Paracetamol Osteo-Tab

Active ingredient(s): paracetamol 665 mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using Paracetamol Osteo-Tab. 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 Paracetamol Osteo-Tab.

Where to find information in this leaflet:

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

1. Why am I using Paracetamol Osteo-Tab?

Paracetamol Osteo-Tab contains the active ingredient paracetamol. Paracetamol Osteo-Tab is effective for the relief of persistent pain associated with:

- Osteoarthritis
- Muscle aches and pains such as backache

Paracetamol, the active ingredient in this medicine, is also used for the fast effective temporary relief of pain and discomfort associated with:

- Headache
- Tension headache
- Period pain
- Toothache and pain after dental procedures
- Cold and flu

Paracetamol also reduce fever.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have recommended it for another reason.

2. What should I know before I use Paracetamol Osteo-Tab?

Warnings

Do not use Paracetamol Osteo-Tab:

• 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.
- if you are taking other prescription or nonprescription 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 any of the following medical conditions:

- 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 illness, including blood infection, are severely malnourished or are a chronic heavy alcohol user, as this may increase the risk of metabolic acidosis (a blood and fluid abnormality). Signs of metabolic acidosis include:
 - deep, rapid, difficult breathing
 - feeling sick (nausea), being sick (vomiting)
 - loss of appetite
 - Drowsiness

Contact a doctor immediately if you think you may be affected.

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.

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 and paracetamol may interfere with each other. These include:

- Warfarin, a medicine used to prevent blood clots
- Metoclopramide, a medicine used to control nausea and vomiting
- Medicines used to treat epilepsy or fits
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Alcohol

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- 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
- Flucloxacillin (an antibiotic)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Paracetamol Osteo-Tab. Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while using this medicine.

4. How do I use Paracetamol Osteo-Tab?

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

Do not exceed the stated dose.

Use the smallest dose that you need to treat your symptoms and use the medicine for the shortest period of time necessary.

How much to take / use

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

Should not be used for more than 48 hours for children aged 12 – 17 years except on medical advice.

Not recommended for children under the age of 12 years.

How to use Paracetamol Osteo-Tab

- Swallow the tablets whole with water or other fluid.
- Do not crush 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 Paracetamol Osteo-Tab

If you think that you have used too much Paracetamol Osteo-Tab, 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 while using Paracetamol Osteo-Tab?

Things you should do

 Talk to your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Paracetamol Osteo-Tab.

Things you should not do

- Do not use for more than a few days at a time unless your doctor tells you to.
- Do not use this medicine to treat any other complaints unless your pharmacist or doctor tells you to.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

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

Looking after your medicine

Store at or below 25°C.

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

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?

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using Paracetamol Osteo-Tab. This medicine helps most people with various types of pain but it may have unwanted 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.

Do not be alarmed by the following list of side effects. These side effects are rare and you may not experience any of them.

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Serious/rare side effects

Serious side effects	What to do
Shortness of breath Wheezing or difficulty breathing Swelling of the face, lips, tongue or other parts of the body Rash, peeling, itching or hives on the skin or mouth ulcers Unexplained bruising or bleeding Serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting)	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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time.

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.

7. Product details

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

What Paracetamol Osteo-Tab contains

Active ingredient	Paracetamol
(main ingredient)	
Other ingredients	Croscarmellose sodium
(inactive ingredients)	Hypromellose
	Opadry II film coating (contains lactose monohydrate)
	Magnesium stearate
	Microcrystalline cellulose
	Povidone
	Pregelatinised maize starch
Potential allergens	Lactose

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

What Paracetamol Osteo-Tab looks like

Paracetamol Osteo-Tab is a white to off-white capsule shaped, biconvex, film coated tablet embossed with ML 77 on one side and plain on the other side.

Blister pack: AUST R 202406 Bottle pack: AUST R 202407

Who distributes Paracetamol Osteo-Tab

AFT Pharmaceuticals Pty Ltd 113 Wicks Road, North Ryde, NSW 2113, Australia

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