SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hot Lemon Cold Relief Powder.

Superdrug Hot Lemon Cold Relief Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol BP 650 mg

3 PHARMACEUTICAL FORM

Powder in sachet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief from cold and flu symptoms

4.2 Posology and method of administration

Adults and Children over 12 years

Contents of one sachet (with hot water).
Dosage should not be repeated more frequently than 4 times in any 24 hour period.
The dosage should not be continued for more than 3 days without consulting a doctor.

4.3. Contra-indications

Should be given with care to patients with impaired kidney or liver function and to alcoholics.

Hypersensitivity to paracetamol or any of the other constituents.

4.4. Special Warnings and Precautions for Use

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

Patients, who are receiving a course of medicinal treatment, consult your doctor before taking this product.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Do not take anything else containing paracetamol while taking this medicine.

Talk to your doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

If you are pregnant or being prescribed medicine by your doctor, seek your doctor's advice before taking this product.

4.5 Interaction 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 cholestyramine.

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.

Should be given with care to patients taking other drugs that affect the liver.

4.6. Fertility, pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. 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

There are unlikely to be any problems with normal use.

4.8. Undesirable Effects

Adverse events of paracetamol from historical clinical trial sate 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.

Post marketing data

Body System	**Undesirable effect**
Blood an lymphatic system disorders	Thrombocytopenia Agranulocytosis Neutropenia Pancytopenia Leukopenia
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
General disorders and administration site conditions	Drug fever

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

Very rare cases of serious skin reactions have been reported.

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.

4.9 Overdose

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 Nacetylcysteine 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol: has analgesic and antipyretic actions similar to Aspirin.

Ascorbic acid: is a water soluble vitamin essential for the synthesis of collagen and intercellular material.

5.2 Pharmacokinetic properties

Paracetamol: is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucoronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about one to four hours. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increased concentration. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed function oxidises in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and can cause liver damage.

Ascorbic Acid: is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. It is reported to be about 25% bound to plasma proteins. The amount of ascorbic acid in the body in health is 1.5 grammes. Ascorbic acid is reversibly oxidised to dehydroascorbic acid, some is metabolised to ascorbate-2-sulphate which is inactive and oxalic acid which are excreted in the urine. Ascorbic Acid crosses the placenta and is distributed into breast milk. It is removed by haemodialysis.

5.3 Preclinical safety data

There is no pre-clinical data of relevance to a prescriber which is additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Sodium citrate

Tartaric acid

Citric acid

Starch Spray dried lemon juice

Lemon aroma

Sodium cyclamate Colour (E100)

Ascorbic Acid

6.2 Incompatibilities

None known

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a dry place below 25°C.

6.5 Nature and contents of container

5, 8 or 10 sachets in a carton. Each sachet contains 5 grammes of powder.

Sachet specifications: each sachet comprised of 44 gsm paper, 10 gsm high density polythene, 8 micron soft tempered aluminium foil and 25 gsm polythene.

or

40 gsm paper, 12gsm low density polyethylene, 15 micron soft tempered aluminium foil and 30 gsm low density polyethylene.

or

paper/polyethylene/aluminium foil/Surlyn.

6.6 Special precautions for disposal

No special instruction necessary.

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Ltd
Wrafton
Braunton
North Devon
EX33 2DL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0043

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/02/2009

10 DATE OF REVISION OF THE TEXT

12/10/2015