

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1. What Panadol Cold and Flu is and what it is used for

Panadol Cold and Flu 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 Cold and Flu

Do not take Panadol Cold and Flu:

- If you are allergic to paracetamol, pseudoephedrine hydrochloride or other sympathomimetics (such as decongestants, appetite suppressants or stimulant drugs called amphetamines), or any of the other ingredients (listed in section 6).
- If you have high blood pressure, overactive thyroid gland, enlarged prostate, heart problems, glaucoma (excessive pressure inside your eyes).
- If you have kidney problems, unless your doctor tells you to.
- 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 antibiotics furazolidone or linezolid, appetite suppressants, or stimulant drugs called amphetamines (sometimes used to treat attention deficit disorders or excessive sleepiness).
- For more than 5 days unless your doctor tells you to.

- If you are under 12 years.

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

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Panadol Cold and Flu:

If you are due to undergo general anaesthesia, or have liver disease, including alcoholic liver disease, diabetes, irregular heart beat or phaeochromocytoma (a tumour near the kidney).

Other medicines and Panadol Cold and Flu

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]);
- cholestyramine (to lower blood cholesterol);
- medicines for high blood pressure;
- medicines for depression (tricyclic antidepressants e.g. amitriptyline);
- sodium bicarbonate (used to treat indigestion and certain kidney conditions).

Pregnancy and breastfeeding

Do not take Panadol Cold and Flu if you are pregnant or breastfeeding.

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 Cold and Flu

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, every 4 hours as needed.

Do not take more than 6 tablets (3 doses) in 24 hours.

Adolescents aged 12 to 18 years:

Give 1 to 2 tablets every 4 hours as needed.

Do not give more than 6 tablets in 24 hours.

Do not take more frequently than every 4 hours.

Do not take for more than 5 days.

Do not take more than the recommended dose.

If you take more Panadol Cold and Flu than you should

, Talk to your 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.

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 Cold and Flu** can cause side effects, although not everybody gets them:

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

- Sudden severe headache.
- Sudden abdominal pain or blood in your stools.
- 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 lips, tongue, throat or face.
- Difficulty in passing urine. This is more likely to occur if you have an enlarged prostate gland.

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 and hallucinations are rare side effects (may affect up to 1 in every 1,000 patients treated).
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Panadol Cold and Flu

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 Cold and Flu contains:**

- The active ingredients are Paracetamol 500 mg and Pseudoephedrine Hydrochloride 30 mg .
- 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 Cold and Flu 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 GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Famar S.A., Anthoussa, Athens, Greece.

This leaflet was last revised in July, 2016

Panadol is a registered trademark owned by or licensed to the GSK group of companies.

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
UK	Panadol Cold and Flu 500 mg/ 30 mg Film-coated Tablets

GSK lozenge/logo

Notes:

** Delete as appropriate.*

***To be completed nationally – the national reporting system listed in QRD Appendix V to be inserted*