Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol Cold & Flu Hot Lemon with Honey Powder for Oral SolutionParacetamol 600mgAscorbic 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 136 mg sodium.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution
Sachets containing an off white free flowing powder for oral solution 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 16 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 16 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 for the shortest duration of treatment.

4.3 Contraindications

This product iscontraindicated in patients with hypersensitivity to paracetamol, ascorbic acid or toany of the excipients listed in section 6.1 and in patients with severe hepaticor 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 may require liver transplant or lead to death.

Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range. These cases were reported in patients with one or more risk factors for hepatotoxicity including

low body weight (<50 Kg), renal and hepatic impairment, chronic alcoholism, sepsis and in acute and chronic malnutrition (low reserves of hepatic glutathione). . The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Paracetamol should be administered with caution to patients with these risk factors.

Caution is also advised in conditions which may predispose to glutathione deficiency (see section 4.9).

Doses of paracetamol should be reviewed at clinically appropriate intervals and patients should be monitored for emergence of new risk factors for hepatotoxicity which may warrant dosage adjustment.

Patients with glutathione depleted states may also be at increased risk of metabolic acidosis.

Keep out of the reach and sight of children.

In general, medicinal products containing paracetamol should be taken for only a few days without the advice of a physician or dentist and not at high doses.
If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.
Patients should be advised not to take other paracetamol containing products concurrently. Taking multiple daily doses in one administration can severely damage the liver; in such case medical assistance should be sought immediately.

Do not exceed the stated dose.

This medicinal product contains 3.7 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicinal product contains 136mg of sodium per dose, equivalent to 6.8% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equal to 40.8% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt 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. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity from paracetamol. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Lactation
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

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 (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥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	Thrombocytopaenia	Very rare
Immune System disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes, angiodema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis. Very rare cases of serious skin reaction have been reported.	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepaticdysfunction	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, website: www.hpra.ie.

4.9 Overdose

Symptoms ofparacetamol overdose in the first 24 hours may include pallor, nausea,vomiting, anorexia, and abdominal pain. Abnormalities of glucose metabolism andmetabolic acidosis may occur. Paracetamol overdose may cause liver failurewhich may require liver transplant or lead to death. Clinical signs of liverinjury occur usually after 24 to 48 hours. Four to 6 days after initialingestion, hepatic necrosis leading to hepatic failure may occur which may leadto coagulation defects, followed byhepatic encephalopathy and failure of multiple organs. Liver damage resultswhen excess quantities of a toxic metabolite (usually adequately detoxified byglutathione when normal doses of paracetamol are ingested) become irreversiblybound to liver tissue. Acute renal failure with acutetubular necrosis may develop even in the absence ofsevere liver damage. Cardiac arrhythmias have been reported and acutepancreatitis has been observed, usually with hepatic dysfunction and livertoxicity.

Some patients may be at increased risk of liver damage from paracetamol toxicity:
Risk factors include;
• Patients with liver disease
• Young children
• Patients who regularly consume ethanol in excess of recommended amounts
• Patients with glutathione depletion e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Treatment

Immediate medical attention 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 the overdose of paracetamol has been ingested within the previous 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.

General Considerations
If overdose is confirmed or suspected, seek immediate advice from your Poison Centre. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.
Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

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 (GI) 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 is no preclinical data of relevance to the prescriber which is additional to that already included in other sections of the SPC.
Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium citrate
Citric acid anhydrous
Maize Starch (dried)
Sodium cyclamate
Saccharin sodium
Lemon Flavour
Honey
Caramel (E150)

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.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/011/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 May 1990

Date of last renewal: 20 October 2007

10 DATE OF REVISION OF THE TEXT

May 2023