MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product

ZAPAR TABLET

2. Qualitative and quantitative composition

Each tablet contains Paracetamol 500mg and Caffeine 30mg.

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Uncoated tablet.

White circular flat beveled edge uncoated tablet.

4. Clinical particulars

4.1 Therapeutic indications

ZAPAR is analgesic and antipyretic and indicated in

- Mild to moderate pain such as headache, migraine, neuralgia, toothache, sore throat, period pain and rheumatic aches and pains
- Fever (pyrexia)
- Relieving aches, pains and fever associated with colds and flu

Caffeine Synergizes analgesic effect of paracetamol.

4.2 Posology and method of administration

One to two tablets three times daily.

For oral administration.

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.

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

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 known.

4.8 Undesirable effects

The following side effects could be observed while taking ZAPAR

- Damage to the liver
- Blood disorders
- Skin rashes

4.9 Overdose

In the event of acute over dosage, the stomach should be emptied by inducing vomiting or by gastric lavage. The patients should be carefully observed and given supportive treatment.

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

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Tablet core contains:

Microcrystalline Cellulose

Sodium Metabisulphite

Starch

Gelatin

Propyl Paraben

Colloidal Silicone Dioxide

Sorbitol

Magnesium Stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dry place at temperature below 30°C. Store in the original packaging.

6.5 Nature and contents of container

Blister strips of Aluminium and PVC in a cardboard outer container.

Pack sizes: 2 blisters of 10 tablets.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

Me Cure Industries Limited

Plot 6 Block H, Debo Industries Compound,

Oshodi Industrial Scheme,

Oshodi,

Lagos,

Nigeria.

8.0 NAFDAC Registration Number: A4-0507