

1. NAME OF THE MEDICINAL PRODUCT

Product Characteristics Summary
Summary of Product Characteristics (SmPC)

Cafenol Tablets

Strength:

Each tablet contains:

Acetylsalicylic Acid 375mg and Caffeine Anhydrous 25mg.

Pharmaceutical Form: Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

- Aspirin
- Caffeine

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets

Presentation

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

ATC Code: N02BA51

4.2 Posology and Method of Administration

Posology

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

Method of Administration

Oral Administration

4.3 Contraindications

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

4.4 Special Warnings and Precautions for Use

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.

4.5 Interaction with other medicinal products 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.

4.6 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.

4.7 Effects on ability to drive and use machines

It does not affect the ability to drive and use machines

4.8 Undesirable effects

There 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.

Warning: Do not exceed the stated doses

4.9 Overdose

Over dosages may cause dizziness, tinnitus, sweating, nausea, mental confusion, hyperventilation, ketosis or coma. High doses of caffeine can cause tremor and palpitations.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Properties

Pharmacotherapeutic group and ATC Code

Pharmacotherapeutic group: **Acetylsalicylic acid, combinations excl psycholeptics**

ATC Code: N02BA51

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.

5.2 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).

5.3 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

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6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Storage Conditions

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

KEEP ALL MEDICINES OUT OF CHILDREN'S REACH

6.5 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

6.6 Special precautions for disposal and other handling

No special requirements

7. MANUFACTURING SITE ADDRESSES

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8. Date of revision of the text

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