PACKAGE LEAFLET  
COFFERGAMIN

ATC code: N02CA51

PHARMACOTHERAPEUTIC GROUP
Antimigraine preparations. Ergot alkaloids, including combinations

COMPOSITION
Caffeine 100mg and Ergotamine tartrate 1 mg in one film coated tablet

ACTION
Combined antimigraine preparation. Its therapeutic effect is due to interaction with neurotransmitter receptors, including alpha-adrenergic, serotonergic and dopaminergic receptors, as well as to the direct vasoconstrictive action of ergotamine on peripheral blood vessels. It influences the tone of the extracerebral branches of the external carotid artery and removes increased tension; removes pain mediated from the sensory receptors in vascular wall. It removes brain hypoxia which is due to atonic cerebral vessels. Ergotamine produces adrenolytic effects by blocking adrenergic receptors and has antihistamine activity, as well. Caffeine increases the intestinal absorption of ergotamine, stimulates CNS, stimulates the vasomotor center and, in this way, potentiates the action of ergotamine.

It is well and rapidly absorbed from the gastrointestinal tract and is distributed to a high degree in body tissues and fluids. It metabolizes in liver and is excreted mostly with urine and less with feces. The onset of its action is within ½ - 1 h following administration.
INDICATIONS
Migraine headache, Horton’s syndrome (histamine cephalgia); for lowering intracranial pressure in vascular, traumatic and infectious diseases of CNS. As antimigraine medication it is effective if administered during the period of the first signs of the attack (before the aura); It is not suitable for treatment during the intervals between the migraine attacks.

CONTRAINDICATIONS
Hypersensitivity to any of the components; angina pectoris and coronary sclerosis, ischemic heart disease, angioplasty, severe uncontrollable hypertension, obliterating endangiitis, peripheral circulatory disturbances; severe liver and kidney failure; hyperthyroidism; agoraphobia; insomnia; peptic ulcer; sepsis and other severe infections.

ADVERSE REACTIONS/SIDE EFFECTS
These are usually dose-dependent and disappear with discontinuation of treatment or dose reduction. Possible reactions include nausea, vomiting, restlessness, anxiety, paresthesias, headache, visual disturbances, localized edema. In elderly patients - ischemia, hypothermia in localized areas (peripheral vasoconstriction).

DRUG AND OTHER INTERACTIONS
Concurrent use with enzyme inhibitors and macrolides inhibits ergotamine metabolism and increases the risk of vasospasm. peripheral vasoconstrictive and vasospastic reactions may occur with beta blocking agents; interaction with vasoconstrictors like cocaine, epinephrine, norepinephrine, phenylephrine and vasoconstrictors in local anesthetic solutions may cause gangrene; with CNS stimulants - over-excitation, sleeplessness, cardiac arrhythmia; with MAO-inhibitors - tachycardia, severe hypertension; it may antagonize the vasodilatory
effect of nitroglycerin; in smokers it increases the risk of peripheral vascular ischemia. It potentiates the therapeutic effect of anticoagulant and antiaggregant preparations. Concurrent use of alcohol during treatment may aggravate headache and migraine symptomatics.

**PRECAUTIONS AND WARNINGS**

Occasional occurrence of peripheral circulatory failure should be monitored, as it requires termination of treatment. It is not recommended for children under 6 years of age. It should be administered to children up to 14 only if other agents fail to produce effect. When migraine attacks are more frequent than twice monthly, it is advisable to supplement therapy with other preparations.

**PREGNANCY AND BREAST FEEDING**

It is not recommended during pregnancy for risk of potentiation of uterotonic activity, vasoconstriction of uterine vessels, and reduced fetal blood flow (dead fetus, miscarriage, intestinal obstruction, and death of the newborn). Caffeine is excreted in small amounts in milk, but it may lead to hyper-excitability, insomnia and other signs of caffeine stimulation in the infant. Ergotamine is also excreted in breast milk.

**EFFECT ON ACTIVE ATTENTION, DRIVING AND OPERATION OF MACHINERY**

There are no reports of adverse effects on active attention, reflexes, and motor activity.

**MODE OF ADMINISTRATION AND DOSAGE**

In the prodromal period or at the onset of attack, 1-2 tablets; if this fails to manage the crisis, 1 tablet every 1/2 h to a maximum of 6 tablets daily. The single dose should not exceed 4 tablets. Prolonged daily use of this preparation is not recommended.
OVERDOSAGE

Symptoms - stomach or abdominal pain, cerebral and/or peripheral ischemia, thrombotic complications, vascular spasm, visual disturbances, ocular vasospasm, bilateral papillitis; signs of CNS toxicity - seizures, convulsions, unilateral paralysis; respiratory depression; tachyarrhythmia; shock.

Treatment - measures to decrease absorption (induction of emesis, gastric lavage with medicinal charcoal or magnesium sulfate). Administration of benzodiazepines, cardiovascular agents, nitroprusside, anticoagulants, low doses of heparin; monitoring of vital functions; warming of ischemic areas. Ergotamine can be removed by dialysis.

DOSAGE FORM AND PACKAGES

Film tablets, 20 tablets in a unit package.

STORAGE

In a dry place, protected from light, at temperature 15-25°C.