SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINALPRODUCT

Panda Cold Drops

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 1ml dropperful contains Paracetamol 100mg, Chlorpheniramine maleate 1mg and Pseudoephedrine HCl 9.36mg
{For a full list of excipients, see section 6.1}

3. PHARMACEUTICALFORM

Light brown liquid with characteristic bitter taste.

4. Clinical particulars

4.1 Therapeutic indications

Panda Cold drops is indicated in the relief of aches associated with common cold, headache, and for the relief of fever.

4.2 Posology and method ofadministration

Up to 3months: 0.4ml every 4-6hours.
3-11months: 1.0ml (1 dropperful) every 4-6hours.

Method of administration

Panda Cold drops is administered orally.

4.3 Contraindications

Special precaution should be taken in giving this product to patients with

hypothyroidism, adrenocortical insufficiency, asthma, impaired kidney or liver function. Ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disease including arteriosclerosis, hypertension or aneurysms. Care should also be taken in patients receiving treatment with monoamine oxidase inhibitors (MAOI).
The administration of preparations containing aluminium hydroxide should not be given concomitantly with this product as this will increase the absorption rate of Pseudoephedrine. Decreases of the absorption rate of Pseudoephdrine occur with preparations containing kaolin and should be avoided.

4.4 Special warnings and precautions for use

Panda Cold drops should not be given to premature infants or neonates.
Caution should also be observed in patients with severe cardiovascular disorder.

4.5 Interaction with other medicinal products and other forms of interaction

a. Warfarin or similar medicines used to thin the blood (The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of Acetaminophen with increased risk of bleeding; occasional doses have no significant effect).
b. Medicines to control blood pressure, such as beta-blockers.
c. Digoxin or similar medicines for heart disease.
d. Medicines to treat depression such as tricyclic antidepressants e.g. amitriptyline.

4.6 Pregnancy and Lactation

Should not be used in pregnancy. Use with caution in breastfeeding.

4.7 Effects on ability to drive and use machines

May cause drowsiness, dizziness, blurred vision, cognitive and psychomotor impairment, which can seriously affect patients' ability to drive and use machinery. If affected they should not drive or operate machinery.

4.8 Undesirable effects

Drowsiness,dry mouth,blurred vision,urinary difficulty and retention,hypersalivation,irritability and weakness,skin rashes

4.9 Overdose

Symptoms of over 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 by increases in serum concentration of aminotransferases and bilirubin and in prothrombin time. Abnormalities of glucose metabolism and metabolic acidosis may occur.

In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported.

Other adverse reactions include nightmares, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hand in infants and children

Some antihistamins act as cerebral stimulant and symptoms of overdosage may include convulsion and hyperpyrexia. Symptoms of stimulation may also arise in some adults and include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsion. Blood disorders including agranulocytosis and haemolytic anaemia though rare, have been reported.

In the event of over dosage, the stomach should be emptied and a laxative may be given to aid peristalsis. Acetyl cysteine therapy may be initiated to nulify the effect of excess paracetamol in the system.
To counteract the overdosage effect of the antihistamine, Diazepeun may be given to

counteract the anti histamine effect of convulsion. Supportive and symptomatic treatment include artificial respiration, external cooling for hyperpyrexia and central nervous fluids.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamics properties

Paracetamol has analgesic and antipyratic properties. it has no useful anti inflammatory properties.

Panda Cold drops containing_Paracetamol can be administered in patients with renal failure by adjusting the dosage interval. A dosage interval of 4 hours is suitable for patients with a glomerular filtration rate (GFR) above 50ml per minutes an interval of 6 hours between doses is advisable for rates between 10ml and 50ml per minute. When the rate is less than 10ml per minutes, the dosage interval should be 8 hours. A dose supplement should be given to patients undergoing haemodialysis. W.M. Bennet et al, Am J. Kidney Dis. 1983, 3, 155)

Chlorpheniramine maleate is an antihistamine which is given by mouth for the symptomatic relief of hypersensitivity reactions and in pruritic skin disorders. They are common ingredients of cough and cold preparations. It is also administered parentrally.

Pseudoephedrine is a sympthomimetic amine with actions and undesirable effects resembling those of ephedrine. It is used as a bronchodilator and peripheral vasoconstrictor in preparations for the relief of nasa and bronchial congestion, particularly in bronchial asthma.

The combination of Paracetamol with Chlorpheniramine maleate serves to relieve and fever associated with common cold and sleep disturbance.

In a single dose study the metabolism of paracetamol as judged by the plasma half life and plasma concentration of metabolites was not depressed in patients with mild liver disease compared with normal subject but was significantly impaired in those with significance difference in the overall 24-hours urinary retention of paracetamol evidence that patients with liver disease were of increased risk of hepatetoxicity when given a single therepeutic dose of paracetamol (J. A. H. Forrest Eur. J. Clin. Pharmac. 1979,15,427)

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5.2 Pharmacokinetic properties

Panda Cold syrup containing paracetamol is readily absorbed from the gastro intestinal tract with peak plasma concentration occurring about 30 minutes to 2 hours after ingestion.
It is metabolised in the liver and excreted in the urine mainly as the glucoronide and sulphate conjugates less than 5% in excreted as unchanged paracetamol. The elimination half life varies from about the 4 hours. Plasma protein building is negligible at usual therapeutic concentration but increases with increasing concentration.

Chlorpheniramine maleate is absorbed relatively slowly from the gastro-intestinal track, peak concentrations occurring about 2.5 to 6 hours after administration by mouth. There is wide interindividual variation in the pharmacokinetics of chlorpheniramine; values ranging from 2 to 43 hours have been reported for the half-life.
Chlorpheniramine maleate is extensively metabolised. Unchanged drug and metabolites are excreted primarily in the urine; excretion is dependent on urinary pH and flow rate. More rapid and extensive absorption, faster clearance, and a shorter half-life have been reported in children.
Pseudoephedrine is rapidly and completely absorbed after oral administration; aluminium hydroxide increases and kaolin decreases the rate of absorption. After oral dose of 180mg, peak plasma concentrations of 500 to 900ng/ml are attained in 1 to 3 hours; after an oral dose of 180mg of a sustained release preparation, peak plasma concentration of about 400ng/ml are attained in 4 to 6 hours. Plasma half-life after dose, 5 to 8 hours which may be increased in subjects with alkaline urine and decreased in subjects with acid urine.

5.3 Preclinical safety data

None

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Propylene glycol

Glycerine

Polyethylene glycol

Methyl paraben

Bronoplol

Sodium saccharine

Sugar

Allura red colour

Vanilla essence powder

Caramel colour powder

Banana flavor liquid

Citric acid

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

Amber glass bottle of 15ml and 30ml with cap and dropper

6.6 Special precautions for disposal

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