SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hot Lemon Cold Relief Powders

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol	650mg
Phenylephrine hydrochloride	10mg

Excipient(s) with known effect
Aspartame
Sucrose
Sodium Citrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of sinus pain and congestion and the symptoms of cold and influenza including headache, sore throat and “feverishness”.

4.2 Posology and method of administration

Posology

Adults, including the elderly and children over 12 years of age:

One sachet up to four times daily. Dissolve the contents of one sachet in a tumbler of hot (not boiling) water. Stir well. Add cold water as necessary and sugar if desired.
Not more than four sachets to be taken in 24 hours. The dose should not be repeated more frequently than every four hours. Do not take continuously for more than 3 days without medical advice.

Children under 12 years:

Not recommended for children under 12 years of age except on medical advice.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Concomitant use of other sympathomimetic decongestants.

Phaeochromocytoma.

Closed angle glaucoma.

Hypertensive patients or those taking or who have taken in the last two weeks monoamine oxidase inhibitors, tricyclic antidepressants or beta-blockers (see section 4.5). Hepatic or renal impairment, diabetes, hyperthyroidism and cardiovascular disease.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Medical advice should be sought before taking this product in patients with these conditions:

- An enlargement of the prostate gland
- Occlusive Vascular disease (e.g. Raynaud's Phenomenon)

This product 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 sucrase-isomaltase insufficiency should not take this medicine.

Contains sucrose. This should be taken into account in patients with diabetes.

This product contains a source of phenylalanine. May be harmful for people with phenylketonuria.

This medicinal product contains 5.3mmol of sodium per dose. To be taken into consideration by patients on a sodium controlled diet.

Do not to exceed the stated dose.

Patients should be advised not to take with any other paracetamol-containing or any other cold, flu or decongestant products concurrently.

Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed, serious liver damage.

If symptoms persist consult your doctor.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol

Anion–exchange resins:	Absorption reduced by colestyramine
Antibacterials	Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4).
Anticoagulants	The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.
Antiepileptics	Carbamazepine, phenobarbital, phenytoin and primidone can reduce the effects of paracetamol and increase the risk of hepatotoxicity. Paracetamol may increase lamotrigine

	metabolism.
Motility stimulants	The speed of absorption of paracetamol may be increased by metoclopramide or domperidone.

Phenylephrine hydrochloride

Adrenergic neurone blockers	May enhance the hypertensive effect of phenylephrine.
Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa)	Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
Digoxin and cardiac glycosides	Increase the risk of irregular heartbeat or heart attack
Ergot alkaloids	(ergotamine and methylsergide) increased risk of ergotism.
Monoamine oxidase inhibitors (including moclobemide)	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see contraindications).
Oxytocin	Potential increased risk of hypertension with oxytocin.
Sympathomimetic amines	Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects (hypertensive effects).
Tricyclic antidepressants (e.g. amitriptyline)	May increase the risk of cardiovascular side effects with phenylephrine.

4.6 Fertility, pregnancy and lactation

Paracetamol
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol use in the recommended dosage, but patients should follow the advice of their doctor regarding its use. A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. 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.

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

Phenylephrine hydrochloride

The safety of phenylephrine during pregnancy has not been established but there is some evidence suggesting a possible association of foetal abnormalities with first trimester exposure to phenylephrine. As an alpha-adrenoceptor stimulant, it might provoke uterine changes, which can result in foetal asphyxia.. There is no information on the excretion of phenylephrine into breast milk; however no clinical problems have been documented.

In view of the above, Hot Lemon Cold Relief Powder should be avoided during pregnancy and lactation unless prescribed by a doctor.

4.7 Effects on ability to drive and use machines

Paracetamol has no or negligible influence on the ability to drive and use machines.

Phenylephrine hydrochloride

May cause dizziness, if affected, do not drive or operate machinery.

4.8 Undesirable effects

Undesirable effects Paracetamol Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis These are not necessarily causally related to paracetamol
Metabolism and nutrition disorders	High anion gap metabolic acidosis
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome/toxic epidermal necrolysis.
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

*There have been cases of bronchospasm with paracetamol but these are more likely in asthmatics sensitive to aspiring or other NSAIDs.

Phenylephrine hydrochloride
The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events.

Body System	**Undesirable effect**
Psychiatric disorders	Nervousness, irritability, restlessness, and excitability
Nervous system disorders	Headache, dizziness, insomnia
Cardiac disorders	Increased blood pressure
Gastrointestinal disorders	Nausea, vomiting

Adverse reactions identified during post-marketing use are listed below. The frequency of these reactions is unknown but likely to be rare.

Eye disorders	Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma
Cardiac disorders	Tachycardia, palpitations
Skin and subcutaneous disorders	Allergic reactions (e.g. rash, urticaria, allergic dermatitis). Hypersensitivity reactions – including that cross-sensitivity may occur with other sympathomimetics
Renal and urinary disorders	Dysuria, urinary retention. This is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Paracetamol

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors
If the patient

a. Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

b. Regularly consumes ethanol in excess of recommended amounts.

Or

c. Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria**,** may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Treatment

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention**.** Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

Phenylephrine hydrochloride

Symptoms
Phenylephrine overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include hypertension and possibly reflux bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than required to cause paracetamol-related toxicity.

Treatment
Treatment should be as clinically appropriate. Severe hypertension may need to be treated with an alpha blocking drug such as phentolamine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In therapeutic doses, paracetamol has antipyretic and mild analgesic actions together with some anti-inflammatory activity. These effects are thought to be related to inhibition of prostaglandin synthesis.

Phenylephrine is a relatively selective α_1-adrenoceptor agonist. It has a weak α_2-adrenoceptor agonist activity and some activity as a β-adrenoceptor. It is also termed a sympathomimetic vasoconstrictor. Its efficacy as a decongestant results from its vasoconstrictor properties. Vasoconstriction within the nasal mucosa decreases the volume of mucosal tissue and decreases the resistance to air flow through the nasal passages.

5.2 Pharmacokinetic properties

Paracetamol

Absorption - Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral ingestion. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours.

Paracetamol is metabolised predominantly in the liver and excreted in the urine, mainly as the glucuronide and sulphate conjugates. Less than 5% is

excreted as unchanged paracetamol. A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine) which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause tissue damage.

Phenylephrine

Phenylephrine is readily absorbed after oral administration but is subject to extensive presystemic metabolism much of which occurs in the enterocytes. As a consequence, systemic bioavailability is only about 40%. Following administration, peak plasma concentrations are achieved in 1-2 hours. The mean plasma half-life is in the range of 2-3 hours. Penetration into the brain appears to be minimal.

Biotransformation and Elimination - Following absorption, the drug is extensively biotransformed in the liver. Both phenylephrine and its metabolites are excreted in urine, with <20% as unchanged drug. There is no evidence that any of the metabolites are pharmacologically active.

Distribution - The volume of distribution is between 200 and 500l, but there are no data on the extent of plasma protein binding.

5.3 Preclinical safety data

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

Caster sugar
Sodium citrate
Citric acid
Tartaric acid
Maize starch
Lemon juice
Ascorbic acid
Aspartame
Natural colour (E100)
Lemon flavour

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years from the date of manufacture.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

The immediate container for Hot Lemon Cold Relief Powder is a laminated sachet. The sachets are packaged in an outer carton, with a patient information leaflet. The pack size is 5 or 10 sachets per carton.

Specification:
40 gsm gloss coated paper
12 gsm polyethylene
8 micron aluminium
23 gsm polyethylene

6.6 Special precautions for disposal

The product should be dissolved in hot water before administration.

7 MARKETING AUTHORISATION HOLDER

Wockhardt UK Ltd
Ash Road North
Wrexham LL13 9UF
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 29831/0168

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th July 1998

10 DATE OF REVISION OF THE TEXT

02/05/2025