

Patient Information Leaflet Text

Panadol Soluble Max 1000mg Paracetamol Effervescent granules PATIENT INFORMATION LEAFLET

WHAT YOU SHOULD KNOW ABOUT THIS MEDICINE.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to use Panadol Soluble Max 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 your doctor if your symptoms do not improve after three days.
- 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 Panadol Soluble Max is and what it is used for
2. Before you take Panadol Soluble Max
3. How to take Panadol Soluble Max
4. Possible side effects
5. How to store and dispose of Panadol Soluble Max
6. Further information

1. What Panadol Soluble Max is and what it is used for

Panadol Soluble Max contains paracetamol. **Paracetamol** is a pain killing drug that also helps to reduce your temperature when you have a fever.

Panadol Soluble Max provides relief from headaches, including migraine and tension headaches, backaches, rheumatic and muscle pain, neuralgia, toothache and period pain. Panadol Soluble Max also relieves the fever, aches and pains of colds and 'flu.

2. Before you take Panadol Soluble Max

<Cross symbol> DO NOT take Panadol Soluble Max if you:

- Are allergic to paracetamol or any of the other ingredients listed in Section 6.
- Are under 16 years old.
- Suffer from severe liver or kidney problems.
- Are taking any **other medicines containing paracetamol.**

<Exclamation point symbol> Take special care with Panadol Soluble Max:

- If your symptoms continue you should consult your doctor. You should not use this medicine for more than 3 days except on the advice of your doctor or pharmacist.
- If you are underweight or malnourished
- If you regularly drink alcohol
- If you suffer from inherited sugar intolerance or sugar absorption problems tell your doctor or pharmacist.

During treatment with Panadol Soluble Max, tell your doctor straight away if:

- 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).

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

<Exclamation point symbol> Important information about some of the ingredients of Panadol Soluble Max:

- Contains 0.933g of sucrose per dose. This should be taken into account if you have diabetes.
- Contains 0.488g sodium. This should be taken into account if you are on a low sodium diet.

<Exclamation point symbol> Taking other medicines with Panadol Soluble Max:

If you are taking or have recently taken any other medicines, including other medicines obtained without a prescription tell your pharmacist or doctor before taking Panadol Soluble Max especially:

- Medicines that you have bought yourself such as cough/cold remedies and other painkillers. Many of these will contain paracetamol and must not be taken while you are taking Panadol Soluble Max.
- An antibiotic called chloramphenicol.
- Any other medicines that might affect your liver. Always check the leaflet that comes with your other medicine.
- Medicines that thin the blood such as warfarin. Paracetamol may increase their effect.
- Medicines used to treat nausea and vomiting, such as metoclopramide or domperidone.
- If you are taking cholestyramine, used to treat high cholesterol.
- 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).

<Exclamation point symbol> Pregnancy and breastfeeding

If necessary, Panadol Soluble Max can be used during **pregnancy**. You should use the lowest possible dose for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced. You can take this product whilst **breastfeeding**.

<Exclamation point symbol> Driving using machines

Panadol Soluble Max has not been shown to affect your ability to drive or operate machinery.

3. How to take Panadol Soluble Max

How many Panadol Soluble Max sachets should I take and how often?

<tick symbol> Adults (including elderly) and children aged 16 years and over:

Dissolve one sachet of Panadol Soluble Max in a cup or mug of hot water and stir. Take one sachet every 4 to 6 hours. Do not take more frequently than every 4 hours. Do not take more than 4 sachets in 24 hours.

Not suitable for children under 16 years of age.

<Exclamation point symbol> Important information:

- Contains paracetamol.
- Do not exceed the stated dose.
- If symptoms persist consult your doctor.
- Prolonged use without medical supervision may be harmful.
- This product should only be used when clearly necessary.
- Always use the lowest effective dose to relieve your symptoms.

What should I do if I forget to take a dose?

Do **NOT** take a double dose to make up for a dose you have forgotten. You must allow at least 4 hours between doses.

WHAT SHOULD YOU DO IF YOU TAKE TOO MANY SACHETS OF PANADOL SOLUBLE MAX?

Immediate medical advice should be sought in the event of overdose because of the risk of irreversible liver damage.

Contact your doctor immediately and say exactly how much you have taken. Your doctor will advise you what to do. It is important to contact your doctor even if you feel well.

4. Possible side effects

Like all medicines, Panadol Soluble Max can have side effects, although not everybody gets them.

Very rare: may affect up to 1 in 10,000 people

Very rare cases of serious skin reactions have been reported. There have been rare reports of blood disorders including:

- A severe reduction in white blood cells which makes infections more likely.
- Stop taking this medicine and tell your doctor immediately if:
- 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. These reactions are very rare.

Not known: frequency cannot be estimated from the available data

A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (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 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 and dispose of this medicine**Keep out of the sight and reach of children.**

- Do not use this medicine after the expiry date (EXP) which is stated on the outer carton and sachets. 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 Panadol Soluble Max contains:**

Each sachet of Panadol Soluble Max contains 1000mg of paracetamol.

The sachets also contain sodium hydrogen carbonate, sucrose, povidone, saccharin sodium, anhydrous citric acid, anhydrous sodium carbonate and flavouring agents: lemon tetraol, orange tetraol (containing maize starch E306 and aromatic natural ingredients).

What Panadol Soluble Max looks like and contents of the pack

Panadol Soluble Max are white effervescent granules which come in sachets. They are available in packs of 5, 6, 10 or 12 sachets. 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 and all enquiries should be sent to this address.

The manufacturer is:

SmithKline Beecham S.A., Avda. de Ajalvir Km 2,500, 28806
Alcalá de Henares, Madrid, Spain.

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