PANADEINE® 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 have severe and/or acute respiratory diseases
- You have acute breathing difficulties such as bronchitis, unstable asthma, emphysema (serious lung disease), respiratory depression (shallow breathing) or respiratory insufficiency (difficulty breathing).
- You have Glucose-6-phosphatedehydrogenase deficiency (an enzyme deficiency)
- You are an ultra-rapid metabolizer of CYP 2D6
- You have chronic constipation
- You have liver failure
- You are breastfeeding or planning to breastfeed.

Do not take codeine if you have a history of drug dependence, including alcohol dependence.

Do not take Panadeine during the third trimester of pregnancy**.**

Do not take codeine during labour, especially if the baby is premature.

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.

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

- difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
- compromised respiratory function (due to emphysema, kyphoscoliosis or obesity)
- known analgesic intolerance
- a history of drug dependence, including alcohol dependence
- pre-existing opioid dependence
- mild to moderate hepatocellular insufficiency
- severe renal insufficiency and sepsis
- chronic alcohol use including recent cessation of alcohol intake
- malnutrition and other sources of low glutathione reserves Gilbert's syndrome
- recent surgery on the stomach, intestine or urinary tract
- chronic constipation
- head injury or trauma
- prostate problems
- heart, liver or kidney problems
- urinary, bowel or gallbladder conditions
- Addison's disease
- Multiple sclerosis
- low blood pressure
- underactive thyroid
- convulsions, fits or seizures

-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.

Tell your doctor or pharmacist if you plan to have surgery.

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 help you relax, sleep or relieve anxiety, such as barbiturates, sedatives, tranquillisers, hypnotics, gabapentinoids, cannabis and centrally-active anti-emetics
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- gabapentin and pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
- medicines containing alcohol (ethanol), e.g. some cough syrups
- antihistamines (medicines used to treat allergies)
- Medicines used to thin the blood such as warfarin
- medicines to treat epilepsy or fits
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting)
- Colestyramine - for lowering blood cholesterol levels
- propantheline, a drug used to relieve stomach cramps or spasms
- medicines used to prevent travel sickness and to treat Parkinson's disease
- medicines used to treat high blood pressure
- medicines for diarrhoea, such as kaolin, pectin, and loperamide
- medicines used to treat depression
- monoamine oxidase inhibitors, medicines used to treat depression, taken within the last 14 days
- other opioid analgesics used to treat pain
- quinidine, a medicine used to treat abnormal or irregular heartbeat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- chloramphenicol, an antibiotic used to treat ear and eye infections
- flucloxacillin, zidovudine or rifampicin, drugs used to treat infections
- chelating resin
- medicines used to treat alcohol and/or opioid dependence (e.g. naltrexone, buprenorphine or methadone)
- medicines used to control electrolytes levels in kidney disease

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

Taking Panadeine with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Tell your doctor or pharmacist if you have allergies to aspirin, other NSAIDs, any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you take sedatives (medicines used to help you relax or sleep).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect 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.
- Do not take Panadeine during the third trimester of pregnancy
- You are breast-feeding or planning to breastfeed.
- Do not take Panadeine while you are breastfeeding. Codeine and morphine passes into breast milk.
- Do not take codeine during labour, especially if the baby is premature. This medicine may produce withdrawal effects in the newborn baby

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 Slow, unusual or difficult breathing, nausea, vomiting, drowsiness, dizziness or unconsciousness, slow or weak heartbeat, covulsions or fits 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.
If you take too many tablets you may feel nauseous, experience stomach pain, sweating, anxiety, lightheaded, dizzy or drowsy for example

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Depending on your body's individual ability to break down codeine, you may experience signs of overdose even when you take Panadeine as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

-If you stop taking Panadeine

If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Panadeine given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

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.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
- If your pain gets worse after you take this medicine, do not take more without first talking to your doctor.
- Talk to your doctor, if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking this medicine.

-Things you must not do

- Children: Do not give Panadeine 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.
- Do not take more than the recommended dose unless your doctor tells you to.
- Do not take Panadeine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- 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

- **Be careful if you are elderly, unwell or taking other medicines**.
  Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.
- **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.
  Children should be supervised while bike riding or engaging in other potentially hazardous activities to avoid potential harm.
- Serotonin Syndrome: Panadeine may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.
- Adrenal insufficiency: Long-term use of Panadeine cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.
- Infertility: Long-term use of Panadeine may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Side Effect

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 about side effects

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • nausea or vomiting • indigestion • constipation • stomach pain **Head and neurology related:** • dizziness • drowsiness or sleepiness • headache • dry mouth **Allergy related:** • skin rashes • sweating	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergy related: • shallow breathing, 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 • flushing of the face **Heart related:** • fast heartbeat **Skin related:** • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills • hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine, yellowing of the skin and eyes) **Head and neurology related:** • dizziness, light headedness	**Call your Doctor straight away, or go straight to the nearest hospital if you notice any of these serious side effects.**

• unusual or extreme mood swings • confusion **Eyes related:** • blurred vision **Metabolism related:** Symptoms of rapid breathing, rapid heart rate, changes in consciousness, drowsiness, nausea or vomiting caused by pyroglutamic acidosis (pyroglutamic acid accumulation due to low glutathione levels).	

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 visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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: Paracetamol and Codeine Phosphate.
- Inactive ingredients: 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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