sores, with fever and fatigue (Stevens-Johnson syndrome) inflamed, reddened and raised skin and blisters (erythema multiforme). Abnormal behaviour, lasting minutes to hours has also rarely been reported, following the use of RAPIVAB™. 		

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

RAPIVABTM

Active ingredient(s): [medicine active ingredient peramivir]

Consumer Medicine Information (CMI)

This leaflet provides important information about using RAPIVAB™. 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 RAPIVAB™.

Where to find information in this leaflet:

- 1. Why am I being given RAPIVAB™?
- 2. What should I know before I am given RAPIVAB™?
- 3. What if I am taking other medicines?
- 4. How is RAPIVAB™ given?
- 5. What should I know while using [medicine name]?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being given RAPIVAB™?

RAPIVAB™ contains the active ingredient peramivir.

RAPIVAB™ is an antiviral medicine that attack the influenza virus and prevent it from spreading inside your body.

RAPIVAB™ injection is used for the treatment of influenza infection (caused by the influenza virus).

2. What should I know before I am given RAPIVAB™?

Warnings

Do not use RAPIVAB™ if:

- you are allergic to peramivir, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- your child must not be given RAPIVAB™ if they are under 2 years old.
- you have or previously have had an allergic reaction to RAPIVAB™ 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
- skin rash, itching or hives.

Check with your doctor if you:

have any other medical conditions

- kidney failure, kidney impairment or kidney disease.
 (Your Doctor may need to give you a smaller dose).
- you have any of the following:
 - hallucinations, or are delirious,
 - high temperature (greater than 38.5°C
 - take any medicines for any other condition

You have any other health problems, especially the following:

You have allergies to any other medicines

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

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.

It is not known whether RAPIVAB™ is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take RAPIVAB™ when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

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.

These medicines may be affected by RAPIVAB™, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you. Live attenuated influenza vaccines are not recommended to be used until 48 hours following RAPIVAB™ treatment, as they may affect how well the vaccine works.

Your doctor has more information on medicines to be careful with or avoid while taking RAPIVAB™.

It is safe to:

- be vaccinated with Inactivated influenza vaccine
- take oral rimantadine, oseltamivir (influenza treatments) or oral contraceptives (containing ethinylestradiol and levonorgestrel), or oral probenecid (a medicine used to treat gout)

Your doctor will tell you if RAPIVAB™ is to be given at the same time as any other medicine.

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

4. How is RAPIVAB™ given?

How much is given

RAPIVAB™ is given by a doctor or nurse in hospital as an infusion, that is, an injection given slowly into the vein.

Your doctor will determine the dose(s) of RAPIVAB™ that you will receive.

If you have any concerns, ask your doctor, or nurse.

When is RAPIVAB™ given

Treatment with RAPIVAB™ should be started as soon as possible, but no later than 48 hours after the first symptoms of influenza appear.

If you forget to use RAPIVAB™

 $\mathsf{RAPIVAB}^{\mathsf{TM}}$ is given by your doctor in hospital as a single dose.

If I am given too much RAPIVAB™

Overdose is unlikely as your doctor or nurse gives you the injection and it is pre-packed in individual single-use vials.

There is no experience of overdose with RAPIVAB™ in people.

If you think that you have been given too much RAPIVAB™ you may need urgent medical attention.

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 when I am given RAPIVAB™?

Things you should do

Keep any follow-up appointments with your doctor or clinic

Remind any doctor, dentist or pharmacist you visit that you have been given RAPIVAB™.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RAPIVAB™ affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

RAPIVAB™ will be stored by your doctor under the recommended conditions.

When to discard your medicine (as relevant)

Your doctor will discard the medicine.

Getting rid of any unwanted medicine

Your doctor will get rid of any unwanted medicine or if it is out of date.

This medicine should not be used 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
 Diarrhoea Constipation Insomnia Earache Hearing loss Fever, nausea, vomiting Headaches, fatigue, vision problems, chest pain. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 Serious skin reactions Mental disorders, such as abnormal behaviour, delirium An allergic reaction: typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body Severe blistering, peeling skin, mouth sores, with fever and fatigue (Stevens-Johnson syndrome) Inflamed, reddened and raised skin and blisters (erythema multiforme) Abnormal behaviour, lasting minutes to hours has also rarely been reported, following the use of RAPIVAB™. 	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 RAPIVAB™ contains

Active ingredient (main ingredient)	•	Peramivir
Other ingredients	•	Sodium chloride
(inactive ingredients)	•	Sodium hydroxide and/or Hydrochloric acid for pH adjustment
	•	Water for injections
Potential allergens	•	None.

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

RAPIVAB $^{\text{m}}$ does <u>not</u> contain lactose, gluten, tartrazine or any azo dyes.

What RAPIVAB™ looks like

RAPIVAB™ injection is a clear, colourless sterile solution supplied in a single-use clear glass vial. Three single-use vials are provided in a carton.

(AUST R 285559).

Who distributes RAPIVAB™

Biocelect Pty Ltd ABN: 88 168 092 171

Level 29 66 Goulburn Street

Sydney 2000 AUSTRALIA

Telephone: 1300 907 411

www.biocelect.com

This leaflet was prepared in June 2022.

RAPIVAB™ is a trademark of BioCryst Pharmaceutical, Inc.