Panadeine
EXTRA STRENGTH TABLETS
Paracetamol 500mg
Codeine Phosphate Hemihydrate 12.8mg

PATIENT INFORMATION LEAFLET

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.
- If you have further questions, ask your doctor or pharmacist.
- If any of the side effects get serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What are Panadeine Extra Strength Tablets and what are they for?
2. Before you take Panadeine Extra Strength Tablets
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4. Possible side-effects
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1. WHAT ARE PANADEINE EXTRA STRENGTH TABLETS AND WHAT ARE THEY FOR?

Panadeine Extra Strength Tablets contain paracetamol and codeine, which are both pain killing 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. Panadeine Extra Strength Tablets provide effective relief for mild to moderate pain, including:

• Joint, muscle and back pain.
• Headaches, including migraine.
• Toothache.
• Sore throat.
• Period pains.
• Feverishness.
• Colds and flu.

Panadeine Extra Strength 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 EXTRA STRENGTH TABLETS

Do NOT take Panadeine Extra Strength Tablets:
• if you are allergic to paracetamol, codeine, other opioid painkillers or any other ingredients (listed in section 6).
• if you are under 12 years.
• if you suffer from acute asthma (have suffered from recent asthma attacks).
• if you suspect or know that you are pregnant.
• 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
• are taking any other medicine containing paracetamol or codeine

•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 Extra Strength tablets:
• if you are elderly and/or in poor health
• if you suffer from any bowel problems
• if you are an alcoholic
• if you suffer from any liver or kidney problems
• if you have recently had gall bladder surgery or a similar operation
• if you suffer from an enlarged prostate (difficulty passing water)
• if you are taking, or have recently taken, drugs for the treatment of depression.
• If you have Gilbert's Syndrome
• If you have haemolytic anaemia

[!] Warnings and Precautions

During treatment with Panadeine Extra Strength Tablets, tell your doctor straight away if:
• you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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

<u>Use in children and adolescents after surgery</u>
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.

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

<u>Adolescents older than 12 years of age</u>
Panadeine Extra Strength is not recommended in adolescents with compromised respiratory function for the treatment of cough or cold.

Taking Panadeine Extra Strength with other medicines:
Tell your pharmacist or doctor before taking Panadeine Extra Strength Tablets if you are taking any other medicines, especially:
• other 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 Extra Strength Tablets.
• medicines for the treatment of depression or anxiety, or medicines known as tranquilisers.
• 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)
flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

You may need to reduce the dose of PANADEINE EXTRA STRENGTH that you are taking. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Concomitant use of Panadeine Extra Strength Tablets and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be lifethreatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Panadeine Extra Strength Tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Taking Panadeine Extra Strength with Food & Drink:
• You should avoid alcohol when taking Panadeine Extra Strength Tablets.

Pregnancy and breastfeeding
Do not use during pregnancy unless advised by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.
Do not take Panadeine Extra Strength while you are breastfeeding. Codeine and morphine passes into breast milk. The use of codeine containing products while breastfeeding may harm your baby.

Driving & using machines:
Panadeine Extra Strength Tablets may make you feel drowsy or dizzy. You should not drive or operate machinery until you know how they affect you.

Important information about some of the ingredients of Panadeine Extra Strength tablets

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PANADEINE EXTRA STRENGTH TABLETS

How many tablets should I take and how often?

Swallow Panadeine Extra Strength tablets with water.

Adults and children 16 years and over:
• Take 1-2 tablets every 6-8 hours as required.

Children aged 12-15 years:
Take 1 tablet every 6-8 hours as required.

• Do not take more often than every 6 hours.
• **Do not take more than 4 doses in 24 hours.**

• **Do not take for more than 3 days without asking your doctor.** 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.

The elderly:
• Normal adult dosage is usually appropriate.
• However, if you are immobile and/or in poor health a reduced frequency of dosing may be appropriate. Please consult your doctor or a pharmacist.

Panadeine Extra Strength tablets should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Do not exceed the stated dose.

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?

Take your normal dose as soon as you remember.
Do **NOT** take a double dose to make up for forgotten tablets. You must allow at least 6 hours between doses.

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

Immediate medical advice should be sought in the event of overdosage 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

When using this product you may experience:

• Dizziness
• Drowsiness
• Nausea
• Vomiting
• Constipation

Stop taking this medicine and tell your doctor immediately if:
• You have previously had gall bladder removal surgery and experienced severe abdominal pain, nausea and vomiting
• You experience allergic reaction such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, face or throat.
• You experience skin rash or peeling, or mouth ulcers.
• You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with this product
• You experience unexplained bruising or bleeding

These reactions are rare.

A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). The frequency of this side effect is not known (cannot be estimated from the available data).

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 the 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 website: www.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 "use by" expiry date which is stated on the blister and carton ('EXP:' is the abbreviation used for expiry date). 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 Extra Strength Tablets contain:

Panadeine Extra Strength Tablets contain 500mg of paracetamol and 12.8mg of codeine phosphate hemihydrate.

The tablets also contain maize starch, pregelatinised starch, potassium sorbate, povidone, talc, magnesium stearate, microcrystalline cellulose, stearic acid and croscarmellose sodium, lactose monohydrate, hypromellose (E464), macrogol 4000, quinoline yellow (E104), erythrosine (E127) and
titanium dioxide (E171).

What Panadeine Extra Strength looks like and contents of the pack:

Panadeine Extra Strength are red capsule-shaped tablets, which are embossed on one side with "Extra". They are available in packs of 4, 6, 10, 12, 16, 20, 24, 32, 48, 60, or 100 tablets. Not all pack sizes may be marketed.

Product Authorisation holder and manufacturer:

The Product Authorisation holder is:
Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland.

The manufacturer is:
Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, X35 RY76, Ireland.

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

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