

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Panadol Cold & Flu Hot Lemon Powder for Oral Solution  
Paracetamol 600mg  
Ascorbic acid 40mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	mg / 6 g powder sachet
Paracetamol	600.00
Ascorbic Acid	40.00

Excipients: each 6 g powder sachet contains 3700 mg sucrose and approximately 113 mg sodium.

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Powder for oral solution.

Sachets containing a pale yellow free flowing powder with an odour of lemon.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

The relief of symptoms of influenza and feverish colds including headache, and aches and pains. Also effective in the relief of menstrual pain, toothache and musculoskeletal disorders.

### 4.2 Posology and method of administration

#### Directions for use

Empty contents of sachet into mug. Half fill with very hot water. Stir well. Add cold water as necessary and sugar if desired.

#### Recommended Dose and Dosage Schedule

##### Adults (including elderly) and children aged 12 years and over:

One sachet to be taken every four hours, if necessary, up to a maximum of six sachets in any 24 hours.

Not to be given to children under 12 years of age except on medical advice.  
Do not take more often than every 4 hours.

Do not take more than 6 sachets in any 24 hours.

The lowest dose necessary to achieve efficacy should be used.

### 4.3 Contraindications

Hypersensitivity to any of the ingredients. Severe hepatic or renal impairment.

### 4.4 Special warnings and precautions for use

Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Caution is advised in the administration of paracetamol to patients with impaired renal and hepatic function or if they are taking other drugs that affect the liver. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Cases of hepatic dysfunction/failure has been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have low body mass index or are chronic heavy users of alcohol.

Caution in patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.

Keep out of the sight and reach of children.

If symptoms persist consult your doctor.

Prolonged use except under medical supervision may be harmful.

Do not take with other products containing paracetamol.

Contains paracetamol.

Do not exceed the stated dose.

This product should only be used when clearly necessary.

Patients with rare hereditary problems of fructose intolerance, glucose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains 113mg sodium per dose. To be taken into account by patients on a sodium-controlled diet.

### 4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol is reported to increase the half-life of chloramphenicol.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. 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. The hepatotoxicity of paracetamol may be potentiated by other drugs that affect the liver.

### 4.6 Fertility, pregnancy and lactation

Use during pregnancy and lactation is not contraindicated. However caution should be exercised and use during pregnancy should be on the advice of a doctor.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following convention has been utilised for the classification of undesirable effects: very common ( $\geq 1/10$ ), common ( $\geq 1/100$ ,  $< 1/10$ ), uncommon ( $\geq 1/1,000$ ,  $< 1/100$ ), rare ( $\geq 1/10,000$ ,  $< 1/1000$ ), very rare ( $< 1/10,000$ ), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through post marketing data.

Paracetamol

Body System	Undesirable Effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune System disorders	Anaphylaxis, Cutaneous hypersensitivity reactions, Angiodema, Stevens Johnson syndrome  Very rare cases of serious skin reactions have been reported.	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

4.9 Overdose

Paracetamol

Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.

Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may cause coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration. Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol.

It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.  
Some patients may be at increased risk of liver damage from paracetamol toxicity.

Risk Factors include: If the patient;

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amount.
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

#### Emergency Procedure:

Immediate transfer to hospital.

Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.

Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour. The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines.

Symptomatic treatment should be implemented.

#### **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.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC code/pharmacotherapeutic group: N02BE51

**Paracetamol:** Provides the analgesic and antipyretic actions.

**Ascorbic acid** is commonly included in combination cold products to compensate for vitamin C losses that may occur in the initial stages of acute viral infections, including the common cold.

### **5.2 Pharmacokinetic properties**

**Paracetamol** - is readily absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine, mainly as glucuronide and sulphate conjugates.

**Ascorbic acid** - is readily absorbed from the GI tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic acid in excess of the body's needs is eliminated in the urine as metabolites.

### **5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose  
Sodium citrate  
Citric acid (anhydrous)  
Sodium cyclamate  
Saccharin sodium  
Colloidal anhydrous silica  
Lemon flavour (containing maltodextrins)  
Natural curcumin (E 100)  
Maize starch (dried)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The product is packed in laminate sachets comprising paper / polythene / aluminium foil / polythene. Five or ten sachets may be contained in a box board carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Limited  
12 Riverwalk  
Citywest Business Campus  
Dublin 24  
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 October 1987  
Date of last renewal: 20 October 2007

**10 DATE OF REVISION OF THE TEXT**

July 2017