Public Assessment Report

Hot Lemon Cold Relief Powders (Paracetamol)
PL 22959/0007

Flu Strength Hot Lemon Paracetamol Powders (Paracetamol)
PL 22959/0006
HOT LEMON COLD RELIEF POWDERS (PARACETAMOL)
PL 22959/0007

FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)
PL 22959/0006

UKPAR

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th></th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lay Summary</td>
<td>3</td>
</tr>
<tr>
<td>Scientific discussion</td>
<td>4</td>
</tr>
<tr>
<td>Steps taken for assessment</td>
<td>11</td>
</tr>
<tr>
<td>Steps taken after authorisation – summary</td>
<td>12</td>
</tr>
<tr>
<td>Summary of Product Characteristics</td>
<td>13</td>
</tr>
<tr>
<td>Patient Information Leaflets</td>
<td>23</td>
</tr>
<tr>
<td>Labelling</td>
<td>26</td>
</tr>
</tbody>
</table>
HOT LEMON COLD RELIEF POWDERS (PARACETAMOL)
PL 22959/0007

FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)
PL 22959/0006

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Line Range Limited Marketing Authorisations (licences) for the medicinal products Hot Lemon Cold Relief Powders (PL 22959/0007) and Flu Strength Hot Lemon Paracetamol Powders (PL 22959/0006). These are general sale list (GSL) medicines for the relief of cold and flu symptoms.

Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Paracetamol Powders contain paracetamol which relieves pain and reduces body temperature in feverish conditions.

These applications are duplicates of previously granted licences for Hot Lemon Cold Relief Powder (PL 05544/0078) and Flu Strength Hot Lemon Powder (PL 05544/0091).

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Paracetamol Powders outweigh the risks, hence Marketing Authorisations have been granted.
HOT LEMON COLD RELIEF POWDERS (PARACETAMOL)
PL 22959/0007

FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)
PL 22959/0006

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical assessment</td>
<td>6</td>
</tr>
<tr>
<td>Preclinical assessment</td>
<td>8</td>
</tr>
<tr>
<td>Clinical assessment</td>
<td>9</td>
</tr>
<tr>
<td>Overall conclusions and risk-benefit assessment</td>
<td>10</td>
</tr>
</tbody>
</table>
INTRODUCTION

The UK granted marketing authorisations for the medicinal products Hot Lemon Cold Relief Powders (PL 18284/0011) and Flu Strength Hot Lemon Paracetamol Powders (PL 18284/0012) to Natural Options Health Products Limited on 19 January 2006. Shortly after (9 February 2006), a Change of Ownership application was approved so that the marketing authorisation holder is now Line Range Limited and the marketing authorisation (MA) numbers are now PL 22959/0007 for Hot Lemon Cold Relief Powders and PL 22959/0006 for Flu Strength Hot Lemon Paracetamol Powders. The products are general sale list (GSL) medicines.

These applications were submitted as simple abridged applications according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Hot Lemon Cold Relief Powders (PL 05544/0078, approved on 27 March 1991) and Flu Strength Hot Lemon Powder (PL 05544/0091, approved on 13 November 1998).

No new data were submitted for these simple applications, nor were any necessary, as the data are identical to that of the previously granted cross-referenced products. As the cross-referenced products were granted prior to the introduction of current legislation, no public assessment reports were generated for them.

The products contain the active ingredient paracetamol, which has analgesic and antipyretic actions similar to aspirin and is indicated for the relief of cold and flu symptoms.

These applications for Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Paracetamol Powders were submitted at the same time and were assessed concurrently. Consequently, all sections of this Scientific Discussion refer to both products. The assessment reports also appear under the original marketing authorisation holder and numbers.
PHARMACEUTICAL ASSESSMENT

PL numbers: PL 18284/0011 and PL 18284/0012
Product: Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Paracetamol Powders
Active(s): Paracetamol
Company: Natural Options Health Products Ltd.
E.C. Article: 10.1(a)i
Legal Status: GSL

Introduction

These national simple abridged applications are for Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Paracetamol Powders. The applications refer to the Marketing Authorisations held by Sussex Pharmaceuticals, PLs 05544/0078 and 05544/0091, granted on 27 March 1991 and 13 November 1998 respectively. It is noted that the cross-referenced licences were cancelled on 12 February 2004, two days after the receipt of this application. A letter of access from Sussex Pharmaceuticals dated 28 January 2004 was provided. This letter authorised the MHRA to refer to PLs 05544/0078 and 05544/0091 in relation to these applications.

Note:
MHRA policy regarding vitamins as active substances in finished products recently changed, such that the ascorbic acid should be classed as an excipient rather than as an active substance. This is in line with the policy not to issue any new licences that name ascorbic acid as an active as there is no recent convincing data on efficacy. As such ascorbic acid was removed from the list of active ingredients for PL 18284/0011.

Pharmaceutical comments

A letter from the applicants confirming that they have access to the pharmaceutical data pertaining to these applications has been provided. Expert reports and information on experts have been provided for the applications. It is noted that the product contains paracetamol, presented within a sachet. This particular container closure system is exempt from the Medicines (Child Safety) Regulations 2003 concerning paracetamol and child-resistant packaging.

The manufacturers of paracetamol named in the application are in line with those for the cross referenced product.

The manufacturing site of the finished products is stated. The qualified person for this site is named and a copy of the manufacturers licence provided.

The batch release and distribution site is Sussex Pharmaceuticals Ltd, Charlwoods Road, East Grinstead, West Sussex.

Finished product specifications, drug substance specifications and methods of manufacturing are all in line with the cross-referenced products.
BSE/TSE compliance

The finished products contains no active substances or excipients of animal or human origin and as such there is no BSE/TSE compliance issue.

Marketing Authorisation Application (MAA) forms

MAA forms are provided and are considered satisfactory.

Summary of Product Characteristics (SPCs)

SPCs are provided and are considered satisfactory.

Labelling and leaflets

Satisfactory mock-ups for patient information leaflets, sachets and carton labels have been provided.

Pharmaceutical conclusions

Marketing authorisations should be granted for these preparations.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for applications of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.
OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with those previously assessed for the cross-referenced products and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Paracetamol is a well-known drug that has been used as an analgesic and antipyretic for many years. These applications are identical to previously granted applications for Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Powder.

No new or unexpected safety concerns arose from these applications.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced products.

RISK-BENEFIT ASSESSMENT

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-referenced products. Extensive clinical experience with paracetamol is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.
HOT LEMON COLD RELIEF POWDERS (PARACETAMOL)  
PL 22959/0007

FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)  
PL 22959/0006

**STEPS TAKEN FOR ASSESSMENT**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation applications for Hot Lemon Cold Relief Powders and Flu Strength Hot Lemon Paracetamol Powders on 10 February 2004.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks the MHRA informed the applicant that its applications were considered valid on 20 February 2004.</td>
</tr>
<tr>
<td>3</td>
<td>The MHRA’s assessment of the submitted data was completed on 14 July 2004.</td>
</tr>
<tr>
<td>4</td>
<td>Further information was requested from the applicant on 19 July 2004.</td>
</tr>
<tr>
<td>5</td>
<td>The applicant submitted its response to further information requests on 8 December 2004.</td>
</tr>
<tr>
<td>6</td>
<td>The applicant submitted product particulars on 24 May 2005 and requested to change marketing authorisation holder during assessment.</td>
</tr>
<tr>
<td>7</td>
<td>Discussion between applicant and MHRA on 10 November 2005 as no longer able to change marketing authorisation holder during assessment.</td>
</tr>
<tr>
<td>8</td>
<td>Applicant submits updated product particulars on 6 January 2006.</td>
</tr>
<tr>
<td>9</td>
<td>Further information was requested from the applicant on 12 and 13 January 2006.</td>
</tr>
<tr>
<td>10</td>
<td>The applicant submitted its response to further information requests on 16 January 2006.</td>
</tr>
<tr>
<td>11</td>
<td>The MHRA completed its assessment of the application on 16 January 2006.</td>
</tr>
<tr>
<td>12</td>
<td>The applications were determined on 19 January 2006*.</td>
</tr>
</tbody>
</table>

*Change of Ownership from Natural Options Health Products Limited to Line Range Limited approved on 9 February 2006.*
HOT LEMON COLD RELIEF POWDERS (PARACETAMOL)
PL 22959/0007

FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)
PL 22959/0006

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. **NAME OF THE MEDICINAL PRODUCT**
   Hot Lemon Cold Relief Powders

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
   Paracetamol BP 650 mg
   For excipients see section 6.1

3. **PHARMACEUTICAL FORM**
   Powder for oral solution

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. **Contraindications**
   Hypersensitivity to paracetamol or any of the other constituents.
   Should be given with care to patients with impaired kidney or liver function and to alcoholics.
   Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency should not take this medicine.

4.4. **Special warnings and precautions for use**
   This medicinal product should be given with care to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
1. Should be given with care to alcoholics.
2. If you are receiving a course of medicinal treatment, consult your doctor or pharmacist.
3. Contains paracetamol.
4. Do not take with any other paracetamol containing-products.
5. 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.
6. Do not exceed the recommended dose.
7. If symptoms persist consult your doctor.
8. Keep out of reach of children

4.5. Interactions with other medicinal products and other forms of interaction

Should be given with care to patients taking other drugs that affect the liver.
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption decreased by colestyramine.
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. 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 effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

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 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.

5. **PHARMACOLOGICAL PROPERTIES**

5.1. **Pharmacodynamic properties**

ATC Code N02B E01 Other analgesics and antipyretics.

Paracetamol: has analgesic and antipyretic actions similar to Aspirin.
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 glucuronide 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.

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

Ascorbic acid
Sucrose
Sodium citrate
Tartaric acid
Citric acid
Starch
Spray dried lemon juice
Lemon aroma
Sodium cyclamate
Colour turmeric (E100).

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

6.6. **Instruction for use and handling (, and disposal)**

No special instruction necessary

6.6. **Instruction for use and handling (, and disposal)**

No special instruction necessary

7. **MARKETING AUTHORISATION HOLDER**

Line Range Ltd ,
494-496 Honeypot Lane,
Stanmore
Middlesex HA7 1JH

8. **MARKETING AUTHORISATION NUMBER**

PL 22959/0007

9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

09/02/2006

10 **DATE OF REVISION OF THE TEXT**

09/02/2006
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Flu Strength Hot Lemon Paracetamol Powders

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol BP 1000 mg
For excipients see section 6.1

3. PHARMACEUTICAL FORM

Powder for oral solution.
Unit dose sachets.

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:
The contents of one sachet dissolved in hot water every 4 hours.
The dose should not be repeated more than four times in any 24-hour period.
The dosage should not be continued for more than 3 days without consulting a doctor.

4.3. Contraindications

Allergic reactions and sensitivity paracetamol or to any of the other constituents.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4. Special warnings and precautions for use

This medicinal product should be given with care to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
Should be given with care to alcoholics.
If you are receiving a course of medicinal treatment, consult your doctor or pharmacist.
Contains paracetamol.
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, because of the risk of delayed, serious liver damage.
Do not exceed the recommended dose.
If symptoms persist consult your doctor.
Keep out of reach of children

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 decreased by colestyramine.
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. 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 effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

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 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.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC Code N02B E01 Other analgesics and antipyretics.

Paracetamol has analgesic and antipyretic actions similar to Aspirin. It has no useful anti-inflammatory properties
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 glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 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 oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdose and can cause liver damage.

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**

Ascorbic acid, sucrose, sodium citrate, tartaric acid, citric acid, tapioca starch, sodium cyclamate, Flav-O-lok Lemon Juice 610399, Lemon Flavour 8476, Turmeric powder extract (Curcumin, E100).

6.2. **Incompatibilities**

None known.

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**

5 or 10 sachets in a carton. Each sachet contains 7.7 grammes of powder. Sachet specifications: 44 gsm paper, 10 gsm high density polythene, 8 micron soft tempered aluminium foil and 25 gsm polythene.
6.6. Instruction for use and handling (use, and disposal)

No special instruction necessary

7. MARKETING AUTHORISATION HOLDER

Line Range Ltd,
494-496 Honeypot Lane,
Stanmore
Middlesex HA7 1JH

8. MARKETING AUTHORISATION NUMBER

PL 22959/0006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/02/2006

10. DATE OF REVISION OF THE TEXT

09/02/2006
Patient Information Leaflets
HOT LEMON COLD RELIEF POWDERS  (PARACETAMOL)
PL 22959/0007

PATIENT INFORMATION LEAFLET
HOT LEMON COLD RELIEF POWDERS (Paracetamol 650mg powder for oral solution)

Please read this leaflet carefully before you start to take Hot Lemon Cold Relief Powders. If you have any questions, or if you are not sure about anything, ask your doctor or pharmacist.

What is this medicine for?
This medicine is used for the relief of cold and flu symptoms. These symptoms include headache, feverishness, aches and pains and painful throats.

How do these sachets work?
Paracetamol relieves pain and reduces body temperature when you have a fever.
Ascorbic acid is included to help replace the vitamin C, which may be lost in the initial stages of colds and flu.

Do not take this medicine if:
- you are allergic to paracetamol, or any of the other ingredients.
- you suffer from any liver or kidney disorders.
- you are an alcoholic.

Talk to your Doctor before taking this product if:
You are taking any other medicines.
The following drugs may affect the absorption of paracetamol:
- clofibrate (used to lower blood cholesterol)
- metoclopramide and domperidone (used to treat nausea and vomiting)
- drugs which thin your blood (anti-platelet drugs, e.g. warfarin).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sodium content 117mg per sachet. To be taken into consideration by patients on a low-sodium diet.

If you are pregnant or breast-feeding:
You should ask your doctor before taking this medicine and only use it if your doctor thinks it is appropriate and necessary.

IMPORTANT: Do not take this medicine with any other Paracetamol-containing products.

How should you take Hot Lemon Cold Relief Powders?
Adults and children aged 12 years and over:
Empty contents of one sachet into a tumbler. Fill with hot water, stir well until dissolved. The contents of one sachet are to be taken every 4 hours as necessary. Do not take more than four sachets in any 24-hour period.

If your symptoms persist for more than 3 days, consult your doctor.
Taking more sachets than recommended on the pack or in this leaflet may be dangerous. 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. The symptoms of overdose during the first 24 hours include pain, nausea (feeling sick), vomiting (being sick), loss of appetite and abdominal pain and may progress to liver damage.

If you miss a dose take one as soon as you remember, but do not double up the next dose to compensate the missed dose.
Do not give to children under 12 years of age.

Does this medicine have any side effects?
The ingredients in Hot Lemon Cold Relief Powders are usually well tolerated in normal use but occasionally allergic reactions such as a skin rash, mouth sores or a fever may occur. More rarely, other blood and metabolic disorders have been reported. If you develop these or any other reaction, stop taking the medicine and report it to your doctor or pharmacist immediately.

How to store this medicine:
Do not store above 25°C and keep in the original packaging.
Keep all medicines out of the reach and sight of children.

Do not take this medicine after the expiry date shown on the pack.
If you have any medicines that are out of date, return them to your pharmacist for safe disposal.

Further Information
What is in the pack?
This pack contains 5, 8 or 10 sachets. Each 5g sachet of powder contains paracetamol 650mg as the active ingredient.
The powder also contains ascorbic acid, xanthine, sodium citrate, tartaric acid, citric acid, tapioca starch, lemon flavour, lemon juice, sodium cyclamate and flavour, gum extract (cornstarch), E100.

Manufacturer and Marketing Authorisation Holder:
This medicine is manufactured by Sussex Pharmaceuticals Ltd., Charwood Road, East Grinstead, West Sussex RH19 2HL for the UK Marketing Authorisation holder: Line Range Ltd., Stanmore, Middlesex HA7 4NB

Leaflet revised: November 2005
FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)
PL 22959/0006

PATIENT INFORMATION LEAFLET
FLU STRENGTH HOT LEMON PARACETAMOL POWDERS
(Paracetamol 1000mg powder for oral solution)

Please read this leaflet carefully before you start to take this medicine. If you have any questions, or if you are not sure about anything, ask your doctor or pharmacist.

What is this medicine for?
This medicine is used for the relief of cold and flu symptoms. These symptoms include headache, feverishness, aches and pain.

How does this medicine work?
This medicine contains paracetamol, which relieves pain and reduces body temperature when you have fever.

Do not take this medicine:
- If you are allergic to paracetamol or any of the other ingredients.
- If you suffer from any liver or kidney disorders.
- If you are an alcoholic.

Do not take this medicine with any other paracetamol containing products.
Talk to your doctor before taking this product if:
You are taking any other medication. The following drugs may affect the absorption of paracetamol:
- Colestyramine (used to lower blood pressure).
- Metoclopramide and Domperidone (used to treat nausea and vomiting).
- Anticoagulants (drugs which thin the blood, such as Warfarin).
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you are pregnant or breast-feeding:
You should ask your doctor before taking this medicine and only use it if your doctor thinks it is appropriate and necessary.

How should you take Flu Strength Hot Lemon Paracetamol Powders?
Adults and children aged 12 years and over: Empty contents of one sachet into a tumbler. Fill with hot water. Stir well until dissolved. The contents of one sachet are to be taken every 4 hours as necessary. Do not take more than four sachets in any 24-hour period.

Do not give to children under 12 years of age.
If symptoms persist for more than 3 days, consult your doctor.

Do not exceed the stated dose.

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. The symptoms of overdose in the first 24 hours include pallor, nausea, vomiting, loss of appetite and abdominal pain and may progress to liver damage.

If you miss a dose, take one as soon as you remember, but do not double the next dose to compensate the missed dose.

Does this medicine have any side effects?
The ingredients in Flu Strength Hot Lemon Paracetamol Powders are usually well tolerated in normal use but occasionally allergic reactions such as a skin rash, mouth sores, or a fever may occur. More rarely other blood and metabolic disorders have been reported but these were not necessarily due to paracetamol.

If you develop any sort of reaction, stop taking the medicine and report to your doctor or pharmacist immediately.

How to store this medicine:

Do not take this medicine after the expiry date shown on the pack. If you have any medicines that are out of date, return them to your pharmacist for safe disposal.

Further Information
What is in the pack?
Flu Strength Hot Lemon Paracetamol Powders contain paracetamol. This pack contains 5 or 10 sachets. Each sachet of 7.7 g of powder contains paracetamol 1000 mg as the active ingredient. The powder also contains ascorbic acid (vitamin C), sucrose, sodium citrate, tartaric acid, citric acid, tapioca starch, lemon flavour, lemon juice, sodium cyclamate and turmeric powder extract (suncrumin, 8100).

Sodium content 560 mg per sachet. To be taken into consideration by patients on a sodium controlled diet.

This medicinal product contains 4.184 g of sucrose. When taken according to the dosage recommendations each dose supplies up to 4.184 g sucrose.

Manufacturer and Marketing Authorisation Holder:
This medicine is manufactured by Sussex Pharmaceutical Ltd., Charwoods Road, East Grinstead, West Sussex, RH19 2HL for the Marketing Authorisation holder: Line Range Ltd., Starmore, Middlesex HA7 3JH.

Leaflet revised: November 2005
Labels/Packaging
HOT LEMON COLD RELIEF POWDERS (PARACETAMOL)
PL 22959/0007

Sachets

Hot Lemon Cold Relief Powders
Paracetamol 650mg Powder for oral solution
Before you take this medicine please read and retain the
leaflet enclosed.

Instructions for use: Empty the contents of one sachet into
a tumbler and fill with hot water. Stir until fully dissolved

Dose: Adults and children over 12 years: One sachet every
4 hours up to a maximum of 4 sachets in any 24-hour period
Do not exceed the stated dose
Do not give to children under 12 years.
If symptoms persist consult your doctor.

CONTAINS PARACETAMOL
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.

Ingredients: Each 5g sachet contains:
Paracetamol BP 650mg
Sucrose 272mg
Sodium 117mg

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
Do not store above 25°C.
PL 22959/0006
MA Holder: Line Range Ltd., Stanmore, Middlesex HA7 1UH

Exp.
Bx No.
Carton
FLU STRENGTH HOT LEMON PARACETAMOL POWDERS (PARACETAMOL)
PL 22959/0006

Sachets

Flu Strength Hot Lemon Paracetamol Powders
(Paracetamol 1000mg powder for oral solution)

Flu Strength Hot Lemon Paracetamol Powders

(Paracetamol 1000mg powder for oral solution)
Before you take this medicine please read and retain the
leaflet enclosed.

Instructions for use: Empty the contents of one sachet into
a tumbler and fill with hot water. Stir until fully dissolved.

Dose: Adults and children over 12 years: One sachet every
4 hours up to a maximum of 4 sachets in any 24-hour period.
Do not exceed the stated dose.
Do not give to children under 12 years.
If symptoms persist consult your doctor.

CONTAINS PARACETAMOL
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.

Ingredients: Each 7.7g sachet contains:
Paracetamol BP 1000mg
Sucrose 4.186g
Sodium content per sachet 180mg

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Do not store above 25°C.

PL 22959 / 0007

MA Holder: Line Range Ltd., Stanmore, Middlesex HA7 1JH

Exp.
Bx No.