PANADOL® Tablets, PANADOL® Mini Caps and PANADOL® Suppositories

500 mg Paracetamol

CONSUMER MEDICINE INFORMATION

Please read this information before you start using this medicine.

What is in this leaflet

This leaflet answers some common questions about PANADOL. It does not contain all the available information.

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

All medicines have risks and benefits

If you have any concerns about using this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may need to read it again.

What PANADOL is used for

The active ingredient in these medicines is paracetamol. Paracetamol is used for the fast effective temporary relief of pain and discomfort associated with

- Headache
- Muscular aches
- Period pain
- Arthritis/Osteoarthritis
- Toothache
- Migraine
- Colds and flu
- Tension headache
- Sinus pain/headache
- Backache

Paracetamol also reduces fever.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever. Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason

Before you use PANADOL

Taking too much paracetamol can cause serious harm to your liver.

When you must not use it

Do not use PANADOL if you have an allergy to:

 Any of the ingredients listed at the end of this leaflet

Do not use this medicine if you are taking any other prescription or nonprescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Always read and follow the label.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

Before you start to use it

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- Liver or kidney problems
- 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.
- You have a severe infection 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.

Keep out of sight and reach of children.

Ask your pharmacist or doctor about using paracetamol if you are pregnant or plan to become pregnant, or breastfeeding.

Paracetamol may be used during pregnancy and if you are breastfeeding but you should always consult your doctor first.

If you have not told your pharmacist or doctor about any of the above, tell them before you use PANADOL.

Using other medicines

Tell your pharmacist or doctor if you are using any other medicines, including any that you get 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

Your pharmacist and doctor will have more information on these and other medicines to be careful with or avoid while using this medicine.

How to use PANADOL

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/bottle, ask your pharmacist or doctor for help.

Do not exceed the stated dose.

Always use the lowest effective dose to relieve your symptoms

How much to use

PANADOL Tablets and Mini Caps

Adults and children aged 12 years and over: Take 1 to 2 tablets or caplets every four to six hours as needed. Do not take more than 8 tablets or caplets in 24 hours.

<u>Children 7 to 11 years:</u> Take ½ to 1 tablet or caplet every four to six hours as needed. Do not take more than 4 tablets or caplets in 24 hours.

Not recommended in children under 7 years.

PANADOL Suppositories

<u>Adults and children aged 12 years</u> <u>and over:</u> Use two suppositories up to 4 times in 24 hours as needed. Do not use more than 8 suppositories in 24 hours.

Children 10 to 11 years:

Use one suppository up to 4 times in 24 hours as needed. Do not use more than 4 suppositories in 24 hours.

Not recommended in children under 10 years.

How to use it

PANADOL Tablets and Mini Caps

Swallow with water or other fluid.

PANADOL Suppositories

If possible, go to the toilet and empty your bowels before using your suppository.

Suppositories work best if your bowels are empty.

Follow these steps to use a suppository.

- 1 Wash your hands thoroughly with soap and water.
- 2 Feel the suppository while it is still in the foil.
- 3 If it feels soft, keep it in the foil, and chill it in the fridge or by holding it under cold water for a few minutes. Do not remove the foil wrapper while you are chilling it.
- 4 Put on a disposable glove, if desired. They are available from pharmacies.
- 5 Remove all of the foil wrapper from the suppository.
- 6 Moisten the suppository by dipping it briefly in cool water.
- 7 Lie on your side and raise your knee to your chest.
- 8 Push the suppository gently, blunt end first, into your rectum, or back passage.
- 9 Remain lying down for a few minutes so that the suppository dissolves.

10 Throw away used materials and wash your hands thoroughly.

How long to use it

PANADOL Tablets and Mini Caps

Adults and children aged 12 years and over:

Only take paracetamol for a few days at a time unless your doctor tells you to take it for longer.

Children 7 to 11 years:

Only give paracetamol to children for up to 48 hours unless a doctor has told you to give it for longer.

PANADOL Suppositories

Adults and children aged 12 years and over:

Only use paracetamol for a few days at a time unless your doctor tells you to take it for longer.

Children 10 to 11 years:

Only give paracetamol to children for up to 48 hours unless a doctor has told you to give it for longer.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 for Australia, 0800 764 766 for New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PANADOL. Do this even if there are no signs of discomfort or poisoning because of the risk of liver failure.

You may need urgent medical attention.

While you are using PANADOL

Things you must 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.

Things you must not do

Children:

Do not give paracetamol for more than 48 hours unless a doctor has told you to.

Adults:

Do not use for more than a few days at a time unless your doctor tells you to.

Do not take more than the recommended dose unless your doctor tells you to.

Do not use PANADOL to treat any other complaints unless your pharmacist or doctor tells you to.

Things to be careful of

Only drink small quantities of alcohol (beer, wine or spirits) while using paracetamol.

Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using

PANADOL. This medicine helps most people with various types of pain but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- Shortness of breath
- Wheezing or difficulty breathing

- Swelling of the face, lips, tongue, throat or other parts of the body
- Rash, peeling, itching or hives on the skin or mouth ulcers
- Unexplained bruising or bleeding

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 pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using PANADOL

Storage

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

Keep your medicine in a cool dry place where the temperature stays below 30°C for PANADOL Tablets and Suppositories and below 25 °C for PANADOL Mini Caps.

Do not store PANADOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in a car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product Description

What it looks like

PANADOL Tablets are a white, film-coated round tablet. They are

marked "PANADOL" on one side and have a break bar on the other side. They come in blister packs of 2, 12, 20, 50 and 100 tablets.

PANADOL Mini Caps are a capsule-shaped tablet with a gelatin coating. One half is green and the other half is white. They come in blister packs of 12, 20, 48 and 96 caplets.

PANADOL Suppositories are a white cylindrical shape with a rounded top. They come in strip packs of 24 suppositories.

Ingredients

PANADOL Tablets contain 500 mg of paracetamol as the active ingredient.

They also contain:

- Starch-pregelatinised maize
- Starch-maize
- Talc-purified
- Stearic acid
- Hypromellose
- Povidone
- Glycerol triacetate
- Potassium sorbate
- Carnauba wax

PANADOL Mini Caps contain 500 mg paracetamol as the active ingredient.

They also contain:

- Gelatin capsules hard
- Starch-pregelatinised maize
- Croscarmellose sodium
- Povidone
- Stearic acid
- Hypromellose
- Titanium dioxide
- Quinoline yellow Brilliant blue FCF
- Allura red AC

PANADOL Suppositories contain 500 mg paracetamol as the active ingredient.

They also contain:

Hard fat

Manufacturer/Supplier

PANADOL Tablets are supplied in Australia and New Zealand by:

GlaxoSmithKline Consumer Healthcare Australia Pty Ltd 82 Hughes Avenue, Ermington, NSW and Auckland, New Zealand

PANADOL Mini Caps are supplied in Australia and New Zealand by:

GlaxoSmithKline Consumer Healthcare Australia Pty Ltd 82 Hughes Avenue, Ermington, NSW and Auckland, New Zealand

PANADOL Suppositories are supplied in Australia by:

GlaxoSmithKline Consumer Healthcare

82 Hughes Avenue, Ermington, NSW

AUST R 13591 (PANADOL Tablets)

AUST R 81007 (PANADOL Mini Caps)

AUST R 15488 (PANADOL Suppositories)

Date of preparation: September 2015

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