PACOFEN TABLETS

DESCRIPTION:

Strawberry Pink, 13.0 mm diameter, round, flat tablets.

COMPOSITION:

Paracetamol BP 500mg/tab Caffeine BP 30mg/tab Codeine Phosphate BP 8mg/tab

PHARMACOLOGY:

Pacofen contains Paracetamol, caffeine anhydrous and codeine phosphate.

- Paracetamol has analgesic and antipyretic effects. It inhibits the prostaglandin synthesis in the brain to relieve pain of moderate intensity. It reduces fever by a direct effect on the heat-regulation centre to increase dissipation of body heat
- Caffeine acts on the CNS to produce a condition of wakefulness and increase mental activity.
- Ingestion of codeine phosphate produces peak plasma-codeine concentration in about one hour.
 - Codeine is metabolised by 0- and N $\,$ demethylation in the liver to morphine and norcodeine.
 - Codeine and its metabolites are excreted almost entirely by the kidney, mainly as conjugates with glucuronic acid.

INDICATIONS:

For relief of aches and pain e.g., headache, toothache and dysmenorrhoea. Codeine is not recommended for the treatment of post-operative pain following surgical procedures such as tonsillectomy or adenoidectomy in children and adolesoents below 18 years old due to the increased risk of respiratory depression.

DOSAGE:

Adults: 1-2 tablets

These doses may be given 3-4 trnes dally as required (Max. 6 tablets a day).

Children and adolescents

Codeine should not be used in children below 12 years old. In those 12 years; old and above, codeine may be used for the short-term treatment of acute moderate pain which is not relieved by analgesics such as Ibuprofen or paracetamol alone. The lowest effective dose should be used for the shortest possible duration.

PRECAUTION / WARNING:

This preparation contains PARACETAMOL. Do not take any other PARACETAMOL containing medicines at the same time. Inappropriate use of product containing paracetamol can result in liver toxicily or severe liver damage. Do not exceed the stated dose.

Should be given with care to patients with impaired renal or liver functions. Chronic use should be avoided.

Special wamings

Caution is advised when codeine is used in patients with underlying respiratory conditions, including those with asthma and other chronic breathing problems.

Parents and caregivers of paediatric patients should be advised on the possible signs and symptoms of respiratory depression In their children, such as unusual sleepiness, confusion and difficult or noisy breathing, and to seek immediate medical attention if these are observed.

Nursing mothers should also be advised to exercise caution when taking codeine, since codeine's metabolite (morphine) may subsequently be found in the breast milk. If the infant shows signs of increased sleepiness, difficulty breastfeeding, breathing difficulties or limpness, immediate medical attention should be sought.

CONTRA-INDICATIONS:

Contraindicated in patients with bronchial asthma, increased intracranial pressure, respiratory depression and nephropathy.

SIDE EFFECTS:

Side effects are usually mild; paracetamol occasionally causes skin rashes, allergy and constipation.

TOXICITY:

Repeated ingestion of high doses of Pacofen tablets may cause cirrhosis (caused by paracetamol).

STORAGE:

Store below 30"C and protect from light.

PACKING:

PVDC/PVC Blisters with Aluminium Foil, blister packs of 10x10x10's.

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For further information, please consult your physician or pharmacist.

Manufactured by:

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