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#### 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.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.
- · Contains Paracetamol.

#### In this leaflet:

- 1. What Panadol Extra Soluble Tablets do
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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, toothache and period pain. They also relieve sore throat and the fever, aches and pains of colds and flu.

The tablets contain two active ingredients. Paracetamol is a painkiller and also 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 prescription or non prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.



# Ask your doctor before you take this medicine:

- if you have liver or kidney disease, including alcoholic liver disease
- if you have been told by your doctor that you have an **intolerance to some sugars**
- 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 are underweight
- · if you regularly drink alcohol
- If you have severe infection or 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)
  - loss of appetite

During treatment with Panadol Extra Soluble Tablets, **tell your doctor straight away** 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 **colestyramine** (to lower

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blood 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 (called metabolic acidosis) that must have urgent treatment (see section 2).



## Pregnancy and breast feeding:

Due to the caffeine content of this product **it should not be used** if you are **pregnant** or **breast feeding**.

### 3. How to take Panadol Extra Soluble Tablets



Adults and children aged 16 years and over:

Take 2 tablets dissolved in a tumbler of water every 4 hours as needed. Do not take more than 8 tablets in 24 hours.



Children aged 12-15 years:

Give 1 tablet dissolved in a tumbler of water every 4 hours as needed. Do not give more than 4 tablets in 24 hours.



- Do not take more frequently than every 4 hours.
- · Do not take more than the recommended dose.
- Do not give to children under 12 years.
- 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.

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

# If you take too many tablets:

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

## 4. Possible side effects

Like all medicines, Panadol Extra Soluble Tablets can have side effects but not everybody gets them. A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

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

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- Skin rash or peeling, or mouth ulcers
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (frequency not known - see section 2).

#### 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 the Yellow Card Scheme at <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 use this medicine after the 'EXP' date shown on the pack. Store below 30°C.

### 6. Further Information

**Active ingredient:** Each tablet contains Paracetamol 500 mg and Caffeine 65 mg. **Other Ingredients:** Sodium bicarbonate, sorbitol powder (E 420), saccharin sodium, sodium lauryl sulphate, citric acid, sodium carbonate, polyvidone and dimeticone.

Packs of Panadol Extra Soluble Tablets contain 24 effervescent tablets.

**The marketing authorisation holder is** Haleon UK Trading Limited, The Heights, Weybridge, KT13 ONY, U.K. and all enquiries should be sent to this address.

**The manufacturer** is Haleon Ireland Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, X35 RY76, Ireland or Famar SA, Anthousa Av., 153 44 Pallini, Attikis, Greece.

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