SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF MEDICINAL PRODUCT

Panda®Tablet 500mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Paracetamol B.P. 500mg

3. PHARMACEUTICAL FORM

A white round tablet with inscriptions P/500 on one side and PANDA on the other

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Panda is suitable for the relief of headache,toothache,muscular pains anfeverish conditions.

4.2 Posology and method of administration

Adults and children over 12 years: 2 tablets 3-4 times daily

Children 6 – 12 years: ½ -1 tablet 3-4 times daily

Method of Administration

Oral administration only

4.3 Contraindications

Hypersensitivity to Paracetamol or any of the other constituents

4.4 Special warnings and precaution for use

Care is advised in the administration of Paracetamol to patients with severe renal or hepatic impairment. The hazard of over dosage is greater in those with non-cirrhotic alcoholic liver disease.

4.5 Interaction with other medicinal product and other forms of interaction.

Colestyramine: The speed of absorption of Paracetamol is reduced by colestyramine. Therefore, the colestyramine should not be taken within one hour if maximal analgesia is required.

Metoclopramide and domperidone: The speed of absorption of Paracetamol mayincreased by metoclopramide and domperidone. However, concurrent use need not be avoided.

Warfarin: 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.

Chloramphenicol: increased plasma concentration of chloramphenicol.

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

None known

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, methaemoglobenaemia and agranulocytosis but these were not necessarily causally related to Paracetamol. Very rare cases of serious skin reactions have been reported.

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

- Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes
- Regularly consumes ethanol in excess of recommended amounts.
- Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of Paracetamolover dosage 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, patient 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).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Properties

Pharmacotherapeutic group: Anilides

ATC code: N02BE01

Mechanisms of action/Effect

Analgesic- the mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system and to a lesser extent, through a peripheral action by blocking pain-impulse generation.

The peripheral action may also be due to inhibition of prostaglandin synthesis or to the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic- Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Absorption and Fate

Paracetamol is rapidly absorbed from the gastrointestinal tract. Theconcentration in plasma reaches a peak in 30 to 2 hours after ingestion.

It is metabolized 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 1 to 4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which usually detoxified by conjugation with liver glutathione may accumulate following Paracetamol over dosage and cause liver damage.

5.3 Preclinical safety data

No relevant information additional to that already contained elsewhere in the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Pregel Starch
- Corn Starch
- Magnesium Stearate
- Aerosil 200
- Talcum Powder
- Sodium Lauryl Sulphate
- Povidon PVP (K-30)
- Sodium Starch Glycollate (Primogel)

6.2 Incompatibilities

The risk of Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes.

6.3 Shelf life

3years

6.4 Special precautions for storage

Store below 30^{o}C in a dry place.

6.4 Nature and contents of container

The primary packaging materials used is: Transparent colorless PVC/PVDC/Aluminum blister

One Aluminum / PVC blisters contain 12 x 8 tablets packed in a printed cardboard case.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

Afrab Chem Limited
22 Abimbola Street, Isolo Industrial Estate,Isolo-Lagos, Nigeria

Tel: 234-1-2700057

Fax: 234-1-2700058

Email: info@afrabchem.com