

Panadeine Tablets

Paracetamol 500mg

Codeine phosphate hemihydrate 8mg

WHAT YOU SHOULD KNOW ABOUT THIS MEDICINE.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT ARE PANADEINE TABLETS AND WHAT ARE THEY FOR?

Panadeine Tablets contain paracetamol and codeine, which are both pain-relieving drugs. By working on your body in different ways paracetamol and codeine combine to relieve pain. Paracetamol also helps to reduce temperature when you have a fever. Codeine has some cough suppressant action.

Panadeine Tablets provide effective relief from pain, including:

- Headache
- Toothache
- Period pain
- Arthritic and rheumatic pain

Panadeine Tablets 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.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

2. BEFORE YOU TAKE PANADEINE TABLETS

Do NOT take Panadeine Tablets:

- if you are allergic to paracetamol, codeine or any of the other ingredients listed (See Section 6).

- if you are under 12 years
- if you suffer from severe asthma (have suffered from recent asthma attacks).
- if you are taking any other medicine containing paracetamol or codeine.
- if you are breastfeeding. The use of codeine containing products while breastfeeding may harm your baby.
- if you know that you metabolise very rapidly codeine into morphine
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Take special care & tell your pharmacist or doctor before taking Panadeine Tablets:

- if you suffer from any bowel disorders.
- if you suffer from any severe liver or kidney problems.
- if you have recently had gall bladder surgery or a similar operation.
- if you have large bowel including blockage of your bowel

[!] Warnings and Precautions

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. 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

Codeine 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 with breathing problems

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

Taking Panadeine Tablets with other medicines:

Tell your pharmacist or doctor before taking Panadeine Tablets if you are taking any other medicines, especially:

- medicines that you have bought yourself such as cough/cold remedies and other painkillers. Many of these will contain paracetamol and/or codeine and must not be taken while you are taking Panadeine Tablets.
- if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers (including monoamine oxidase inhibitors-MAOIs).
- medicines to help you sleep.

- medicine for high cholesterol levels or for the treatment of diarrhoea (cholestyramine).
- medicines to stop you feeling sick or vomiting (domperidone or metoclopramide).
- medicines to prevent blood clots (such as warfarin).

Taking Panadeine Tablets with food and drink:

- You should avoid alcohol when taking Panadeine Tablets.

Pregnancy & Breastfeeding:

Do not be use during pregnancy, unless advised by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Do not use this product or any codeine-containing products while breastfeeding. Codeine and morphine passes into breast milk. Use of these products may harm your baby.

Driving & using machines:

Panadeine Tablets may make you feel drowsy or dizzy. You should not drive or operate machinery until you know how they affect you.

3. HOW TO TAKE PANADEINE TABLETS

How many tablets should I take and how often?

Swallow Panadeine Tablets with water.

Adults, including the elderly, and children 12 years and over:

- Take 1-2 tablets every 6 hours as required.
- Do not take more often than every 6 hours.
- Do not take more than 8 tablets in 24 hours.
- Do not take for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.
- Do not take this product with any other product containing paracetamol or codeine.
- This product should be taken at the lowest dose for the shortest time necessary to relieve your symptoms. Taking this medicine regularly for a long time can lead to addiction.

Do not use in children under 12 years, due to the risk of severe breathing problems.

Do not exceed the stated dose.

If symptoms persist please consult your doctor.

Prolonged use except under medical supervision may be harmful. This product should only be used when completely necessary.

What should I do if I forget to take a dose?

Do not take a double dose to make up for a forgotten dose. You must allow at least 6 hours between doses.

WHAT SHOULD YOU DO IF YOU TAKE TOO MANY PANADEINE TABLETS?

Immediate medical advice should be sought in the event of overdose because of the risk of

irreversible liver damage.

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

4. POSSIBLE SIDE-EFFECTS

This medicine may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down. You may also become constipated. You may experience problems with your blood which mean that you may bleed or bruise easily (known as thrombocytopenia) or which make it more likely that you may get an infection (known as agranulocytosis).

If you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting, or if you have previously experienced breathing problems with aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product, stop taking this medicine and tell your doctor immediately.

Taking any type of pain reliever for headaches for a long period of time can make them worse. If this situation is experienced or suspected, stop taking this medicine and talk to your doctor.

Very rarely, some of the following side effects may occur:

- allergic reactions such as skin rash or itching, sometimes with breathing problems, or swelling of the lips, tongue, throat or face.
- skin rash or peeling of the skin which may be accompanied by mouth ulcers.

These effects go away once you stop taking the medicine. If any of these effects occur, or get serious, or if you notice any other side effect not listed in this leaflet, stop taking this medicine, and tell your doctor or pharmacist immediately.

This product contains codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

- **Keep out of the sight and reach of children.**

- Do not take this medicine after the expiry date (EXP) which is stated on the outer carton and blisters. The expiry date refers to the last day of that month.
- Do not store this medicine above 25°C.
- 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 protect the environment.

6. FURTHER INFORMATION

What Panadeine Tablets contain:

Panadeine Tablets contain paracetamol 500mg and codeine phosphate hemihydrate 8mg. The tablets also contain maize starch, povidone, potassium sorbate, microcrystalline cellulose, stearic acid, magnesium stearate, talc, pre-gelatinised starch.

What Panadeine Tablets looks like and contents of the pack:

Panadeine Tablets are white, flat, circular, bevel-edged tablets marked with the word "Panadeine" on one surface and a single scoreline on the other. The scoreline allows the tablet to be divided into equal halves. They are available in packs of 12, 24 or 48 tablets. Not all may be marketed.

Marketing authorisation holder and manufacturer:

The Product Authorisation holder is: GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24 Ireland, and all enquiries should be sent to this address.

The manufacturer is: GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford.

Panadeine is a registered trademark of the GlaxoSmithKline group of companies.

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