

Product Characteristics Summary

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1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT AND THE INTERNATIONAL NONPROPRIETARY NAME OF PRINCIPLE(S) ACTIVE INGREDIENT(S)

Cafenol Tablets

International Nonproprietary Name of Principle Active Ingredients: Aspirin & Caffeine

1.1 Pharmaceutical Form

Tablets

1.2 Strength:

Each tablet contains: Aspirin 375mg and Caffeine 25mg.

1.3 Presentation

A white, circular tablet with a break line on one side and '*Cafenol*' embossment on the other side. Free from foreign matter

1.4 Administrative Route

Oral Administration

2. QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE SUBSTANCES AND EXCIPIENTS

2.1 Qualitative Composition

Active Substances

- Aspirin
- Caffeine

Excipients

- Maize Starch

2.2 Quantitative Composition

Each 5ml contains:

Component	Specifications	Quantity per Tablet	Function
<i>Active Substances</i>			
Aspirin Granules	BP	224.780 mg	Active
Aspirin Crystals	BP	149.912 mg	Active
Caffeine anhydrous	BP	25.000 mg	Active
<i>Excipients</i>			
Maize Starch	BP	41.226 mg	Binder

3. PHARMACOLOGICAL CLASS

3.1 Therapeutic Class

Therapeutic group: Acetylsalicylic acid, combinations excl psycholeptics

ATC Code: N02BA51

3.2 Therapeutic Indications

For relief of headaches, toothaches, rheumatic pains, menstrual pains and other feverish conditions.

3.3 Dosage and Administrative Route

Dosage

Adults and children over the age of 12 years: 1-2 tablets every 3 to 4 hours as required

Not for use in children below 12 years of age.

Do not take more than 10 tablets within 24 hours unless recommended by the physician

Not to be taken on an empty stomach

Not to be taken by ulcer patients and pregnant women

OR as directed by the physician

Administrative Route

Oral Administration

3.4 Contraindications

In patients with haemophilia or those with intolerance to Aspirin, or Caffeine.

3.5 Side Effects

Side effects are mild and infrequent, but there is a high incidence of gastro-intestinal irritation with slight asymptomatic blood loss. Increased bleeding time. Aspirin may precipitate bronchospasm and induce asthma attacks or other hypersensitivity reactions in susceptible individuals. Aspirin may induce gastro-intestinal hemorrhage, occasionally major. It may precipitate gout in susceptible individuals. Possible risk of Reye's syndrome in children under 16 years.

High doses of caffeine can cause tremor and palpitations.

3.6 Precautions and Warnings

Warning: Do not exceed the stated doses.

Precautions: Not to be taken when on anticoagulant drugs. Children under 12 years should not use this medicine as Reye syndrome, which is associated with the use of aspirin in children, may occur. Not to be taken by those allergic to aspirin or have asthma, or recurrent ulcers. Should be given with care to patients with impaired kidney or liver function.

3.7 Precautions for Use during Pregnancy and Lactation

Pregnancy

Cafenol Tablet is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with Caffeine consumption

Lactation

Caffeine in breast milk may potentially have a stimulating effect on breast fed infants.

3.8 Precautions when driving

It does not affect the ability to drive and use machines

3.9 Interaction with other Drugs and other Forms of Interaction

Aspirin

Antacids and Absorbents: Increase excretion of aspirin in alkaline urine.

Mifepristone: Increased risk of bleeding – avoid use of aspirin for 8-12 days after administration of mifepristone.

Spirolactone: Antagonism of diuretic effect.

Heparin: Increased risk of bleeding.

Phenindione: Increased risk of bleeding.

Warfarin & other coumarins: Increased risk of bleeding.

Domperidone & Metoclopramide: Enhance the effect of aspirin.

Phenytoin & valproate: Enhance the effect of phenytoin and valproate.

Methotrexate: Delayed excretion and increased toxicity of methotrexate.

Uricosurics: Inhibition of uricosurics.

Caffeine

- **Ephedrine interacts with Caffeine**

Stimulant drugs speed up the nervous system. Caffeine and ephedrine are both stimulant drugs. Taking caffeine along with ephedrine might cause too much stimulation and sometimes serious side effects and heart problems. Do not take caffeine-containing products and ephedrine at the same time.

3.10 Overdose

Over dosages may cause dizziness, tinnitus, sweating, nausea, mental confusion, hyperventilation, ketosis or coma.

Treatment of over dosage:

For mild intoxication emptying the stomach by emesis or aspiration or gastric lavage. Prompt administration of 50g activated charcoal and ½ liter of iced mannitol reduces absorption. In severe intoxication the risk of severe liver damage can be significantly reduced by the administration of methionine 2.5g by mouth every four hours until 10g has been given or IV 20% N-acetyl cysteine should be administered.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic Properties

Aspirin

Mechanism of action/effect:

Salicylate inhibits the activity of the enzyme cyclo-oxygenase to decrease the formation of precursors of prostaglandin's and thromboxane from arachidonic acid. Although many of the therapeutic effects may result from inhibition of prostaglandin synthesis (and consequent reduction of prostaglandin activity) in various tissues, other actions may also contribute significantly to the therapeutic effects.

Analgesic: Produces analgesia through a peripheral action by blocking pain impulse generation and via a central action, possibly in the hypothalamus.

Anti-inflammatory (non-steroidal): Exact mechanisms have not been determined. Salicylates may act peripherally in inflamed tissue probably by inhibiting the synthesis of prostaglandins and possibly by inhibiting the synthesis and/or actions of other mediators of the inflammatory response.

Caffeine

Central nervous system stimulant – Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

Analgesia Adjunct:

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain. It is believed that caffeine helps to relieve headache by providing a more rapid onset of action and/or enhanced pain relief with lower doses of analgesic. Recent studies with ergotamine indicate that the enhancement of effect by the addition of caffeine may also be due to improved gastrointestinal absorption of ergotamine when administered with caffeine.

4.2 Pharmacokinetic Properties

Aspirin

Absorption is generally rapid and complete following oral administration. It is largely hydrolyzed in the gastrointestinal tract, liver and blood to salicylate which is further metabolized primarily in the liver.

Caffeine

Caffeine is completely and rapidly absorbed after oral administration with peak concentrations occurring between 5 and 90 minutes after dose in fasted subjects. There is no evidence of pre-systemic metabolism. Elimination is almost entirely by hepatic metabolism in adults.

In adults, marked individual variability in the rate of elimination occurs. The mean plasma elimination half-life is 4.9 hours with a range of 1.9 – 12.2 hours. Caffeine distributes into all body fluids. The mean plasma protein binding of caffeine is 35%.

Caffeine is metabolized almost completely via oxidation, demethylation, and acetylation, and is excreted in the urine. The major metabolites are 1-methylxanthine, 7-methylxanthine, 1,7-dimethylxanthine (paraxanthine). Minor metabolites include 1-methyluric acid and 5-acetylamino-6-formylamino-3-methyluracil (AMFU).

4.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

5. PHARMACEUTICAL PARTICULARS

5.1 Duration of Stability for Reconstituted Forms if necessary before and after reconstitution of the product

Not Applicable

5.2 Storage Conditions

Store in a cool dry place below 30⁰C .Protect from light

5.3 Nature of Primary Packaging

Cafenol Tablets are packed in PVC Aluminium blister pack of 8x20 Tablets and contained in cardboard dispenser carton with paper literature insert.

Pack sizes: 160's

5.4 Registration for a Poisons List

Not Applicable

6. MARKETING AUTHORIZATION HOLDER & MANUFACTURING SITE ADDRESSES

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7. Date of revision of the text

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