PANADOL Rapid Caplets PANADOL Rapid Caplets (reformulation) PANADOL Rapid Soluble Tablets

500 mg Paracetamol

INFORMATION LEAFLET

Please read this information before you start using this medicine.

What is in this leaflet

This leaflet answers some common questions about PANADOL Rapid, PANADOL Rapid (reformulation) and PANADOL Rapid Soluble. 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 Rapid, PANADOL Rapid (reformulation) and PANADOL Rapid Soluble are 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
- Toothache
- Migraine headache
- Colds and flu
- Tension headache

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 Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble

When you must not use it

Do not take more than the recommended dose as it may **cause serious harm to your liver.**

Do not use PANADOL Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble 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.

PANADOL Rapid Soluble tablets contain phenylalanine. Do not use it if you are a phenylketonuric.

Each PANADOL Rapid Soluble tablet contains 50 mg sorbitol. Do not take this medicine if you have fructose intolerance.

Do not give PANADOL Rapid or PANADOL Rapid (reformulation) to children under 12 years of age.

Do not give PANADOL Rapid Soluble to children under 12 years of age.

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.

ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE. IF SYMPTOMS PERSIST, SEE YOUR HEALTHCARE PROFESSIONAL. INCORRECT USE COULD BE HARMFUL. v2 GDS v9.0

- You 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.

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.

Consider taking the lowest effective dose for the shortest period of time.

Two PANADOL Rapid caplets contain 344 mg sodium, two PANADOL Rapid caplets (reformulation) contain 352 mg sodium and each PANADOL Rapid Soluble tablet contains 425.5 mg sodium. If you are on a low sodium diet, ask your doctor about using these medicines before you take them.

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

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 or similar medicines used to thin blood
- 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
- 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

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 Rapid, PANADOL Rapid (reformulation) and PANADOL Rapid Soluble

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 use

PANADOL Rapid or PANADOL Rapid (reformulation) Caplets

<u>Adults and children aged 12 years</u> <u>and over:</u> Take 2 caplets every four to six hours as needed. Do not take more than 8 caplets in 24 hours.

Take the caplets with water or other fluids.

Do not use in children under 12 years.

PANADOL Rapid Soluble Tablets

<u>Adults and children aged 12 years</u> <u>and over:</u> Take 2 tablets every four to six hours as needed. Do not take more than 8 tablets in 24 hours.

Dissolve the tablets in a glass of water at room temperature then drink it.

Do not use in children under 12 years.

How long to use it

PANADOL Rapid or PANADOL Rapid (reformulation)

Adults:

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

<u>Children aged 12 to 17 years</u>: Only give PANADOL Rapid caplets to children for up to 48 hours unless a doctor has told you to give it for longer.

PANADOL Rapid Soluble Tablets

Adults:

Only take PANADOL Rapid Soluble tablets for a few days at a time unless your doctor tells you to take it for longer.

Children aged 12 to 17 years:

Only give PANADOL Rapid Soluble tablets 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 Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble. Do this even if there are no signs of discomfort or poisoning because of the risk of delayed, serious liver damage/failure if left untreated.

You may need urgent medical attention.

While you are using PANADOL Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble

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 Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble 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 Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble. 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, stop use and 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
- Allergic skin reaction such as rash, peeling, itching or hives
- 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 Rapid, PANADOL Rapid (reformulation) or PANADOL Rapid Soluble

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.

Do not store PANADOL Rapid, PANADOL Rapid (reformulation), PANADOL Rapid Soluble 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 Rapid caplets are a white, film-coated capsule-shaped tablet with flat edges. They are marked with the letter "P" on one side. **Panadol Rapid caplets** (reformulation) are a white to off-white capsule shaped film coated tablets with flat edges. One face of the tablet is debossed with the letter "P" and "--" on the other side.

PANADOL Rapid Soluble tablets are round, white, flat tablets with bevelled edges. They have no markings on them.

Ingredients

PANADOL Rapid caplets contain 500 mg of paracetamol as the active ingredient.

They also contain:

- Sodium bicarbonate
- Cellulose microcrystalline
- Starch pregelatinised maize
- Starch maize
- Water purified
- Hypromellose
- Magnesium stearate
- Titanium dioxide
- Polydextrose
- Povidone
- Calcium phosphate
- Glycerol triacetate
- Potassium sorbate
- Macrogol 8000
- Carnauba wax

Contains sodium.

PANADOL Rapid caplets (reformulation) contain 500 mg of paracetamol as the active ingredient.

They also contain:

- Sodium bicarbonate
- Cellulose microcrystalline
- Starch pregelatinised maize
- Sodium Starch Glycolate
- Starch maize
- Water purified
- Magnesium stearate
- Hypromellose
- Colloidal Anhydrous Silica
- Povidone
- Titanium dioxide
- Polydextrose
- Glycerol triacetate
- Carnauba wax
- Macrogol 8000

PANADOL Rapid Soluble tablets

contain 500 mg of paracetamol as the active ingredient.

They also contain:

- Sodium bicarbonate
- Citric acid anhydrous
- Sodium carbonate anhydrous
- Sorbitol
- Lemon flavour
- Aspartame

- Dimethicone 200
- Povidone
- Saccharin sodium
- Candied sugar flavour
- Sodium lauryl sulphate

Contains sodium, phenylalanine, saccharin sodium, sucrose and aspartame.

Manufacturer/Supplier

Haleon Australia Level 48, 8 Parramatta Square, 10 Darcy Street, Parramatta NSW 2150 and Auckland, New Zealand

AUST R 78692 (PANADOL Rapid caplets)

AUST R 332528 (PANADOL Rapid caplets (reformulation)) AUST R 15509 (PANADOL Rapid Soluble Tablets)

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