

Panadol® Cold + Flu Vapour Release + Decongestant

Powder for oral solution in sachet.

Patient information leaflet

Description

Each sachet contains:

Paracetamol 600.0 MG
Phenylephrine Hydrochloride 10.0 MG

Other Ingredients:

Citric Acid Anhydrous, Honey Flavour, Maltose Starch Dried, Honey Flavour (F 7624P), Caramel Colour (E150c), Sodium Aspartate, Sucrose, Lemon Flavour (E13959), Sodium Citrate, Ascorbic Acid, Saccharin Sodium, Menthol Flavour (E41550).

What is Panadol Cold + Flu Vapour Release + Decongestant and what is it used for:

Panadol Cold + Flu Vapour Release + Decongestant is recommended for short term symptomatic relief of cold & flu symptoms including headache, sore throat, nasal congestion, sinusitis and its associated pain, body aches and pains, and fever.

Panadol Cold + Flu Vapour Release + Decongestant is also recommended for short term relief of sinusitis symptoms including sinus headache, sinus pain and nasal congestion.

How to take Panadol Cold + Flu Vapour Release + Decongestant ?

- Powder for oral solution.
- If symptoms persist, consult a doctor.
- Do not take more frequently than every 4 hours.
- Adults and children aged 12 years and over:**
- One sachet to be taken every 4-6 hours as required.
- Empty the contents of the sachet into a cup and half fill with very hot water. Stir well. Add cold water as necessary.
- Do not take more than 6 sachets in 24 hrs.
- Do not use for more than 7 days without medical advice.

Children under 12 years:

- Do not use for children under the age of 12 years.

Before you take Panadol Cold + Flu Vapour Release + Decongestant:

A. Do not take Panadol Cold + Flu Vapour Release + Decongestant in case of:

- Known or previous history of hypersensitivity to paracetamol, phenylephrine, ascorbic acid or any of the other ingredients in the product.
- You are taking, or have taken, within the last two weeks, monoamine oxidase inhibitors (MAOIs), usually used to treat depression.

B. Take special care with Panadol Cold + Flu Vapour Release + Decongestant:

- Do not exceed the recommended dose.
- This product contains Paracetamol, Phenylephrine. Do not take with any other product containing Paracetamol or other medicines for the relief of cough and colds, congestion or blocked nose.
- Keep this and all medication out of sight and reach of children.

Please see your doctor if your symptoms do not improve or persist or get worse or new symptoms occur because these could be signs of a serious condition.

Medical advice should be sought before taking Panadol Cold + Flu Vapour Release + Decongestant if you:

- Have been diagnosed with liver or kidney impairment. (Because Paracetamol is metabolised in the liver and excreted by the kidney in urine).
- You have high blood pressure, heart disease or blood vessel disease as occlusive vascular disease such as Raynaud's phenomenon (which may appear as pain in the fingers or toes in response to cold or stress).
- You are diabetic.
- You have hyperthyroidism (overactive thyroid).
- You have angle closure glaucoma (excessive pressure inside your eyes)
- You have pheochromocytoma (a tumour near the kidney)
- You have enlargement or problem of the prostate gland or difficulty urinating
- You are pregnant, trying to become pregnant or breastfeeding.

Use with caution if are you:

- Taking beta-blockers and other antihypertensive drugs.
- Taking tricyclic antidepressants.
- You are diabetic as this product contains sucrose 3.755g/sachet.
- Phenylephrine patient as it contains aspartame, a source of phenylalanine

Panadol Cold + Flu Vapour Release + Decongestant should not be used by:

- Patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency. This product contains sucrose.

C. Taking other medicines:

Paracetamol
The liver toxic effects of Paracetamol Cold + Flu Vapour Release + Decongestant may be increased by the use of alcohol.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Phenylephrine

Medical consultation should be sought before taking Panadol Cold + Flu Vapour Release + Decongestant if you are:

- Taking beta-adrenergic blocking agents and other antihypertensive. Phenylephrine may reduce the efficacy of beta blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
- Taking tricyclic antidepressants (used to treat depression), which may increase the risk of cardiovascular side effects with phenylephrine.
- Taking other sympathomimetics (such as decongestants, appetite suppressants, and amphetamine-like psychostimulants). Concomitant use of phenylephrine with sympathomimetic amines can increase the risk of cardiovascular side effects.

- Taking Digoxin and cardiac glycosides. Concomitant use of phenylephrine with digoxin or cardiac glycosides may increase the risk of irregular heartbeat or heart attack.
- Taking Monoamine oxidase inhibitors. Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular and hypertensive side effects.

D. Pregnancy and breast feeding:

Panadol Cold + Flu Vapour Release + Decongestant should not be used during pregnancy or breast feeding without medical advice.

Phenylephrine may be excreted in breast milk.

E. Ability to perform tasks that require judgement, motor or cognitive skills:

should not drive or operate machinery if affected by dizziness.

Possible side effects:

Paracetamol

If you are in doubt of any symptoms or sign please consult your physician.

Stop using Panadol Cold + Flu Vapour Release + Decongestant and consult 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 or bronchospasm with aspirin or non-steroidal anti-inflammatory, and experience a similar reaction with this product.
- You experience unusual fast pulse rate, or a sensation of an unusually fast or irregular heartbeat.
- You experience unexplained bruising or bleeding.
- You experienced liver dysfunction related symptoms or signs.
- You experience loss of vision, which may be due to abnormally high blood pressure in the eye. This is more likely to occur in those with glaucoma.
- You experience difficulty in passing water. This is more likely to occur in men with an enlarged prostate gland.

These reactions are rare

Phenylephrine

Adverse events have been observed in clinical trials with phenylephrine: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting. The reactions frequency of adverse events reported is unknown but likely to be rare as mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, and allergic dermatitis), dysuria, and urinary retention (this is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

* If any of the side effects gets serious or if you notice any side effects listed or not listed in this leaflet stop taking Panadol Cold + Flu Vapour Release + Decongestant and tell your doctor.

Overdosage:

Paracetamol

In massive over dosage exceeding 10g of paracetamol may cause liver damage. Early symptoms may include pallor, nausea, vomiting, (diaphoresis) and general malaise.

Clinical and laboratory evidence of liver damage may not be apparent until 48 to 72 hours post ingestion. Overdose should be promptly treated by gastric lavage followed by intravenous N-acetylcysteine or methionine without waiting for the results of plasma paracetamol levels and the time elapsed since ingestion.

*Additional antidote therapy is normally considered in light of further plasma paracetamol levels and the time elapsed since ingestion.

In all cases of suspected overdose, immediate medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Phenylephrine

Overdose of Phenylephrine is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include inability, restlessness, hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking drug such as Phentolamine.

Ascorbic Acid

High doses of ascorbic acid (>3000mg) may cause transient osmotic diarrhoea and gastrointestinal effects such as nausea and abdominal discomfort.

Effects of overdose of ascorbic acid would be subsumed by serious liver toxicity caused by paracetamol overdose.

How to store Panadol Cold + Flu Vapour Release + Decongestant?

Store below 30°C

Store in original container. Protect from Light and Heat.

Do not use the product if the sachet has been opened before or tampered in any way.

THIS IS A MEDICINE

- Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctors' prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and pharmacist are experts in the use of medicines, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribe for you.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICINE OUT OF REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists



GlaxoSmithKline

PANADOL™ is a registered trade mark of the GlaxoSmithKline group of companies.

Manufactured by: SmithKline Beecham SA, Alcala, Spain.

For GlaxoSmithKline

Updated based on GDS: V2
Date of Revision: 20th Nov 2012

No bleed
is required

First Bar

40mm

is required