1. Name of the medicinal product

Paracetamol and Caffeine Tablets (Jeocap Tablets)

2. Qualitative and quantitative composition

Each Uncoated tablet contains:
Paracetamol BP……500 mg
Caffeine (Anhydrous) ……..30 mg
Excipients…….qs

3. Pharmaceutical form

Uncoated Tablet.

White colour round shape embossed with "jeocap and star" design on one side and other side 'star' uncoated tablets

4. Clinical particulars

4.1 Therapeutic indications

Paracetamol & Caffeine 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 dysmenorrhoea, and relief of the symptoms of colds, influenza and sore throat.

4.2 Posology and method of administration

Paracetamol & Caffeine Tablets should be dissolved in at least half a tumbler of water.

Dosage

Adults

One to two tablets dissolved in water not more frequently than every 4-6 hours when necessary to a maximum of 8 tablets in 24 hours.

Elderly

Same as adult dose. A reduced dose may be required

Paediatric population:

Children aged 16-18 years:

One to two tablets dissolved in water every 4-6 hours when necessary to a maximum of 8 tablets in 24 hours.

Children aged 12-15 years:

One tablet dissolved in water every 6 hours when necessary to a maximum of 4 tablets in 24 hours.

Children aged less than 12 years:

Not recommended for children under 12years.

Method of Administration

Paracetamol & Caffeine 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 caffeine (e.g. coffee, tea, chocolate and some fizzy drinks) 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 sight and reach of children.

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

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:

Talk to a 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.

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 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. However, paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data on paracetamol do not contraindicate breast feeding. Caffeine in breast milk may potentially have a stimulating effect on breast fed infants.

Therefore, due to the caffeine content of this product it should not be used if you are pregnant or breast feeding."

4.7 Effects on ability to drive and use machines
None.

4.8 Undesirable effects

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post- marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

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.

Post marketing data

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction
Skin and Subcutaneous disorders	Very rare cases of serious skin reactions have been reported

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

Caffeine	
Central Nervous system	Dizziness

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.

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

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

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.

Sodium bicarbonate

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of sodium bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly.

5. Pharmacological properties

5.1 Pharmacodynamic properties
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.

6. Pharmaceutical particulars

6.1 List of excipients
Micro Crystalline Cellulose Powder 101, Starch, PVPK-30, Methyl Paraben Sodium, Propyl Paraben Sodium, Ethyl Cellulose, Sod. Starch Glycolate, Magnesium Stearate, Talcum Purified, Cross Povidone and Aerosil

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
4 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

Pack size: 50x10x2x10 Tabs.

6.6 Special precautions for disposal and other handling
No special requirements.