

FRONT

LEADING EDGE



Film-coated tablets Paracetamol 500mg Caffeine 65mg

PATIENT INFORMATION LEAFLET

Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Panadol Extra tablets carefully to get the best results from them.

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

In this leaflet:

1. What Panadol Extra tablets do
2. Check before you take Panadol Extra tablets
3. How to take Panadol Extra tablets
4. Possible side effects
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1. What Panadol Extra tablets do

Panadol Extra tablets are used for the relief of headache, migraine, backache, rheumatic pain, muscle pain, neuralgia, toothache and period pain. They also relieve discomfort in colds, flu, and sore throat and help reduce temperature. The tablets contain two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.



2. Check before you take Panadol Extra tablets



Do not take Panadol Extra tablets:

- if you have ever had an **allergic reaction** to paracetamol, caffeine or to any of the other ingredients (listed in Section 6).
- if you are taking any **other medicines containing paracetamol**.
- If you are **under 12 years**.



Check with your doctor before use if you:

- have **liver** or **kidney** problems, including **alcoholic liver disease**
- are underweight or malnourished
- regularly drink alcohol
- have a **severe infection** as this may increase the risk of **metabolic acidosis**.
Signs of metabolic acidosis include:
- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you get a combination of these symptoms.

You may need to avoid using this product altogether or limit the amount of paracetamol that you take.



If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick]) or **cholestyramine** (for **high cholesterol**). If you take **blood thinning drugs** (anticoagulants e.g. **warfarin**) and you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding. But you can still take **occasional** doses of Panadol Extra tablets at the same time as anticoagulants.



Important information about some of the ingredients

Contains parahydroxybenzoates which may cause allergic reaction (possibly delayed).



Pregnancy and breastfeeding

Not recommended during pregnancy, unless recommended by your doctor.

Use during breastfeeding should be avoided.

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3. How to take Panadol Extra tablets



Adults, elderly and children aged 12 years and over:

Swallow 2 tablets with water up to 4 times daily as needed.



- **Contains paracetamol**
- **Do not take more frequently than every 4 hours.**
- **Do not take more than 8 tablets in 24 hours.**
- **Do not take more than the recommended dose.**
- **If symptoms persist consult your doctor.**
- **Prolonged use except under medical supervision may be harmful.**
- **Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.**
- **Always use the lowest effective dose to relieve your symptoms.**

If your symptoms continue or your headache becomes persistent, **see your doctor.**

If you take too many tablets

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4. Possible side effects

Like all medicines Panadol Extra tablets can have side effects, but not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop taking the medicine and tell your doctor if you experience:

- allergic reactions such as skin rash, or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- or have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product.
- severe rash, peeling of the skin which may be accompanied by mouth ulcers.

These reactions are very rare.

The following side effects may also occur. **Tell your doctor** if you get them.

- In all the years paracetamol has been used there have been very rare reports of blood disorders, but these were not necessarily

caused by paracetamol. These effects should go away once you stop taking the medicine.

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 Panadol Extra tablets

Keep out of the sight and reach of children.

Store below 25°C. Do not use this medicine after the expiry date (EXP) shown on the carton and blisters. The expiry date refers to the last day of that month. 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.

6. Further information

Panadol Extra tablets are white to off white oval shaped coated tablets debossed "xPx" with P inside a circle on one side.

Active ingredient Each tablet contains Paracetamol 500mg and Caffeine 65mg.

Other ingredients Starch pregelatinised, Povidone K-25, Calcium carbonate, Crospovidone, Sodium methyl parahydroxybenzoate (E219), Sodium ethyl parahydroxybenzoate (E215), Sodium propyl parahydroxybenzoate (E217), Alginate Acid and Magnesium stearate.

Film coat Titanium dioxide, Hypromellose, Macrogol and Polysorbate 80.

Polishing agent Carnauba wax.

Packs of Panadol Extra tablets contain 4, 6, 12, 24, 30, 48, 60 and 96 tablets in blister strips. Not all pack sizes may be marketed.

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 Dunganvar Ltd., Knockbrack, Dunganvar, Co. Waterford, Ireland.

This leaflet was last revised in July 2017.

Panadol is a registered trademark of the GSK group of companies.

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