

Package leaflet: Information for the user

Vicks Cold, Flu & Cough All In One 500mg/200mg/10mg powder for oral solution
Paracetamol, Phenylephrine hydrochloride, Guaifenesin

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

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Vicks Cold, Flu & Cough All In One is and what it is used for
2. What you need to know before you take Vicks Cold, Flu & Cough All In One
3. How to take Vicks Cold, Flu & Cough All In One
4. Possible side effects
5. How to store Vicks Cold, Flu & Cough All In One
6. Contents of the pack and other information

1. What Vicks Cold, Flu & Cough All In One is and what it is used for

Vicks Cold, Flu & Cough All In One contains three active ingredients:

- Paracetamol is a well-known pain killer (analgesic). It is effective against aches and pains including headache and sore throat and can also reduce fever (antipyretic).
- Guaifenesin (an expectorant) loosens phlegm which helps relieve chesty coughs.
- Phenylephrine hydrochloride (a nasal decongestant) reduces swelling in the passages of the nose and so relieves a blocked nose.

Vicks Cold, Flu & Cough All In One is designed for the short-term relief of symptoms of colds, chills, and flu (mild to moderate pain, fever, nasal congestion with an expectorant effect on chesty cough) in adults and adolescents aged 12 years and over.

You should only use Vicks Cold, Flu & Cough All In One if you have a combination of cold and flu symptoms such as pain and/or fever, nasal congestion, and chesty cough.

You must talk to your doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Vicks Cold, Flu & Cough All In One

Do not take Vicks Cold, Flu & Cough All In One:

- if you are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride, or to any of the other ingredients of this medicine (see section 6),
- if you have heart disease,
- if you have high blood pressure (hypertension),
- if you have impaired liver function or severe impairment of kidney function,
- if you have overactivity of the thyroid gland,
- if you are already taking another sympathomimetic medicine (such as pseudoephedrine, oxymetazoline, clonidine, salbutamol, and others),

- if you are diabetic,
- if you have glaucoma (increased pressure in the eye) of the narrow-angle type,
- if you have porphyria, which is a hereditary disorder characterised by excessive amounts of pigments in the urine,
- if you are taking tricyclic antidepressants,
- if you are taking beta blockers,
- if you are taking monoamine oxidase inhibitors (MAOIs) - used in treatment of depression or Parkinson's disease or have taken them in the last 14 days.

Warnings and precautions

Important: Contains paracetamol. Do not take with any other paracetamol-containing products.

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.

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

Talk to your doctor or pharmacist before taking Vicks Cold, Flu & Cough All In One:

- if you have alcoholic liver disease or regularly drink alcohol. Regular consumption of alcohol impairs liver function and may increase the risk of liver toxicity of products containing paracetamol,
- if you are male and have an enlarged prostate gland, as you may have more difficulty passing water,
- if you have a blood circulation problem (including Raynaud's syndrome),
- if you have a persistent cough that lasts for more than one week, a cough that brings up a lot of mucus (phlegm) or a chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema,
- if you have severe haemolytic anaemia, glucose-6-dehydrogenase deficit, chronic malnutrition disorder or if you are dehydrated.

During treatment with Vicks Cold, Flu & Cough All In One, tell your doctor straight away 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).

Children and adolescents

Vicks Cold, Flu & Cough All In One is not intended for children under 12 years of age.

Other medicines and Vicks Cold, Flu & Cough All In One

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor or pharmacist before you take Vicks Cold, Flu & Cough All In One if you are taking:

- medicine containing **paracetamol or other decongestants** for **colds and flu**.

If you are taking these, do not take Vicks Cold, Flu & Cough All In One:

- **monoamine oxidase inhibitors** (MAOIs) used in the treatment of **depression** or Parkinson's disease. **Do not take** Vicks Cold, Flu & Cough All In One if you have taken MAOIs in the last 14 days.
- **tricyclic antidepressants** for **depression**, such as amitriptyline or imipramine.
- medicine for **high blood pressure** (antihypertensives), or for improving heart function or correcting abnormal heart rhythms (digoxin, lanoxin, digitoxin).
- atropine sulfate, commonly used for eye examination, to treat low heart rate, and as an antidote for poisoning.
- **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment (see section 2).

- medicine for **nausea and vomiting** (such as metoclopramide or domperidone).
- medicine for **thinning the blood** (anticoagulants), such as warfarin or other coumarins.
- medicine for **high cholesterol** (such as cholestyramine).
- sedatives (barbiturates).
- medicines to control epilepsy, e.g. lamotrigine and barbiturates.
- acetylsalicylic acid and other salicylates used in reduction of pain, fever, and blood clots.
- alpha-adrenergic agonist such as medicines for attention-deficit/hyperactivity disorder (clonidine, guanfacine), medicines for spasticity (tizanidine).
- medicines for migraine headaches (ergotamine, dihydroergotamine).
- probenecid or AZT (zidovudine).
- isoniazid or rifampicin (used to treat or prevent tuberculosis).

Vicks Cold, Flu & Cough All In One with food, drink and alcohol

Do not take this product with alcoholic drinks.

Pregnancy, breast-feeding and fertility

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. If necessary and only if advised by a doctor or pharmacist, Vicks Cold, Flu & Cough All In One can be used during pregnancy. This product should only be used for breastfeeding under medical supervision. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor or midwife if the pain and/or fever are not reduced or if you need to take the medicine more often.

Driving and using machines

This product may cause dizziness or confusion. If you are affected do not drive or operate machinery.

Vicks Cold, Flu & Cough All In One contains Aspartame, Sucrose and Sodium:

- Aspartame (E951): This medicine contains 6 mg aspartame in each sachet. 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.
- Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sodium: This medicine contains 157 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 7.85% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Vicks Cold, Flu & Cough All In One

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.

The recommended dose is:

Adults and adolescents aged 12 years and over:

The recommended dose is one sachet which can be taken up to four times a day as required with the interval of at least four hours between doses. Do not take more than 4 sachets in any 24-hour period.

Do not exceed the stated dose.

Use in children and adolescents

This medicine is not intended for children under 12 years of age.

Method of administration

This medicine is a powder to be dissolved in water and taken as a hot drink.

Pour one sachet of powder into a mug of standard size and fill with hot but not boiling water (approx.250 ml). Allow to cool to a drinkable temperature and drink the opalescent yellow solution with citrus/menthol odour and taste.

Duration of treatment

If symptoms persist for more than 3 days or worsen, consult your doctor.

If you take more Vicks Cold, Flu & Cough All In One than you should:

Seek medical advice immediately if you accidentally take more than you should or if the medicine was accidentally ingested by a child, **even if you/the child feel well because of the risk of delayed, serious liver damage.**

If you forget to take Vicks Cold, Flu & Cough All In One.

Do not take a double dose to make up for a forgotten sachet.

If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking the medicine immediately and seek for urgent medical advice:

- Severe allergic reactions (anaphylaxis), e.g. skin rash, itching, swelling of lips, tongue, throat, face, wheezing or breathing difficulties may occur rarely (may affect up to 1 in 1,000 people).
- Very rare cases of serious skin reactions have been reported (may affect up to 1 in 10,000 people). If a skin reaction occurs, stop use and seek medical help right away. Steven-Johnson Syndrome/Toxic Epidermal Necrolysis can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals, and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- Certain disorders of the blood cells e.g. an increase in the number of nose bleeds or notice that you bruise more easily, may occur very rarely with paracetamol (may affect up to 1 in 10,000 people).

Other side effects

Frequency	Side effect
Common (may affect up to 1 in 10 people)	Loss of appetite, nausea, or vomiting
Rare (may affect less than 1 in 1,000 people)	Mild allergic reactions (such as skin rashes or hives) Stomachache, diarrhoea, headache, dizziness Rapid or irregular heartbeat (palpitations) High blood pressure Difficulty sleeping (insomnia), nervousness, shaking (tremor), irritability, restlessness, confusion, or anxiety Changes in blood tests that measure how your liver is working, jaundice
Very rare (may affect up to 1 in 10,000 people)	Severe reduction in blood cells which makes infections more likely
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 or pharmacist. This includes any possible 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vicks Cold, Flu & Cough All In One

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

Do not store above 25 °C.

Do take Vicks Cold, Flu & Cough All In One after the expiry date which is printed on the sachet or carton. The expiry date refers to the last day of that month.

Duration of storage after reconstitution: The reconstituted solution is stable for 90 minutes.

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

6. Contents of the pack and other information

What Vicks Cold, Flu & Cough All In One contains

The active substances are paracetamol, guaifenesin and phenylephrine hydrochloride. Each sachet of this medicine provides a single dose containing the **active ingredients**: paracetamol 500mg, guaifenesin 200mg and phenylephrine hydrochloride 10mg.

The **other ingredients** are: sucrose, citric acid, tartaric acid, sodium cyclamate, sodium citrate, aspartame (E951), acesulfame potassium (E950), powdered menthol, lemon flavour, lemon juice flavour, quinoline yellow (E104). See end of section 2.

What Vicks Cold, Flu & Cough All In One looks like and contents of the pack

Vicks Cold, Flu & Cough All In One is an off-white powder which is packed in laminated sachets in a carton box. 5 or 10 sachets are packed in a box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Procter & Gamble (Health & Beauty Care) Ltd.,
Weybridge, Surrey, KT13 0XP, UK

Manufacturer

Wrafton Laboratories Limited
Braunton, Devon, EX33 2DL
United Kingdom

This leaflet was last revised in January 2025