



Extra 500mg/65mg Soluble Effervescent tablets

500mg Paracetamol
65mg Caffeine

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 Soluble 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.

What is in this leaflet:

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

Panadol Extra Soluble tablets are used for the relief of headache, migraine, backache, rheumatic pain, muscle pain, 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 Soluble tablets



Do not take Panadol Extra Soluble 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.**



Ask your doctor before you take this medicine:

- if you have **liver or kidney disease**, including **alcoholic liver disease**
- if you are underweight or malnourished
- if you regularly drink alcohol
- if you 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** (for **nausea** [feeling sick] or **vomiting** [being sick]) or **chloramphenicol** (used to treat infections) or **colestyramine** (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 Soluble tablets at the same time as anticoagulants.



Taking Panadol Extra Soluble with food and drink

Panadol Extra Soluble contains 65mg of caffeine per tablet, therefore 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.



Pregnancy and breastfeeding

Not recommended for use during pregnancy. Use during breastfeeding should be avoided.



Important information about some of the ingredients of Panadol Extra Soluble tablets

Talk to your doctor or pharmacist if you need 1 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

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

3. How to take Panadol Extra Soluble tablets

Panadol Extra Soluble tablets should be dissolved in at least half a tumbler of water.



Adults, elderly and children aged 16 years and over:

Take 2 tablets, up to 4 times daily as required.

Children aged 12-15 years:

1 tablet up to 4 times daily as required.

Children under 12 years:

Do not give to children under 12 years.



- **Contains paracetamol.**
- **Do not take more frequently than every 4 hours.**

- **Do not take more than 4 doses in 24 hours.**
- **Do not exceed the stated dose.**
- **This product should be used only when clearly necessary.**
- **If symptoms persist consult your doctor.**
- **Prolonged use except under medical supervision may be harmful.**
- **If your symptoms continue or your headache becomes persistent, see your doctor.**
- **Always use the lowest effective dose to relieve your symptoms.**

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 Soluble tablets can cause side effects, although not everybody gets them. Very rare cases of serious skin reactions have been reported.

Stop taking the medicine and tell your doctor immediately if:

Very Rare (affects less than 1 in 10,000 people)

- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- You experience a 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 unexpected bruising or bleeding.
- You experience changes in blood tests that measure the function of your liver.

Other side effects include: insomnia, restlessness, anxiety, irritability, headaches, upset stomach, palpitations, nervousness and dizziness.

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 Panadol Extra Soluble tablets

Keep out of the sight and reach of children.

Do not store above 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 protect the environment.

6. Further information

Panadol Extra Soluble Effervescent Tablets. Flat, white tablets with bevelled edges, plain on one side, breakline on the other. The tablet can be divided into equal halves.

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

Other ingredients Sorbitol, saccharin sodium, sodium hydrogen carbonate, povidone, sodium laurilsulfate, dimeticone, citric acid (anhydrous) and sodium carbonate (anhydrous).

Packs of Panadol Extra Soluble contains 12 or 24 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 Dungarvan Ltd., Knockbrack, Dungarvan, Co. Waterford, Ireland.

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