

Patient Information Leaflet

Panadol 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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What Panadol Extra Soluble tablets do

Panadol Extra Soluble tablets are used for the relief of headache, 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 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
- are underweight (<50kg) or malnourished
- regularly drink alcohol

- suffer from severe dehydration
- are taking medicines that affect your liver
- 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(see Section 3).

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. This product is not recommended if you are taking lithium.

Please inform your doctor or pharmacist if you are taking flucloxacillin(antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis(when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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 or breastfeeding.

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. Do not take more than 8 tablets in 24 hours.

Do not take more than 4 tablets a day in the following situations, unless directed by your doctor:

- Weight less than 50kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

Children aged 12-15 years:

1 tablet up to 4 times daily as required. Do not take more than 4 tablets in 24 hours.

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 exceed the stated dose.**
- **This product should be used only when clearly necessary.**
- **If you have a high fever, or if symptoms get worse or persist for longer than 3 days, consult your doctor.**
- **Prolonged use except under medical supervision may be harmful.**
- **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 this medicine and tell your doctor immediately if you experience:

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

- allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.

- a skin rash or peeling, or mouth ulcers.
- or have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction with this product.
- unexpected bruising or bleeding.
- 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 to 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 Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland and all enquiries should be sent to this address.

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

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