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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>.

## Rapivab™

contains the active ingredient peramivir

#### **Consumer Medicine Information**

### What is in this leaflet

This leaflet answers some common questions about  $\mathbf{Rapivab^{TM}}$  injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or nurse.

All medicines have risks and benefits. Your doctor considers the risks of you having **Rapivab<sup>TM</sup>** injection and the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor or nurse. Keep this leaflet.

You may need to read it again.

### What Rapivab™ injection is used for

 $Rapivab^{TM}$  injection is an antiviral medicine containing the active ingredient peramivir.

**Rapivab**<sup>TM</sup> injection is used for the treatment of influenza infection (caused by the influenza virus).

# How Rapivab™ works

Rapivab™ belongs to a group of medicines called neuraminidase inhibitors. These medicines attack the influenza virus and prevent it from spreading inside your body.

**Rapivab**<sup>TM</sup> is delivered to the key sites of influenza infection and treats the cause. Taking **Rapivab**<sup>TM</sup> means you feel better faster. You will also be less likely to develop complications of influenza.

Treatment of influenza requires one dose of  $Rapivab^{TM}$ .

**Rapivab**<sup>TM</sup> is a prescription only medicine.

Ask your doctor about having the influenza vaccination.

**Rapivab**<sup>TM</sup> is not a substitute for influenza vaccination. Vaccination every year is the best way to prevent influenza.

# Before you are given Rapivab™

When you must not be given Rapivab™

Your child must not be given Rapivab if they are under 2 years old.

You must not be given Rapivab $^{TM}$  if:

 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.

Before you are given Rapivab™

# Tell your doctor if:

1. You are pregnant or plan to become pregnant

It is not known whether  $\mathbf{Rapivab^{TM}}$  is harmful to an unborn baby when taken

by a pregnant woman. If there is a need to take **Rapivab<sup>TM</sup>** when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

# 2. You are breast-feeding or plan to breast-feed

**Rapivab™** may pass into breast milk. Your doctor will discuss the risks and benefits of using **Rapivab™** if you are breast-feeding.

3. You have any other health problems, especially the following:

Kidney failure, kidney impairment or kidney disease. (Your Doctor may need to give you a smaller dose).

- 4. You have any of the following:
- · hallucinations, or are delirious,
- high temperature (greater than 38.5°C)
- 5. You have allergies to: any other medicines

#### Taking other medicines

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

These medicines may be affected by **Rapivab<sup>TM</sup>**, 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<sup>TM</sup>** 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**<sup>TM</sup>.

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<sup>TM</sup>** is to be given at the same time as any other medicine.

# How Rapivab™ is given

## How it is given

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

# How much is given

Your doctor will determine the dose(s) of  $\mathbf{Rapivab^{TM}}$  that you will receive.

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

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

# When it is given

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

# After having Rapivab™

Things you must do

Keep any follow-up appointments with your doctor or clinic.

#### Side effects

# Tell your doctor, or nurse as soon as possible if you feel unwell after being treated with Rapivab $^{TM}$ .

Rapivab<sup>™</sup> 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 treatment for some of the side effects.

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

The following are the more common side effects of **Rapivab<sup>TM</sup>**. Mostly these are mild and short-lived.

# Tell your doctor, or nurse if you notice any of the following and they worry you:

- diarrhea
- · constipation
- insomnia
- earache
- hearing lossfever, nausea, vomiting
- headaches, fatigue, vision problems, chest pain.

Abnormal behaviour, lasting minutes to hours has also rarely been reported, following the use of **Rapivab<sup>TM</sup>**.

The following may be serious side effects and you may need urgent medical attention. However, these side effects are rare.

# Tell your doctor immediately if you notice any of the following:

- serious skin reactions
- mental disorders, such as abnormal behaviour, delirium.

The following are very serious side effects and you may need urgent medical attention or hospitalisation. All of these side effects are rare.

# If any of the following happen to you, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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).

Other side effects not listed may occur in some people. Tell your doctor or nurse if

you notice anything that makes you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

# Storing Rapivab™

Rapivab<sup>TM</sup> will be stored by your doctor under the recommended conditions.

**Rapivab<sup>TM</sup>** should not be used after the expiry date on the packaging.

### Product description

#### What it 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.

# Ingredients

Active ingredient:

Peramivir (10 mg/mL)

Other ingredients

- Sodium chloride
- sodium hydroxide and/or hydrochloric acid for pH adjustment
- · water for injections

**Rapivab<sup>TM</sup>** does not contain lactose, gluten, tartrazine or any azo dyes.

Ask your doctor or nurse if you are unsure about anything or want more information about Rapivab $^{\mathrm{TM}}$ 

### Name and Address of Sponsor

Biocelect Pty Ltd ABN: 88 168 092 171 Suite 405, Level 4 51 Rawson Street Epping NSW 2121 AUSTRALIA Telephone: 1300 907 411 www.biocelect.com

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RAPIVAB $^{\text{TM}}$  is a trademark of BioCryst Pharmaceutical, Inc.