

PACKAGE LEAFLET : INFORMATION FOR THE USER

Panadol Fever and Congestion 500 mg / 30 mg Film Coated Tablets Paracetamol and Pseudoephedrine Hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet:

1. What Panadol Fever and Congestion is and what it is used for
2. What you need to know before you take Panadol Fever and Congestion
3. How to take Panadol Fever and Congestion
4. Possible side effects
5. How to store Panadol Fever and Congestion
6. Contents of the pack and other information

1. What Panadol Fever and Congestion is and what it is used for

Panadol Fever and Congestion is used for the relief of nasal congestion when combined with fever and/or pain such as sore throat, sinus pain or headache in the common cold or flu. The medicine contains two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever. Pseudoephedrine hydrochloride is a decongestant which unblocks your nose and sinuses helping you breathe more easily without drowsiness.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you take Panadol Fever and Congestion

Do not take Panadol Fever and Congestion:

- If you are allergic to paracetamol, pseudoephedrine hydrochloride or any of the other ingredients in the product (listed in section 6).
- If you are taking other sympathomimetics (such as decongestants, tricyclic antidepressants).
- If you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication.
- If you have an overactive thyroid gland, enlarged prostate, heart problems, glaucoma (excessive pressure inside your eyes).
- If you have severe acute (sudden) or chronic (long term) kidney disease or kidney failure.
- If you have taken monoamine oxidase inhibitors (MAOIs), usually prescribed for depression, in the last two weeks.
- If you are taking the drug moclobemide for depression, beta-blockers for high blood pressure, the oxazolidinone class of antibiotics (e.g. furazolidone or linezolid), appetite suppressants, stimulant drugs called amphetamines (sometimes used to treat attention deficit disorders or excessive sleepiness).
- If you develop a feverish generalised erythema associated with pustules, stop

taking Panadol Fever and Congestion and contact your doctor or seek medical attention immediately. See section 4.

- If you are under 12 years.

Do not take anything else containing paracetamol while taking this medicine.

Warnings and precautions

Contains paracetamol.

Do not take more than the recommended dose as it may cause serious harm to your liver.

Do not use this medicine if you are taking any other medicines which may contain paracetamol including prescription or non-prescription medicines to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Do not take with any other flu, cold or decongestant product.

One of the active ingredients in Panadol Fever and Congestion, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Panadol Fever and Congestion than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

Pseudoephedrine causes narrowing of blood vessels (vasoconstriction). This action may be associated with the occurrence of the following sudden medical conditions. These conditions require immediate medical attention:

Acute Coronary Syndrome (ACS): This includes conditions such as a heart attack or unstable angina. Both are associated with a type of severe chest pain caused by blocked blood supply to parts of the heart. The sudden chest pain or discomfort (a feeling of pressure or tightness) can spread from your chest to your arms, jaw, neck, back or tummy. You may also feel lightheaded or dizzy, be sweating or experience shortness of breath while at rest. Stop using Panadol Fever and Congestion immediately and seek immediate medical assistance if you develop symptoms that may be signs of ACS.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Panadol Fever and Congestion immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

Sudden abdominal pain or rectal bleeding may occur with Panadol Fever and Congestion, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Panadol Fever and Congestion and contact your doctor or seek medical attention immediately. See section 4.

Reduction of blood flow to your optic nerve may occur with Panadol Fever and Congestion. If you develop sudden loss of vision, stop taking Panadol Fever and Congestion and contact your doctor or seek medical attention immediately. See section 4.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Talk to your doctor or pharmacist before taking Panadol Fever and Congestion:

- If you are due to undergo general anaesthesia, or have liver disease, including alcoholic

liver disease, or kidney problems, diabetes (too much sugar in your blood), psychosis (severe mental health problems in which the person loses contact with reality and is unable to think and judge clearly) irregular heart beat or phaeochromocytoma (a tumour near the kidney). You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

- If you suffer from glutathione depletion due to metabolic deficiencies.
- If you are more than 60 years old, as there is increased possibility of unwanted effects.
- If you are taking medicines that affect your liver.

Check with your doctor before use if you have liver or kidney problems, are underweight (<50 kg), become malnourished or regularly drink alcohol, as this may increase your risk of liver damage. You may need to reduce the amount of paracetamol that you take or avoid using this product altogether.

Other medicines and Panadol Fever and Congestion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines particularly:

- anticoagulants (used to thin the blood, e.g. warfarin);
- metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]);
- colestyramine (to lower blood cholesterol);
- medicines for high blood pressure; or vasoconstrictor agents such as ergot derivatives (sometimes prescribed for migraine or hyperprolactinemia)
- medicines for depression (tricyclic antidepressants e.g. amitriptyline);
- sodium bicarbonate (used to treat indigestion and certain kidney conditions).
- In case of surgery, it is advisable to stop treatment at least 24 hours before.
- The pseudoephedrine content in this product may induce a positive reaction during antidoping control tests.
- 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.

Pregnancy and breastfeeding

Panadol Fever and Congestion is not recommended during pregnancy or whilst breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This product can cause dizziness as a side effect which could affect your ability to drive or use machines. Do not drive or operate machinery if affected.

3. How to take Panadol Fever and Congestion

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the tablets with a glass of water.

The recommended dose is:

Adults (including the elderly):

Swallow 2 tablets up to 3 times daily

Leave at least 4 hours between doses.

Do not take more than 6 tablets in 24 hours.

Adolescents aged 16 to 18 years:

Give 1 to 2 tablets up to 3 times daily.

Leave at least 4 hours between doses.

Do not give more than 6 tablets in 24 hours.

Adolescents aged 12 to 15 years:

Give 1 tablets up to 3 times daily.

Leave at least 4 hours between doses.

Do not give more than 3 tablets in 24 hours.

Always use the lowest effective dose to relieve your symptoms for the shortest period of time necessary.

Do not take more frequently than every 4 hours.

Do not take for more than 5 days.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

If you take more Panadol Fever and Congestion than you should

Talk to your doctor immediately if you take too much of this medicine, even if you feel well. This is because too much paracetamol may cause delayed, serious and irreversible liver damage.

If your symptoms persist, see your doctor or pharmacist.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines **Panadol Fever and Congestion** can cause side effects, although not everybody gets them:

Stop taking this medicine and seek immediate medical attention if you experience:

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) Stop using immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include: • severe headache with a sudden onset • feeling sick • vomiting • confusion • seizures changes in vision.
- Inflammation of the colon due to insufficient blood supply (ischemic colitis)
- Breathing problems, especially if you have experienced a similar reaction with aspirin or non-steroidal anti-inflammatories.
- Skin rash or peeling, or mouth ulcers.
- Unexplained bruising or bleeding, or infections such as sore throat - this may be a sign of very rare changes in the blood.
- Allergic reactions such as skin rash or itching, sometimes with breathing problems (or a hissing sound when you breathe) or swelling of the mouth, lips, tongue, throat or face.
- Difficulty in passing urine. This is more likely to occur in men if you have an enlarged prostate gland.
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms

of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with Panadol Fever and Congestion. See section 2.

- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy). The frequency is “not known”. See section 2.

Other side effects

The following side effects may occur. Tell your doctor or pharmacist if you get them.

- Nausea [feeling sick], vomiting [being sick], dry mouth, sleep disturbance, nervousness and dizziness. These are common side effects, (may affect up to 1 in every 10 patients treated).
- Rapid or irregular heart rate, agitation and restlessness. These are uncommon side effects (may affect up to 1 in every 100 patients treated).
- High blood pressure, palpitations and hallucinations (particularly in children) are rare side effects, (may affect up to 1 in every 1,000 patients treated).
- Anxiety, headache and tremor [shivering]
- This product may have side effects that you would not notice yourself. These include changes in some liver test results.

Reporting side effects

If you get any side effects, tell your doctor, pharmacist or nurse. This includes any 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 Fever and Congestion

Keep this medicine out of the sight and reach of children.

Do not take the medicine after the “EXP” shown on the blister and outer carton. The expiry date refers to the last day of that month.

Do not use the medicine if you notice the tablets are soft.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Panadol Fever and Congestion contains:

- The active ingredients are Paracetamol 500mg and Pseudoephedrine Hydrochloride 30mg.
- The other ingredients are cellulose microcrystalline (E460), silica, colloidal anhydrous (E551), stearic acid (E570), magnesium stearate (E572), starch pregelatinised, povidone, crospovidone, croscarmellose sodium (E468), hypromellose (E464), macrogol, carnuba wax (E903), indigo carmine (E132).

What Panadol Fever and Congestion looks like and contents of the pack

The tablets are blue and white and marked with a figure “2” in a circle.

Packs contain 2, 5, 6, 10, 12, 16, 18, 24, 30 or 32 tablets.

Marketing Authorisation Holder and Manufacturer

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 Famar A.V.E., Anthoussa Plant, Anthoussa Avenue 7, Anthoussa Attiki, 15349, Greece.

This leaflet was last revised in May 2024.

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This medicinal product is authorised in the Member States of the EEA under the following names:

Greece	Panadol Cold & Flu 500mg / 30mg Επικαλυμμένα με λεπτό υμένιο δισκία
Ireland	Panadol Fever and Congestion Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg
Malta	Panadol Cold and Flu 500 mg / 30 mg Film-coated Tablets
Cyprus	Panadol Cold and Flu 500 mg / 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία
UK	Day Nurse 500 mg/ 30 mg Film-coated Tablets