SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cold Relief Capsules
Superdrug Paracetamol Cold Relief with Decongestant
Sudafed Blocked Nose & Headache Capsules
Non-Drowsy Decongestant with Paracetamol
Wilko Non-Drowsy Decongestant with Paracetamol
Boots Blocked Nose & Headache Relief Capsules
Health Essentials Cold Relief Capsules
Boots Cold & Flu Relief Capsules
Sainsbury’s Healthcare Sinus Dual Relief Capsules
The Local Independent Trading Company Ltd Cold Relief Capsules
Spar Cold Relief Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>QTY</th>
<th>UNIT</th>
<th>DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>300</td>
<td>mg</td>
<td>Capsule</td>
</tr>
<tr>
<td>Caffeine</td>
<td>25</td>
<td>mg</td>
<td>Capsule</td>
</tr>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>5</td>
<td>mg</td>
<td>Capsule</td>
</tr>
</tbody>
</table>

3 PHARMACEUTICAL FORM

Capsule, hard [Capsule].

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For the relief of the symptoms of colds and flu, including headache, feverishness, nasal and sinus congestion and its associated, pressure and pain, catarrh, aches and pains.

4.2 Posology and method of administration
Route of administration: Oral.

Adults, the elderly and children 12 years and over:
2 capsules every 4 to 6 hours as required, up to a maximum of 12 capsules in any 24 hour period.

This product is contraindicated in children under the age of 12 years (see section 4.3).
4.3 **Contraindications**
Hypersensitivity to paracetamol and/or other constituents.
Concurrent administration of monoamine oxidase inhibitors and tricyclic antidepressants, severe hypertension, myocardial infarction, hyperthyroidism and pregnancy.
Not to be used in children under the age of 12 years.

4.4 **Special warnings and precautions for use**
Medical advice should be sought before using this product in patients with these conditions:

An enlargement of the prostate gland

Occlusive vascular disease (e.g. Raynaud's phenomenon)

Cardiovascular disease

This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) (see interactions).

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

Keep out of the reach and sight of children

Contains Paracetamol

Do not exceed the stated dose

If symptoms persist consult your doctor

If you are under the care of your doctor or receiving prescribed medicines consult your doctor before taking this product.

Do not take other flu, cold or decongestant medicines or other paracetamol-containing medicines, with this product.
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.

Label Warnings

Do not exceed the stated dose.
If symptoms persist or worsen, consult your doctor.
Keep out of the reach and sight of children.
Do not take alcohol.
If you are taking medication or are under medical care, consult your doctor before using this medicine.
Contains paracetamol. Do not take any other paracetamol-containing products.
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.
Do not take any other flu, cold or decongestant products.

Leaflet warnings:

Contains paracetamol. Do not take any other paracetamol-containing products.
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.
If you are taking medication or are under medical care, consult your doctor before using this medicine.

Do not take any other flu, cold or decongestant products.

4.5 Interaction with other medicinal products and other forms of interaction

PARACETAMOL
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone. Colestyramine may reduce the speed of absorption of paracetamol.
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.

PHENYLEPHRINE HYDROCHLORIDE
Phenylephrine hydrochloride may cause hypertension, sometimes severe, where used concurrently with both monoamine oxidase and tricyclic type antidepressants, ganglion blocking agents, adrenergic blocking drugs, and methyldopa.
4.6 Pregnancy and lactation

PREGNANCY

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

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 hydrochloride in pregnancy has not been established and unless advised medically its use should be avoided.

Although excreted in breast milk, provided maternal intake is not excessive, no harm should come to the neonate during lactation.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Adverse events of paracetamol 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.

Paracetamol

<table>
<thead>
<tr>
<th>Body System</th>
<th>Undesirable effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Thrombocytopenia</td>
</tr>
<tr>
<td></td>
<td>Agranulocytosis</td>
</tr>
<tr>
<td></td>
<td>These are not necessarily causally related to paracetamol.</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Anaphylaxis</td>
</tr>
<tr>
<td></td>
<td>Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens</td>
</tr>
<tr>
<td></td>
<td>Johnson syndrome, toxic epidermal necrolysis</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Bronchospasm*</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>Hepatic dysfunction</td>
</tr>
</tbody>
</table>

* 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.
Caffeine

Adverse reactions identified through post-marketing use with caffeine are listed below. The frequency of these reactions is unknown.

<table>
<thead>
<tr>
<th>Central Nervous system</th>
<th>Nervousness and anxiety</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Irritability, Restlessness and Excitability</td>
</tr>
<tr>
<td></td>
<td>Dizziness</td>
</tr>
</tbody>
</table>

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Phenylephrine

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

<table>
<thead>
<tr>
<th>Body System</th>
<th>Undesirable effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychiatric disorders</td>
<td>Nervousness</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache, dizziness, insomnia</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Increased blood pressure</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea, vomiting, diarrhoea</td>
</tr>
</tbody>
</table>

Adverse reactions identified during post-marketing use are listed below. The frequency of these reactions is unknown.

| 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 |

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](http://www.mhra.gov.uk/yellowcard)
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.

**CAFFEINE**

Doses over 1g are probably necessary to induce toxicity, 2 - 5g to produce severe toxicity and 5 - 10g is likely to be lethal.

Symptoms include: epigastric pain, vomiting, diuresis, tachycardia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors, convulsions).
No specific antidote is available, reduce or stop dosage and avoid excessive intake of coffee or tea.

**PHENYLEPHRINE HYDROCHLORIDE**

Severe overdosage may produce hypertension and associated reflex bradycardia. Treatment measures include early gastric lavage and symptomatic and supportive measures. The hypertensive effects may be treated with an alpha-receptor blocking agent (such as phentolamine mesilate 6 - 10mg) given intravenously, and the bradycardia treated with atropine, preferably only after the pressure has been controlled.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 Pharmacodynamic properties

**PARACETAMOL**

**Analgesic:**

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

**Antipyretic:**

Paracetamol probably produces antipyresis by acting on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

**CAFFEINE**

Central nervous system stimulant - Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

**Analgesia Adjunct:**

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain. It is believed that caffeine helps to relieve headache by providing a more rapid onset of action and/or enhanced pain relief with lower doses of analgesic. Recent studies with ergotamine indicate that the enhancement of effect by the addition of caffeine may also be due to improved gastrointestinal absorption of ergotamine when administered with caffeine.

**PHENYLEPHRINE HYDROCHLORIDE**

Sympathomimetic amines, such as phenylephrine, act on alpha-adrenergic receptors of the respiratory tract to produce vasoconstriction, which temporarily reduces the swelling associated with inflammation of the mucous membranes lining the nasal and sinus passages. This allows the free drainage of the sinusoidal fluid from the sinuses.

In addition to reducing mucosal lining swelling, decongestants also suppress the production of mucus, therefore preventing a build up of fluid within the cavities which could otherwise lead to pressure and pain.
5.2 Pharmacokinetic properties

PARACETAMOL
Absorption and Fate:
Paracetamol is rapidly absorbed from the gastrointestinal tract with peak plasma concentrations occurring between 10 and 120 minutes after oral administration. 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 1 to 4 hours.
Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.
A minor hydroxylated metabolite 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 liver damage.

CAFFEINE
Absorption and Fate:
Caffeine is absorbed readily after oral administration and is widely distributed throughout the body. Caffeine is metabolised almost completely via oxidation, demethylation, and acetylation, and is excreted in the urine as 1-methyluric acid, 1-methylxanthine, 7-methylxanthine, 1,7-dimethylxanthine (paraxanthine), 5-acetylamino-6-formylamino-3-methyluracil (AFMU), and other metabolites with only about 1% unchanged.

PHENYLEPHRINE HYDROCHLORIDE
Absorption and Fate:
Phenylephrine has reduced bioavailability from the gastrointestinal tract owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver.

5.3 Preclinical safety data
There are no preclinical data of relevance to the prescriber additional to that already covered in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Capsule contents
Maize Starch
Crocarmellose Sodium
Sodium Lauryl Sulphate
Magnesium Stearate
Capsule
Gelatin
Titanium Dioxide (E171)
Iron Oxide Yellow (E172)
Patent Blue V (E131)
Quinoline Yellow (E104)

6.2 **Incompatibilities**
None other than those listed in 4.3 and 4.5

6.3 **Shelf life**
3 years

6.4 **Special precautions for storage**
None

6.5 **Nature and contents of container**
White opaque UPVC/aluminium foil blisters in cartons of 8, 10, 12, 16, 24, 32 and 48.

30 micron pyramidally embossed hard temper aluminium (with 250 micron PVC blisters).

6.6 **Special precautions for disposal**
None

7 **MARKETING AUTHORISATION HOLDER**
Wrafton Laboratories Limited
Wrafton
Braunton
North Devon EX33 2DL
8 MARKETING AUTHORISATION NUMBER(S)
PL 12063/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
05/07/1993 / 27/08/2004

10 DATE OF REVISION OF THE TEXT
08/11/2016