1. NAME OF THE MEDICINAL PRODUCT

FORPAIN, caplet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each caplet contains:

Paracetamol 500 mg

Caffeine 30 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Forpain is a double-layer caplet with green color on one side and yellow Engraved BODE on the other side, it has bitter taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

FORPAIN is indicated for headaches, backaches, toothaches, joint and muscle pains associated with common cold or "flu", sorethroat, period pain (dysmenorrhoea) and reduce fever.

4.2 Posology and method of administration

Adults : 1 – 2 caplets 3 or 4 times daily.
Do not take more than 8 caplets in 24 hours.
Do not give to children under 12 years of age.

4.3 Contraindications

Patients with impaired liver or renal function, allergy to one of its components.

4.4 Special warnings and precautions for use

- Keep medicine out of reach of children.
- Avoid drinking too much coffee or tea while taking FORPAIN.
- Do not take this product for pains for more than 10 days unless directed by a doctor.
- In case of suspected overdose, seek prompt medical attention even if you do not notice any sign or symptom.
- If symptoms persists for more than 2 days, please consult your doctor.
- FOR PROFESSIONAL ADVICE ON MEDICINES, PLEASE CONSULT YOUR PHARMACIST.

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

Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption.
Caffeine in breast milk may potentially have a stimulating effect in breast fed infants but significant toxicity has not been observed

4.7 Effect on ability to drive and use machines

None

4.8 Undesirable Effects

For a minority of patients, FORPAIN can cause gastric irritation, palpitation of the heart and sleep disturbance.

Paracetamol		
Body System	**Undesirable effect**	**Frequency**
Blood and Lymphatic system disorders	Thrombocytopenia	Very rare (<1/10,000)
Immune System disorders	Anaphylaxis, Cutaneous, hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson Syndrome	Very rare (<1/10,000)
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare (<1/10,000)
Hepatobiliary disorders	Hepatic dysfunction	Very rare (1/10,000)

Caffeine		
Body System	**Undesirable effect**	**Frequency**
Central Nervous System	Nervousness	Not Known
	Dizziness	Not Known
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		

4.9 Overdose

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors.
Treatment of overdose requires assessment of plasma paracetamol levels for antidote treatment,

with signs and symptoms of caffeine toxicity being managed symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anilides ATC code: N02B E51

The combination of paracetamol and caffeine is a well established analgesic combination. Paracetamol is an antipyretic and analgesic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system. The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or on concomitant medication where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of GI bleeding or the elderly).

5.2 Pharmacokinetics properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal 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 rapidly absorbed from the gastrointestinal tract and is widely distributed throughout the body. It is almost completely metabolized in the liver by oxidation and demethylation to various xanthine derivatives, which are excreted in the urine. The mean plasma half life is about 4.9 hours.

5.3 Preclinical safety data

No data available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch, Magnesium stearate, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sodium starch glycolate, Talc, Gellatin, Glycerin, FD&C Yellow 5 Al Lake HT 38%, FD&C Blue 1 Al Lake HT 30% and purified water.

6.2 Incompatibilities

None

6.3 Shelflife

60 months

6.4 Special precaution for storage

Store below 30^{o}C

6.5 Special precautions for disposal

None

6.6 Nature and content of container

10 caplets are packed into PVC rigid film 250 µm / aluhard tempered 20 µm + heat seal coating 6-8 gsm blister. 2 blisters are packed in a folding box of duplex carton 250 gsm.

7. MARKETING AUTHORIZATION HOLDER

Applicant
Orange Drug Ltd.
66/68 Town Planning Way Ilupeju
Lagos – NIGERIA

Manufacturer
PT. Tempo Scan Pacific
EJIP Industrial Park, Plot 1 G-H, Cikarang, Bekasi 17550 - INDONESIA