Panamax[®]

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Panamax?

Panamax contains the active ingredient paracetamol. Panamax is used to relieve pain and fever in adults (including arthritis, headache and muscular pain) and children (including teething, earache and immunisation). For more information, see Section 1. Why am I using Panamax? in the full CMI.

2. What should I know before I use Panamax?

Do not use if you have ever had an allergic reaction to Panamax or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use Panamax? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Panamax and affect how it works. A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How do I use Panamax?

- The label on the pack or bottle will tell you how to take your medicine and how often. If you are unsure about the directions ask your pharmacist or doctor.
- The dose will be different depending upon which product you are taking and whether you are an adult or child.

More instructions can be found in Section 4. How do I use Panamax? in the full CMI.

5. What should I know while using Panamax?

Things you should do	 Take Panamax exactly as directed. Remind any doctor, dentist or pharmacist you visit that you are using Panamax.
Things you should not do	 Do not take more than the recommended dose unless your doctor tells you to. In children, do not give Panamax for more than 48 hours unless a doctor has told you to. Panamax Tablets: Adults - do not take more than 8 tablets in 24 hours; Children (7 years or older) - do not take more than 4 tablets in 24 hours. Panamax Elixir: Do not give more than 4 doses in 24 hours. Do not use in infants below 1 month old. Panamax 240 Elixir: Do not give more than 4 doses in 24 hours. Do not use in children under 5 years old.
Drinking alcohol	Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol.
Looking after your medicine	 Store below 30°C in a cool dry place away from moisture, heat and sunlight. Keep your tablets in the blister pack until it is time to take them.

For more information, see Section <u>5. What should I know while using Panamax?</u> in the full CMI.

6. Are there any side effects?

- Less serious side effects include nausea and stomach pain.
- Tell your doctor or pharmacist immediately if you notice any of the following side effects shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin. They may be the signs of an allergic reaction.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Panamax[®]

Active ingredient: paracetamol

Consumer Medicine Information (CMI)

This leaflet provides important information about using Panamax. 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 Panamax.

Where to find information in this leaflet:

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

1. Why am I using Panamax?

Panamax contains the active ingredient paracetamol. Panamax is an analgesic.

Panamax is used to relieve pain and fever in adults (including arthritis, headache and muscular pain) and children (including teething, earache and immunisation).

Panamax works to stop the pain messages from getting through to the brain. Panamax also acts in the brain to reduce fever.

2. What should I know before I use Panamax?

Warnings

Do not use Panamax if:

• you are allergic to paracetamol, or any of the ingredients listed at the end of this leaflet.

The 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
- rash, itching or hives on the skin
- Always check the ingredients to make sure you can use this medicine.
- Do not take this medicine if you have liver or kidney problems.
- Do not take Panamax if you have glucose-6phosphate-dehydrogenase deficiency (an enzyme deficiency).
- Do not use Panamax if the packaging is torn or shows signs of tampering.
- Do not use Panamax after the expiry date (EXP) printed on the pack or bottle.
- If it has expired or is damaged, return it to your pharmacist for disposal.

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

Check with your doctor or pharmacist if you:

- have allergies to any ingredients listed under Product Details at the end of this leaflet
- have allergies to aspirin or any other NSAID medicine
- have liver or kidney problems
- have malnutrition and other sources of low glutathione reserves
- severe renal insufficiency and sepsis
- chronic alcohol use including recent cessation of alcohol intake
- have Gilbert's syndrome
- have acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- drink large quantities of alcohol
- take any medicines for any other condition

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant or if you are breastfeeding or intend to breastfeed.

Panamax may be used during pregnancy and if you are breastfeeding. However, it is recommended that non-drug therapy such as rest and massage be tried first. If Panamax is needed during pregnancy, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

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 Panamax and affect how it works.

These include:

- Any medicines which thin the blood, for example warfarin
- Medicines to treat epilepsy
- Metoclopramide or domperidone, medicines used to control nausea and vomiting
- Propantheline, a drug used to treat stomach ulcers
- Other pain relief medication
- Alcohol and medicines containing alcohol (ethanol) eg, some cough syrups
- Medicines used to treat depression

- Medicines used to aid sleep
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Flucloxacillin, zidovudine and rifampicin, drugs used to treat infections
- Probenecid, a drug used to treat high uric acid levels in the blood associated with gout
- Cholestyramine, a drug used to reduce blood cholesterol
- Chelating resin

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

4. How do I use Panamax?

How much to take

There are three different Panamax products:

- Panamax Tablets
- Panamax Elixir
- Panamax 240 Elixir

The dose will be different depending upon which product you are taking.

Panamax Tablets

The usual dose is:

Adults:

- 1 to 2 tablets.
- This dosage may be repeated every 4 to 6 hours if necessary.
- You should not take more than 8 tablets in 24 hours.

Children (7-12 years):

- Half (1/2) to 1 tablet.
- This dosage may be repeated every 4 to 6 hours if necessary.
- Children should not take more than 4 tablets in 24 hours.

Panamax tablets are not recommended for children under 7 years.

Swallow tablets whole with a little water or other liquid.

Panamax Elixir

The usual dose is:

Infants:

1 to 3 months (4 - 6 kg): 2 to 4 mL;

3 to 6 months (6 - 8 kg): 4 to 5 mL;

6 to 12 months (8 - 10 kg): 5 to 6 mL.

Children:

1 to 2 years (10 - 12 kg): 6 to 8 mL;

2 to 4 years (12 - 16 kg): 8 to 10 mL;

4 to 6 years (16 - 20 kg):10 to 13 mL;

6 to 8 years (20 - 25 kg): 13 to 16 mL;

8 to 10 years (25 - 32 kg): 16 to 20 mL;

10 to 12 years (32 - 41 kg): 20 to 26 mL.

This dosage may be repeated every 4 to 6 hours if necessary.

Do not give more than 4 doses in 24 hours.

Panamax Elixir is not recommended for infants under 1 month.

It can be given in water.

Panamax 240 Elixir

Children:

5 to 6 years (18 - 20 kg): 6 mL;

6 to 8 years (20 to 25 kg): 6 to 8 mL;

8 to 10 years (25 - 32 kg): 8 to 10 mL;

10 to 12 years (32 - 41 kg): 10 to 12 mL.

Do not give more than 4 doses in 24 hours.

Adults:

10 to 20 mL

This dosage may be repeated every 4 to 6 hours if necessary up to 4 times in 24 hours.

Do not take more than 80 mL per day.

Panamax 240 Elixir is not recommended for children under 5 years of age.

When to take Panamax

 The label on the pack or bottle will tell you how to take your medicine and how often. If you are unsure about the directions ask your pharmacist or doctor.

It can be given in water if necessary.

Your doctor may ask you to take a different dose. If so, you should follow the doctor's instructions.

If you are unsure what dose to take ask your pharmacist.

If you forget to use Panamax

If you miss a dose, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Panamax

If you think that you have used too much Panamax, you may need urgent medical attention.

If you take too much Panamax you may feel nauseous, dizzy or sweaty.

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 Panamax?

Things you should do

Take Panamax exactly as directed.

Remind any doctor, dentist or pharmacist you visit that you are using Panamax.

Things you should not do

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

Children:

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

Adults:

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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

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

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.
- If you take the tablets out of the box or the blister pack they will not keep well.
- Keep bottles tightly closed, and ensure that the child resistant cap is engaged after use.
- Store below 30°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?

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.

Less serious side effects

Less serious side effects	What to do
General	Speak to your doctor if you
Nausea and vomitingSweating	have any of these less serious side effects and they worry you.
Gut related	
Stomach painIndigestion	

Serious side effects

Serious side effects	What to do		
Skin related Skin rashes Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills Liver related	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you		
Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)	notice any of these serious side effects.		
Metabolism Related			
Symptoms of rapid breathing, rapid heart rate, changes in consciousness, drowsiness, nausea or vomiting caused by pyroglutamic acidosis (an accumulation of pyroglutamic acid due to low levels of a protein called glutathione).			
Allergic reaction			
 shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals rash, itching or hives on the skin 			

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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Panamax tablets contain

Active ingredient (main ingredient)	Paracetamol 500 mg
Other ingredients (inactive ingredients)	 Maize starch Purified talc Pregelatinised maize starch Povidone Stearic acid Potassium sorbate

Panamax tablets do not contain gluten, lactose, sucrose, tartrazine or any azo dyes.

What Panamax Elixir (100 mL) contains

Active ingredient (main ingredient)	Paracetamol 120 mg in 5 mL
Other ingredients (inactive ingredients)	 Macrogol 1500 Glycerol Propylene Glycol Potassium Sorbate Benzoic Acid Ponceau SX Tutti Frutti Flavour 51880 A7 Raspberry Flavour 54428 A7 Lycasin Sodium Saccharin Water - Purified

What Panamax 240 Elixir (200 mL) contains

Active ingredient (main ingredient)	Paracetamol 240 mg in 5 mL
Other ingredients	Macrogol 1500
(inactive	Propylene Glycol
ingredients)	Potassium Sorbate
mg. curemes,	Benzoic Acid
	Allura Red AC
	Glycerol
	Raspberry Flavour PHL-
	217843
	Sorbitol solution 70%
	crystallising
	Sodium Saccharin
	Water - Purified

Imitation candied sugar 510155U

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

What Panamax looks like

Panamax comes as a white tablet, marked PANAMAX.

A box may contain 50 or 100 tablets.

Panamax is also available as an Elixir (100 mL) or 240 Elixir (200 mL). A clear light red coloured syrup liquid.

AUST R 15490 (Tablets)

AUST R 13750 (Elixir)

AUST R 49623 (240 Elixir)

Who distributes Panamax

sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113

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