

HedonTM

DAWA YA KICHWA NA ROMA

PRESENTATION

Hedon tablets are available as White, caplet shaped tablet, each tablet containing: Aspirin BP 300mg; Paracetamol BP 250mg and Caffeine BP 30mg.

PHARMACOLOGICAL ACTION

Hedon has analgesic, antipyretic and anti-inflammatory actions.

Prostaglandins are associated with the development of pain. Aspirin and Paracetamol inhibit the synthesis of prostaglandins, thus producing analgesia.

In fever, prostaglandins (PGE₂) act within the hypothalamus to produce the resultant elevation of body temperature by processes that appear to be mediated by cyclic AMP. Aspirin and paracetamol suppress this response by inhibiting the synthesis of PGE₂. Aspirin also has anti-inflammatory action as it is a much stronger inhibitor of prostaglandin (which are involved in the pathogenesis of inflammation) synthesis than paracetamol.

Caffeine relaxes smooth muscle, stimulates the central nervous system and cardiac muscles. Due to these effects it causes a reduction in drowsiness and fatigue, and also causes a more rapid and clearer flow of thought.

PHARMACOKINETICS

Orally ingested aspirin is absorbed rapidly, partly from the stomach but mostly from the upper small intestines. Appreciable concentrations are found in plasma in less

than 30 minutes: after a single dose, a peak value is reached in about 2 hours and then gradually declines. Rate of absorption is determined by many factors, particularly the disintegration and dissolution rates if tablets are given, the pH at the mucosal surfaces, and gastric emptying time. After absorption, aspirin is distributed throughout most body tissues and most transcellular fluids, primarily by pH-dependant passive processes. Aspirin is actively transported by a low-capacity, saturable system out of the CSF across the choroids plexus.

The drug readily crosses the placental barrier. The biotransformation of aspirin takes place in many tissues, but particularly in the hepatic endoplasmic reticulum and mitochondria. The three chief metabolic products are salicylic acid the glycine conjugate, the ether or phenolic glucuronide, and the ester or acyl glucuronide. IN addition, a small fraction is oxidized to gentisic acid (2,5-dihydroxybenzoic acid) and to 2,3-dihydroxybenzoic and 2,3,5-trihydroxybenzoic acids; gentisuric acid, the glycine conjugate of gentisic acid, is also formed. Aspirin is excreted in the urine as free salicylic acid (10%), salicylic acid (75%), salicylic phenolic (10%) and acyl (5%) glucuronides, and gentisic acid (<1%). However, excretion of free salicylate is extremely variable and depends upon both the dose and the urinary pH. In alkaline urine, more than 30% of the ingested drug may be eliminated as free salicylate, whereas in acidic urine this may be as low as %. The plasma half-life for aspirin is approximately 15 minutes.

Paracetamol is metabolized primarily by the hepatic microsomal enzymes. Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes, and the half-life in plasma is about 2 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; only 20 to 50% may be bound at the concentrations encountered during acute intoxication. After therapeutic doses, 90 to 100% of the drug may be recovered in the urine within the first day, primarily after hepatic conjugation with glucuronic acid (about 60%), sulfuric acid (about 35%), or cysteine (about 3%); small amounts of hydroxylated and deacetylated metabolites have also been detected. Children have less capacity for glucuronidation of the drug than do adults.

Caffeine is readily absorbed after oral administration, and maximum plasma concentrations are achieved within 1 hour. Caffeine is distributed into all body compartments. It is eliminated primarily by metabolism in the liver. Less than 5% of the amount administered is recovered in the urine unchanged. Caffeine has a half-life of 3 to 7 hours.

INDICATION

Hedon tablets are indicated for mild to moderate pain, headaches, inflammatory pyrexia, acute and chronic rheumatic disease, and musculoskeletal disorders.

DOSAGE and ADMINISTRATION

- To be taken every 3-4 hours
 - Adults and children over 12 years: 1-2 tablets
 - Maximum daily dosage of 8 tablets.
- If symptoms persist, seek medical advice.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.
Hypoprothrombinaemia, haemophilia and active peptic ulceration.

PRECAUTIONS

Hedon should be used with caution in patients with a history of peptic ulceration, coagulation abnormalities, impaired renal or hepatic function, or in dehydrated patients.

Hedon may enhance the effects of anti-coagulants, oral hypoglycaemic agents, phenytoin and sodium valproate. It may inhibit the uricosuric action of probenecid and increase the toxicity of sulphonamides.

Hedon may precipitate bronchospasm or induce attacks of asthma in susceptible patients.

Hedon should be avoided in the last 3 months of pregnancy.

Hedon should not be given to children below 12 years.

SIDE EFFECTS

Hedon may induce hypersensitivity, asthma, urate kidney stones, chronic gastro-intestinal blood loss, tinnitus, nausea and vomiting. Hedon may rarely cause allergic reactions such as skin rashes, hives or itching.

STORAGE

Store below 25°C, in a dry and dark place. Keep out of reach of children.

LEGAL CATEGORY

General Sale (GSL)

PACKAGE QUANTITIES

50 x 2 Strip Pack

Ref: P07H04/1



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