# **PARAMYL OSTEO**

Active ingredient(s): Paracetamol

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Paramyl Osteo. 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 Paramyl Osteo.

#### Where to find information in this leaflet:

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

# 1. Why am I using Paramyl Osteo?

# Paramyl Osteo contains the active ingredient

**paracetamol.** Paramyl Osteo is an analgesic and works to stop the pain messages from getting through to the brain.

Paramyl Osteo provides effective relief of persistent pain associated with osteoarthritis for up to 8 hours.

# 2. What should I know before I use Paramyl Osteo?

### Warnings

### Do not use Paramyl Osteo if:

- you are allergic to paracetamol, 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 are taking other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

## Check with your doctor or pharmacist if you:

- have or have had liver or kidney disease
- are underweight or malnourished
- regularly drink alcohol

You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

 have a severe infection, are severely malnourished or are a chronic, heavy alcohol user as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include deep, rapid, difficult breathing, feeling sick (nausea), being sick (vomiting), loss

of appetite. Contact a doctor immediately if you get a combination of these symptoms.

Please see your doctor if your symptoms do not improve.

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 or pharmacist if you are pregnant or intend to become pregnant.

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

Paracetamol may be used during pregnancy and if you are breastfeeding but you should always consult your doctor first. Consider taking the lowest effective dose for the shortest period of time.

# 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 Paramyl Osteo and affect each other.

- Warfarin, a medicine used to prevent blood clots
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits
- Propantheline
- Certain medicines used to treat depression or to control pain
- Chloramphenicol, an antibiotic used to treat ear and eye infections.
- Alcohol
- Probenecid, a medicine used to treat gout or sometimes given with an antibiotic
- Cholestyramine, a medicine used to treat high cholesterol levels in the blood.

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

### 4. How do I use Paramyl Osteo?

### How much to take / use

Adults and children aged 12 years and over: Take 2 tablets three times a day, every six to eight hours as needed. Do not take more than 6 tablets in 24 hours.

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Not recommended for children under 12 years.

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
- Use the smallest dose that you need to treat your symptoms.

### When to take / use Paramyl Osteo

- Paramyl Osteo should only be used for a few days at a time in adults or no more than 48 hours for children aged 12 – 17 years
- unless your doctor tells you to take it for longer.
- Use for the shortest period of time necessary.

### **How to take Paramyl Osteo**

- Swallow the tablets whole with water or other fluid.
- Do not crush or chew the tablets.
- They can be taken with or without food.
- Try to space the doses at equal intervals throughout the day.

### If you use too much Paramyl Osteo

If you think that you have used too much Paramyl Osteo, 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 because of the risk of liver failure.

# 5. What should I know while using Paramyl Osteo?

### Things you should do

Remind any doctor, dentist, pharmacist or other health professionals you visit that you are using Paramyl Osteo. Talk to your pharmacist or doctor if your symptoms do not improve. They will assess your condition and decide if you should continue to take the medicine.

### Things you should not do

- Do not use for more than a few days at a time in adults or more than 48 hours for children aged 12 – 17 years unless your doctor tells you to.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not use Paramyl Osteo to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Paramyl Osteo affects you.

### **Drinking alcohol**

### Tell your doctor or pharmacist if you drink alcohol.

Only drink small quantities of alcohol (beer, wine or spirits) while using Paramyl Osteo. Drinking large quantities of alcohol may increase the risk of liver side effects.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your medicine in the original pack until it is time to take it.

Store below 30°C.

Store it in a cool, dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

### 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.

### Very rare side effects

Very rare side effects	What to do
<ul> <li>Shortness of breath</li> <li>Wheezing or difficulty breathing</li> <li>Swelling of the face, lips, tongue or other parts of the body</li> <li>Rash, peeling, itching or hives on the skin or mouth ulcers</li> <li>Unexplained bruising or bleeding</li> </ul>	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.

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# **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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### **What Paramyl Osteo contains**

Active ingredient	Paracetamol
(main ingredient)	
Other ingredients	Hypromellose
(inactive ingredients)	Maize starch
	Povidone
	Croscarmellose sodium
	Magnesium stearate
	Titanium dioxide
	Macrogol 400

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

## What Paramyl Osteo looks like

Paramyl Osteo is a white to off-white, capsule-shaped, biconvex tablet, plain on both sides (AUST R 459289).

### **Who distributes Paramyl Osteo**

SANDOZ Pty Ltd North Sydney, NSW 2060, AUSTRALIA Tel 1800 726 369

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