

PATIENT INFORMATION LEAFLET

Panadol Actifast Lemon 500 mg Soluble Tablets

paracetamol

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

This medicine is available without prescription. However, you still need to take Panadol Actifast Lemon Soluble Tablets carefully to get the best results from it.

- 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 if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Panadol Actifast Lemon Soluble Tablets are and what they are used for

Panadol Actifast Lemon Soluble Tablets provide fast and effective relief of headaches, toothache, backache, rheumatic and muscle pains and period pain. It also relieves sore throat and the feverishness, aches and pains of colds and flu. Panadol Actifast Lemon Soluble tablets also provide relief from the pain associated with osteoarthritis as diagnosed by a doctor. Panadol Actifast Lemon Soluble tablets contain paracetamol which is an analgesic (a pain reliever which reduces aches and shivers) and an antipyretic (it reduces body temperature when you have a fever).

2. Before you take Panadol Actifast Lemon Soluble Tablets

<Cross symbol> Do not take Panadol Soluble Actifast Lemon tablets:

- If you are allergic to paracetamol or any of the other ingredients (listed in Section 6).
- If you are taking any **other medicines containing paracetamol**.
- If you are under **10 years of age**.

<Exclamation point symbol> Take special care & tell your pharmacist or doctor before taking Panadol Actifast Lemon Soluble Tablets

- If you have liver or kidney problems.
- If you have heart or blood pressure problems.
- If you retain fluid.
- If you are underweight or malnourished.
- If you regularly drink alcohol.

During treatment with Panadol Actifast Lemon 500 mg Soluble Tablets, tell your doctor straight away 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)

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.

<Exclamation point symbol> Taking Panadol Actifast Lemon Soluble Tablets with 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]),
- **colestyramine** (to lower **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. However you can still take **occasional** doses of Panadol Actifast Lemon Soluble tablets at the same time as anticoagulants.
- 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).

<Exclamation point symbol> Important information about some of the ingredients of Panadol Actifast Lemon Soluble Tablets

Each Panadol Actifast Lemon Soluble tablet contains 427 mg of sodium per tablet. The maximum recommended adult daily dose of this medicinal product contains 3416 mg sodium (found in table salt). This is equivalent to 171% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Panadol Actifast Lemon Soluble tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

Each Panadol Actifast Lemon Soluble tablet contains 50 mg of sorbitol (E420) in each tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Each Panadol Actifast Lemon Soluble Tablet contains 25 mg of aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

<Exclamation point symbol> Pregnancy and breastfeeding

If necessary, Panadol Actifast Lemon Soluble tablets 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**.

3. How to take Panadol Actifast Lemon Soluble Tablets

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Adults (including the elderly) and children aged 16 years and over:

1-2 tablets dissolved in water every 4 to 6 hours as required.

Do not take more than 8 tablets in 24 hours.

Children (10 to 15 years):

Give 1 tablet dissolved in water every 4 to 6 hours as required.

Do not give more than 4 tablets in 24 hours.

Do not give to children for more than 3 days without consulting a doctor.

Children under 10 years:

Do not give to children under the age of 10 years.

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Contains paracetamol.

Do not exceed the stated dose.

Do not take more frequently than every 4 hours.

Do not take with any other product containing paracetamol.

Please see your doctor if your symptoms do not improve.

Prolonged use, except under medical supervision, may be harmful.

This medicine should only be taken when necessary.

Always use the lowest effective dose to relieve your symptoms.

If you take more Panadol Actifast Lemon Soluble Tablets than you should

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 Actifast Lemon 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:

Very rare reactions (may affect up to 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.

These reactions are very rare.

Unknown frequency (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 Panadol Actifast Lemon Soluble Tablets

Keep this medicine out of the sight and reach of children. Do not use Panadol Actifast Lemon Soluble Tablets after the expiry date (EXP) which is stated on the carton and sachets. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

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. Contents of the pack and other information

What Panadol Actifast Lemon Soluble Tablets contain

Active ingredient: Each soluble tablet contains 500 mg of paracetamol.

Other ingredients: The soluble tablets also contain saccharin sodium, citric acid (anhydrous), sorbitol powder (E420), sodium hydrogen carbonate, sodium laurilsulfate, anhydrous sodium carbonate, povidone, dimeticone, aspartame, Drydex Imitation Lemon Flavour, Lemon Powder Flavour, Imitation Lemon Flavour and Imitation Candied Sugar Flavour.

What Panadol Actifast Lemon Soluble Tablets looks like and contents of the pack

Panadol Actifast Lemon Soluble Tablets are round white tablets with bevelled edges.

Panadol Actifast Lemon Soluble Tablets contain 12 or 24 tablets packed into sachets. The sachets are then enclosed in cardboard cartons. Not all pack sizes may be marketed.

The marketing 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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