

# PANADEINE<sup>®</sup> TABLET

Paracetamol / Codeine Phosphate (500mg / 8mg)

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## What Panadeine is used for

Panadeine is used for the temporary relief of pain and discomfort such as:

- Headache
- Menstrual pain
- Musculoskeletal pain
- Muscle pain
- Nerve pain (neuralgia)
- Toothache
- Dental procedures
- Cold and flu symptoms
- Viral infections
- Fever
- Sore throat

This medicine can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

## How Panadeine works

Panadeine contains two different medicines called codeine phosphate and paracetamol. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other painkillers such as paracetamol.

## Before you use Panadeine

### -When you must not use it

Do not take Panadeine if:

- You are allergic (hypersensitive) to paracetamol, codeine phosphate or to any of the other ingredients of this medicine.
- Signs of an allergic reaction include a rash or breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.
- The person going to take the tablets is under 12 years of age. Panadeine must not be given to children under 12 years of age.

- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome
  - You know you metabolise very rapidly codeine into morphine
  - You are breastfeeding or planning to breastfeed.
- Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Panadeine.

### -Before you start to use it

Take special care and check with your doctor before taking Panadeine if:

- You have severe kidney or liver problems.
- If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

## Children and adolescents

*Use in children and adolescents after surgery:*

Panadeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

*Use in children and adolescents with breathing problems:*

Panadeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Panadeine is not recommended in adolescents over 12 years of age with breathing problems for the treatment of colds.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking Panadeine.

### -Taking other medicines

Tell your doctor if you are taking any of the following medicines:

- other medicines which contain paracetamol. This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

- Medicines used to thin the blood such as warfarin

- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Panadeine.

## Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant.
- You are breast-feeding or planning to breastfeed.
- Do not take Panadeine while you are breastfeeding. Codeine and morphine passes into breast milk.

## How to use Panadeine

Always take Panadeine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Do not take more than the recommended dose
- Do not take for longer than your doctor tells you to
- Swallow the tablets whole with a drink of water

### -How much to use

#### **Adults and children over 12 years:**

Two tablets, to be taken with a glass of water, not more frequently than every 4 hours, do not exceed 8 tablets in any 24 hour period.

#### **Children aged less than 12 years:**

Codeine should not be used in children below the age of 12 years because of the risk of opioid toxicity due to the variable and unpredictable metabolism of codeine to morphine.

Panadeine is contraindicated in children below the age of 12 years for the symptomatic treatment of cold.

#### **Children aged 12 years to 18 years:**

Panadeine is not recommended for use in children aged 12 years to 18 years with compromised respiratory function for the symptomatic treatment of colds.

### -When to use it

Take Panadeine at about the same time each day unless your doctor tells you otherwise.

**-How long to use it**

Please follow doctor instruction.  
Taking this medicine regularly for a long time can lead to addiction.

**-If you forget to use it**

- If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time.  
- Do not take a double dose to make up for a forgotten tablet. Remember to leave at least 4 hours between doses.  
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

**-If you use too much (overdose)**

- Talk to a doctor if you experience symptom such as pallor, nausea, vomiting, eating disorder, abdominal pain, respiratory depression, because you may be taking too much of this medicine.
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

**While you are using it**

**-Things you must do**

- Tell all the doctors and pharmacists who are treating you that you are taking Panadeine.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Panadeine.
- If symptoms persist or get worse, consult a doctor because this could be a signs of a serious condition.

**-Things you must not do**

- Do not take for longer than your doctor tells you to
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets
- This preparation contains PARACETAMOL.  
Do not take any other paracetamol containing medicines at the same time.

**-Things to be careful of**

**Driving and using machines**

Panadeine can make you feel dizzy or light headedness which may impair your ability to concentrate and react. If you are affected, do not drive or do not operate machines.

**Side Effect**

Tell your doctor or pharmacist if any of the following side effects appear:

- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem.
- You get swelling of the hands, feet, ankles, face, lips, or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This means you have an allergic reaction to Panadeine.
- Dizziness, light-headedness, drowsiness, confusion
- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.
- Constipation, nausea, vomiting
- Very rare cases of serious skin reactions such as Toxic Epidermal Necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis, fixed drug eruption, allergic reactions (hypersensitivity) including skin rash have been reported.
- Difficulty in passing water

**Allergy alert:** Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.

These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI /Vaccine Safety).

**Storage and Disposal of Panadeine**

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

**-Storage**

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Panadeine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 30°C.

**-Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

**-What it looks like**

Round, white, flat, beveled edge tablet with characteristic marking.

**-Ingredients:**

- Active ingredients are Paracetamol and Codeine Phosphate.
- Inactive ingredients are Potassium Sorbate, Stearic acid, Povidone, Maize Starch, Talc, Microcrystalline Cellulose, Pregelatinised Starch, Magnesium Stearate.

**-MAL Numbers:**

MAL19950068AZ

**Manufacturer**

Sanofi India Limited  
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**Product Registration Holder**

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