

## Package leaflet: Information for the user

### **Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution**

**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 Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution is and what it is used for**
- 2. What you need to know before you take Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution**
- 3. How to take Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution**
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- 1. What Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution is and what it is used for**

Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution is designed for the relief of symptoms of colds and flu.

It 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.

You should only use Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution if you have pain/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 Care Daymed Complete Hot Drink**

**Do not take Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution:**

- if you are allergic to paracetamol, guaifenesin, phenylephrine hydrochloride, or to any of the ingredients (see section 6)
- if you have heart disease
- if you have high blood pressure (hypertension)
- if you have a problem with your liver or severe kidney disease

- if you have overactivity of the thyroid gland
- 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
- if you are taking medicines to lower your blood pressure or treat angina.

### 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 Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution:

- if you have a problem with your liver functions
- 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 persistent or 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.

### Children and adolescents

Do not give Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution to children under 12 years of age.

### Other medicines and Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution

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 Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution if you are taking:

- medicine containing **paracetamol or other decongestants** for **colds and flu**.  
If you are taking these, do not take Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution.
- 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.
- **monoamine oxidase inhibitors** (MAOIs) used in the treatment of **depression** or Parkinson's disease. **Do not take** Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution 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), including beta-blockers, or for improving heart function or correcting abnormal heart rhythms (digoxin, lanoxin, digitoxin).
- phenothiazines (which are used either as antipsychotic drugs to treat conditions such as schizophrenia or paranoia, or to prevent nausea and vomiting).
- 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)

- probenecid or AZT (zidovudine)
- isoniazid (used to treat or prevent tuberculosis)

**Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution with food, drink and alcohol**

Do not take this product with alcoholic drinks.

**Pregnancy, breast-feeding and fertility**

Taking Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution during pregnancy or breast feeding is not recommended: you should ask your doctor or pharmacist for advice before use.

**Driving and using machines**

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

**Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution 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 Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution**

Always take this medicine exactly 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 children over 12 years:**

**1 sachet every 4-6 hours as required. Do not take more than 4 sachets in any 24 hour period.**

Do not exceed the stated dose.

Do not take this medicine with alcoholic drinks

**Use in children and adolescents**

Do not give to 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**

Long term use of the product is not recommended.

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

**If you take more Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution than you should:**

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

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

**If you forget to take Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution**

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

#### **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:

- Very rare cases of serious skin reactions have been reported. Severe allergic reactions (anaphylaxis), wheezing or breathing difficulties may occur rarely. (Rare: affects less than 1 in 1000 people, but more than 1 in 10,000 people; Very rare: affects less than 1 in 10,000 people ).
- Certain disorders of the blood cells and pancreatitis (inflammation of the pancreas) may occur very rarely with paracetamol (affect less than 1 in 10,000 people).

#### **Other side effects**

<b>Frequency</b>	<b>Side effect</b>
Common (affect less than 1 in 10 people, but more than 1 in 100 people).	Loss of appetite, nausea or vomiting
Rare (affect less than 1 in 1000 people, but more than 1 in 10,000 people).	Mild allergic reactions (such as skin rashes or hives) Stomach ache, diarrhoea Headache, dizziness Rapid heartbeat (palpitations); High blood pressure Difficulty sleeping (insomnia), nervousness, shaking (tremor), irritability, restlessness, confusion or anxiety. Abnormal liver blood test

#### **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 HPRC Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution**

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

Store below 25 °C.

Do not use this medicine 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 Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution 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 200 mg and phenylephrine hydrochloride 10 mg.

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 Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution looks like and contents of the pack**

Paracetamol 500 mg, Guaifenesin 200 mg, Phenylephrine HCl 10 mg, Powder for oral solution is an off-white coloured powder which is packed in laminated sachets in a carton box. The product is available in cartons of 5 and 10 sachets.

Not all pack sizes may be marketed

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