PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS

PL 36390/0040

UKPAR

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PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS

PL 36390/0040

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted STD Chemicals Limited, a Marketing Authorisation for the medicinal product, Paracetamol & Caffeine 500 mg/65 mg Effervescent Tablets (PL 36390/0040), on 15 June 2011. The product is a general sales list (GSL) medicine and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

The tablets contain two active ingredients, paracetamol and caffeine, this combination has been widely available for many years. Paracetamol is a painkiller and reduces your temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

This application is identical to the already granted and currently marketed medicine Paracetamol & Caffeine 500/65mg Soluble Tablets (PL 08137/0157).

The proposed product contains an established combination of paracetamol and caffeine, and this combination is widely available.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Paracetamol & Caffeine 500 mg/65 mg Effervescent Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS

PL 36390/0040

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted STD Chemicals Limited, a Marketing Authorisation for the medicinal product, Paracetamol & caffeine 500 mg / 65 mg Effervescent Tablets (PL 36390/0040), on 15 June 2011. The product is a general sales list medicine (GSL).

This is a simple, abridged, ‘informed consent’ application submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross referring to Paracetamol and Caffeine 500/65 Soluble Tablets (PL 08137/0157), authorised to Neolab Limited on 2 July 2010 which cross-referred to the originator product Panadol Extra Soluble Tablets (PL 00071/0379) authorised to SmithKline Beecham granted in March 1991.

The product contains the active ingredients paracetamol and caffeine. The active ingredients exert their effect by unrelated pharmacological mechanisms. Paracetamol is a centrally acting analgesic (a pain killer that acts on pain centres on the brain), which is used to relieve mild to moderate pain in the body and also acts as an antipyretic to help reduce body temperature; caffeine is a mild stimulant.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. A Public Assessment Report (PAR) has been generated for the reference product Paracetamol and Caffeine 500/65 Soluble Tablets (PL 08137/0157).
1. INTRODUCTION
This is a simple, informed consent application for Paracetamol & Caffeine 500 mg 65 mg Effervescent Tablets submitted under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is STD Chemicals Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, UK.

The application cross-refers to Paracetamol & Caffeine 500/65mg Soluble Tablets (PL 08137/0157) authorised to Neolab Limited on 2 July 2010 as an abridged application which cross-referred to the originator product, Panadol Extra Soluble Tablets, authorised to SmithKline Beecham granted in March 1991. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)
The proposed name of the product is Paracetamol & Caffeine 500 mg / 65 mg Effervescent Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each effervescent tablet contains 500 mg paracetamol and 65 mg caffeine.

The finished product is licensed for marketing in blister strips comprising of 4-Ply laminate strip blister pack. The blister strips are packaged with the Patient Information Leaflet (PIL) into cardboard outer cartons and are available in pack sizes of 24 tablets.

All primary product packaging complies with EU legislation regarding contact with food. The proposed shelf-life is 3 years. Storage conditions for the product are “Store in the original package and protect from moisture”. The shelf-life and storage conditions are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, this product will be available as a general sales list (GSL) available at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

2.4 Marketing authorisation holder/Contact Persons/Company
STD Chemicals Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, UK.

The Quality Person (QP) responsible for pharmacovigilance is stated and his curriculum vita has been provided.
2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
The applicant has provided a declaration confirming that there are no materials of human or animal origin contained in or used in the manufacturing process for the proposed product. This is consistent with the cross-reference product.

3. EXPERT REPORTS
A satisfactory expert report and curriculum vita of the expert are provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The medicinal product are presented as white to off white coloured circular flat bevelled tablets plain on both sides. The appearance of the product is consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The PIL is satisfactory and in line with the approved SmPC. It has been prepared according to the Quality Review of Documents (QRD) template and is consistent with the details registered for the cross-reference product.

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.
Carton and label
Mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. In line with current legislation the applicant has included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with this application is acceptable. A Marketing Authorisation was, therefore, granted.
NON-CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10c of EC Directive 2001/83 (as amended). The application is identical to the reference product Paracetamol & Caffeine 500/ 65 mg Soluble Tablets (PL 08137/0157) authorised to Neolab Limited, therefore, no new preclinical data have been supplied with this application and none are required. A non-clinical overview report has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

The marketing authorisation holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As this application is identical to an already authorised reference product, it is not expected that the environmental exposure to paracetamol and caffeine will increase following the marketing approval of the proposed product.
CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to Paracetamol & caffeine 500/65 mg Soluble Tablets (PL 08137/0157) authorised to Neolab Limited.

No new clinical data has been supplied with this application and none are required. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.

The marketing authorisation holder (MAH) has provided adequate justification for not submitting a Risk Management Plan (RMP). As this application is identical to an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active is well-established.

The MAH has provided a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the MAH has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application is consistent with those previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
This application is considered identical to the previously granted licence for Paracetamol & caffeine 500/65 mg Soluble Tablets (PL 08137/0157) authorised to Neolab Limited.

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC, PIL and labelling are satisfactory, and consistent with those for the cross-reference product.

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

Mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with paracetamol and caffeine is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.
PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS

PL 36390/0040

STEPS TAKEN FOR ASSESSMENT

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<td>The MHRA received the marketing authorisation application on 25 January 2011.</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 9 February 2011.</td>
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<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 20 April 2011.</td>
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<td><strong>4</strong></td>
<td>The applicant responded to the MHRA’s requests, providing further information on 12 May 2011.</td>
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<td><strong>5</strong></td>
<td>The application was determined on 15 June 2011.</td>
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PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS

PL 36390/0040

STEPS TAKEN AFTER ASSESSMENT

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PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS
PL 36390/0040

SUMMARY OF PRODUCT CHARACTERISTICS
The UK Summary of Product Characteristics (SmPC) for Paracetamol & Caffeine 500 mg / 65 mg Effervescent Tablets (PL 36390/0040) is as follows:

1 NAME OF THE MEDICINAL PRODUCT
Paracetamol & Caffeine 500 mg / 65 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains Paracetamol 500 mg and Caffeine 65 mg.
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Effervescent Tablet.
Paracetamol & Caffeine 500 mg / 65 mg Effervescent Tablets are white to off white coloured circular flat bevelled tablets plain on both sides.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Paracetamol & Caffeine Effervescent Tablets are a mild analgesic and antipyretic formulated to give extra pain relief. The tablets are recommended for the treatment of most painful and febrile conditions, for example, headache, including migraine, backache, toothache, rheumatic pain and dysmenorrhea, and relief of the symptoms of colds, influenza and sore throat.

4.2 Posology and method of administration
Paracetamol & Caffeine Effervescent Tablets should be dissolved in at least half a tumbler of water.

Adults:
Two tablets up to four times daily.
Do not exceed 8 tablets in 24 hours.
Elderly:
As for adults.
Children:
Not recommended for children under 12 years.
Method of Administration
Paracetamol & Caffeine Effervescent Tablets are for oral administration only.

4.3 Contraindications
Hypersensitivity to paracetamol, caffeine 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 severe renal or severe hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.
Excessive intake of tea or coffee should be avoided while taking this product.
Do not exceed the stated dose.
Patients should be advised to consult their doctor if their headaches become persistent.
Patients should be advised not to take other paracetamol-containing products concurrently.
If symptoms persist consult your doctor.
Keep out of the reach and sight of children.
Pack Label:
Immediate medical advice should be sought in the event of an overdose, even if you feel well. Do not take with any other paracetamol-containing products.

Patient Information Leaflet:
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.

This product contains aspartame, a source of phenylalanine which may be harmful for people with phenylketonuria.

Each of these tablets contains 409 mg of sodium. This may interfere if you are on a low sodium diet.

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 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.

4.6 Pregnancy and lactation
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol and caffeine used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol and caffeine are 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
None.

4.8 Undesirable effects
Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been very rare reports of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol.

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

Risk Factors:
If the patient
• Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.
Or

• Regularly consumes ethanol in excess of recommended amounts.
Or

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

Symptoms
Symptoms of paracetamol overdose 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**

**Symptoms**

Overdose of caffeine may produce nervousness, restlessness, insomnia, excitement, diuresis, facial flushing, muscle twitching, GI disturbance, tachycardia or cardiac arrhythmia, "rambling" flow of thought and speech, psychomotor agitation, or periods of inexhaustibility.

**Management**

Patients should receive general supportive care (e.g. hydration and maintenance of vital signs). The administration of activated charcoal may be beneficial when performed within one hour of the overdose, but can be considered for up to four hours after the overdose. The CNS effects of overdose may be treated with intravenous sedatives.

**Summary**

Treatment of overdose with Cope Sachets requires assessment of plasma paracetamol levels for antidote treatment, with signs and symptoms of codeine and caffeine toxicity being managed symptomatically.

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**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other Analgesics and Antipyretics – Anilides.

ATC Code – N02B E51

The combination of paracetamol and caffeine is a well established analgesic combination.

**5.2 Pharmacokinetic properties**

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract, it is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal, in the form of conjugated metabolites. Caffeine is absorbed readily after oral administration, maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours. 65 - 80% of administered caffeine is excreted in the urine as 1-methyluric acid and 1-methylxanthine.

**5.3 Preclinical safety data**

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

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**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Citric Acid (anhydrous) (E330), Povidone, Saccharin Sodium, Sodium Hydrogen Carbonate (E500) , Sodium Carbonate Anhydrous, Simeticone, Polysorbate 80 (E433), and Aspartame (E951).

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years.
6.4 Special precautions for storage
Store in the original package and protect from moisture.

6.5 Nature and contents of container
4- Ply laminate strip pack

These tablets are available in a pack size of 24.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHOURISATION HOLDER
STD Chemicals Ltd,
Hillbrow House,
Hillbrow Road,
Esher,
Surrey,
KT10 9NW

8 MARKETING AUTHORISATION NUMBER(S)
PL 36390/0040

9 DATE OF FIRST AUTHOURISATION/RENEWAL OF THE AUTHORISATION
15/06/2011

10 DATE OF REVISION OF THE TEXT
15/06/2011
PARACETAMOL & CAFFEINE 500MG/65MG EFFEREVESCENT TABLETS
PL 36390/0040
PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET
PARACETAMOL & CAFFEINE 500mg/65mg EFFEREVESCENT TABLETS
(paracetamol and caffeine)

The name of this medicine is Paracetamol & Caffeine 500mg/65mg Effervescent Tablets, which will be referred to as Paracetamol & Caffeine Tablets throughout this leaflet.

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to use Paracetamol & Caffeine Tablets carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Paracetamol & Caffeine Tablets are and what they are used for
2. Before you take Paracetamol & Caffeine Tablets
3. How to take Paracetamol & Caffeine Tablets
4. Possible side effects
5. How to store Paracetamol & Caffeine Tablets
6. Further information

1. WHAT PARACETAMOL & CAFFEINE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredients in your tablets are paracetamol and caffeine. Paracetamol is an analgesic and an antipyretic; it works by relieving pain and reducing body temperature when you have a fever. Caffeine acts to further help the effectiveness of paracetamol.

Paracetamol & Caffeine Tablets are used to treat headache, migraine, backache, rheumatism and muscle pain, colds, and toothache. They also relieve discomfort in colds, infections, sore throats, and the reduce temperature.

2. BEFORE YOU TAKE PARACETAMOL & CAFFEINE TABLETS

Do not take Paracetamol & Caffeine Tablets if you:
- are allergic (hypersensitive) to paracetamol, caffeine, or to any of the other ingredients. These are listed in section 6. Further information.
- are taking any other paracetamol-containing products
- are under 12 years of age.

Take special care with Paracetamol & Caffeine Tablets
Before you take Paracetamol & Caffeine Tablets you should tell your doctor or pharmacist if you:
- have severe liver disease
- have severe liver disease, including alcohol-related liver disease
- have persistent headaches.

Taking other medicines
Tell your doctor or pharmacist before taking this medicine if you are taking any prescribed medicine; in particular:
- medroxyprogesterone or drospirenone - for nausea (feeling sick) or vomiting (being sick)
- cholestyramine - used to treat high cholesterol.

If you take blood thinning medicines (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding.

You may still be able to take Paracetamol & Caffeine Tablets but your doctor or pharmacist will be able to advise you.

Taking your medicine with food and drink
Paracetamol & Caffeine Tablets should be dissolved in a glass of water and then can be taken with or without a meal.

You should avoid drinking too much coffee or tea when taking these tablets.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant, think you might be pregnant, are planning to become pregnant or are breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
It is unlikely that Paracetamol & Caffeine Tablets will affect your ability to drive or operate machines.

Important information about some of the ingredients of Paracetamol & Caffeine Tablets
Each of these tablets contains 65mg of sodium. This may interfere if you are on a low sodium diet.
This product also contains aspartame (a source of phenylalanine), which should not be given to anyone with phenylketonuria.
3. HOW TO TAKE PARACETAMOL & CAFFEINE TABLETS

Dosage
Adults and children aged 12 years and over
2 tablets dissolved in a glass of water every 4 hours as required.
Do not take more frequently than every 4 hours. Do not take more than 8 tablets in 24 hours. Do not take more than the recommended dose.
Not recommended for children under 12 years of age.

Method of administration
For oral administration only. These tablets should be dissolved in a glass of water before taking them. These tablets are meant to be dissolved first so don’t try to swallow them whole.
If you take more Paracetamol & Caffeine Tablets than you should:
If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty emergency department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.
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. An overdose of paracetamol can cause serious liver damage, which may not show any signs for a day or two, by which time treatment may not be successful.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol and Caffeine Tablets can cause side effects although not everybody gets them. If you get any of the following symptoms after taking these tablets you should contact your doctor or pharmacist immediately:
- any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat
- skin rash

Very rare effects on the blood have been reported, resulting in:
- an increased tendency to bruise or bleed easily
- an increased susceptibility to infection.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PARACETAMOL & CAFFEINE TABLETS

Keep out of the reach and sight of children.
Do not take this medicine after the expiry date (EXP) stated. The expiry date refers to the last day of that month.
Store in the original packaging and protect from moisture.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Paracetamol & Caffeine Tablets contain:
The active ingredients are paracetamol and caffeine. Each tablet contains 500 mg of paracetamol and 65 mg of caffeine.
Other ingredients are: citric acid (anhydrous) (E330), povidone, saccharin sodium, sodium hydrogen carbonate (E330), sodium carbonate anhydrous, simeticone (E966), Polygumate 80 (E435) and aspartame (E951).

What Paracetamol & Caffeine Tablets look like and contents of the pack:
Paracetamol & Caffeine Tablets are white to off-white coloured circular flat bevelled tablets plain on both sides.
Your medicine is available in packs of 24 tablets.

Marketing Authorisation Holder and Manufacturer:
The Product Licence holder is SITD Chemicals Ltd, Hillburn House, Hillburn Road, Erith, Kent, DA8 3NA. The manufacturer responsible for batch release is Neolab Ltd, 57 High Street, Oxtotam, Hants. RG29 1LF.

This leaflet is available in formats suitable for the blind and partially-sighted upon request.

This leaflet was last revised in April 2011.
PARACETAMOL & CAFFEINE 500MG/65MG EFERENCE TABLETS
PL 36390/0040
LABELLING

CARTON

BLISTER FOIL