SUMMARY OF PRODUCT CHARACTERISTICS

1) Name Of The Medicinal Product

Beechams Cold & Flu Hot Lemon

2) Qualitative and Quantitative Composition

Active Constituents	mg / 6g powder
Paracetamol	600.00
Phenylephrine Hydrochloride	10.00

3) Pharmaceutical Form

Powder

4) Clinical Particulars

4.1 Therapeutic Indications

The relief of symptoms of influenza, feverishness, chills and feverish colds including headache, sore throat pain, aches and pains, nasal congestion, sinusitis and its associated pain, and acute nasal catarrh.

4.2 Posology and Method of Administration

Directions for use

Empty contents of sachet into beaker. 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 to six hours, as necessary. Do not exceed six sachets per 24 hours.

Do not take continuously for more than 7 days without medical advice.

Not to be given to children under 16 years, of age except on medical advice.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.
Concomitant use of other sympathomimetic decongestants

Phaeochromocytoma
Closed angle glaucoma
Hypertensive patients or those taking or 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.

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

- An enlargement of the prostate gland
- Occulusive 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 4g sucrose per dose. This should be taken into account in patients with diabetes.

Do not exceed the stated dose.
Patients should be advised not to take other paracetamol-containing or any other cold, flu or decongestant products concurrently.
If symptoms persist consult your doctor.
Keep out of the reach and sight of children.

Special label warnings
Do not take with other flu, cold or decongestant products. 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.
Special leaflet warnings
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.

4.5 Interactions with other Medicinal Products and other forms of Interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. 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.

Phenylephrine should be used with caution in combination with the following drugs as interactions have been reported

Monoamine oxidase inhibitors (including moclobemide)	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see contraindications).
Sympathomimetic amines	Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.
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.
Tricyclic antidepressants (e.g. amitriptyline)	May increase the risk of cardiovascular side effects with phenylephrine.
Ergot alkaloids	(ergotamine and methylsergide) increased risk of ergotism
Digoxin and cardiac glycosides	Increase the risk of irregular heartbeat or heart attack

4.6 Pregnancy and lactation

Due to the phenylephrine content this product should not be used in pregnancy or whilst breast-feeding without medical advice. Phenylephrine may be excreted in breast milk.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by dizziness.

4.8 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
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bromchospasm *
Hepatobiliary disorders	Hepatic dysfunction

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

Phenylephrine

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.

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, phenobarbitone, 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.

Management:

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

Symptoms and signs
Phenylephrine overdosage is likely to result in effects similar to those listed under advserse reactions. Additional symptoms may include hypertension and possibly reflux bradycardia. In severe cases confusion, hallucinations, seizures and arrythmias 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 Particulars

Paracetamol provides the analgesic and antipyretic actions.

Phenylephrine Hydrochloride is a sympathomimetic agent and provides relief from nasal congestion due to its vasoconstrictor action.

5.2 Pharmacokinetic Particulars

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.

Phenylephrine Hydrochloride - Due to irregular absorption and first pass metabolism by monoamine oxidase in the gut and liver, phenylephrine has reduced bioavailability from the gastrointestinal tract. It is excreted in the urine almost entirely as the sulphate conjugate.

5.3 Preclinical Safety Data

None

6) Pharmaceutical Properties

6.1 List of Excipients

Ascorbic Acid, Sucrose, Sodium citrate, Citric acid, Maize starch, Sodium cyclamate, Saccharin sodium, Colloidal anhydrous silica, Lemon Flavour, Natural curcumin (E100).

6.2 Incompatibilities

None stated.

6.3 Shelf Life

36 months.

6.4 Special Precautions for Storage

Store below 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.

6.6 Instructions for use/handling

None

7) Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom

8) Marketing Authorisation Number

MA932/00103

9) Date of First Authorisation/Renewal of Authorisation

23.02.2006 / 11.07.2011

10) Date of Revision of Text

07-08-2019