

Amiphen Plus®

Capsule

Category: Analgesic, Anti-pyretic, Anti-Inflammatory

Composition: Each capsule contains 325 mg Acetaminophen, 40 mg Caffeine and 200 mg Ibuprofen

Mechanism of action:

Acetaminophen may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. Acetaminophen probably produces antipyresis by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss.

Ibuprofen may block pain impulse generation via a peripheral action that may involve reduction of the activity of prostaglandins, and possibly inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation. It probably produces antipyresis by acting centrally on the hypothalamic heat regulating center to produce peripheral vasodilation, resulting to heat loss.

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain.

Pharmacokinetics:

Acetaminophen:

Absorption: Oral - Rapid and almost complete.

Biotransformation: 90 to 95% of a dose is metabolized in the liver.

Half-life: 1 to 4 hours

Time to peak concentration: 0.5 to 2 hours.

Duration of action: 3 to 4 hours.

Elimination: Renal

Ibuprofen

Absorption: Rapid Duration of action: 4-6 hours Protein binding: >90% Elimination: Renal

Caffeine

Absorption: Readily absorbed after oral administration. Protein binding: Low (25 to 36%).

Half-life: Adults - 3 to 7 hours.

Time to peak plasma concentration: In adults - 50 to 75 minutes.

Elimination: Adult-Renal.

Indications:

Acetaminophen is indicated to relieve mild to moderate pain and reduce fever. Ibuprofen is indicated for treatment of rheumatoid arthritis, osteoarthritis, juvenile arthritis and psoriatic arthritis, pain, gouty arthritis, fever and dysmenorrhoea.

Contraindications:

-Severe allergic reaction, such as history of anaphylaxis or angioedema, induced by aspirin or other NSAIDs or nasal polyps associated with bronchospasm, aspirin-induced.

Precautions:

Pregnancy: Ibuprofen: Avoid unless the potential benefit outweighs the risk. Avoid during the third trimester (risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn); onset of labour may be delayed and duration may be increased.

Breast-feeding: Ibuprofen: Use with caution during breast-feeding.

Risk- benefit should be considered when the following medical problems exist:

Alcoholism, hepatic disease or viral hepatic, history of gastrointestinal bleeding (GL), or inflammatory or ulcerative disease of the upper or lower gastrointestinal tract, stomatitis, renal function impairment, anxiety disorders, sever cardiac disease, hypertension.

Drug interactions:

Hepatic enzyme inducers, hepatotoxic medications, anticoagulants, nonsteroidal anti - inflammatory drugs, aspirin or other salicylates.

Other CNS stimulation - producing medications, lithium, monoamine oxidase (MAO) inhibitors including furazolidone, procarbazine and selegiline.

ACE inhibitors, alcohol, anticoagulants, corticosteroids, antidiabetic agents, antihypertensives, cyclosporine, probenecid, methotrexate and valproic acid.

Side/Adverse effects:

Those indicating need for medical attention

Agranulocytosis, anemia, allergic dermatitis, hepatitis, renal failure, sterile pyuria, excessive CNS stimulation, hyperglycemia, hypoglycemia, gastrointestinal effects, ringing or buzzing in ears.

Administration and dosage:

Recommended dosage in adults and children over 12 years: one capsule three times a day.

 ${\bf Packaging:}$ Amiphen Plus $^{\circledR}$ capsules are available in packages of 30's (3 blisters of 10's).



Manufactured by Amin Isfahan-Iran

