

PANLOR®DC Package Insert

Description

PANLOR® DC is supplied in capsule form for oral administration.

Each red capsule contains:

Acetaminophen 356.4 mg

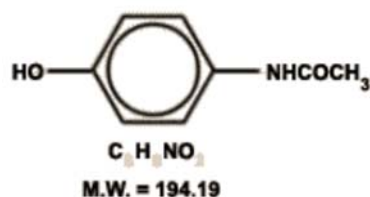
Caffeine 30 mg

Dihydrocodeine bitartrate . . 16 mg

Warning: May be habit forming

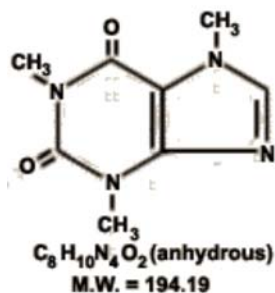
Acetaminophen (4'-hydroxyacetanilide), a slightly bitter, white, odorless, crystalline powder, is a non-opiate, non-salicylate analgesic and antipyretic.

It has the following structural formula:



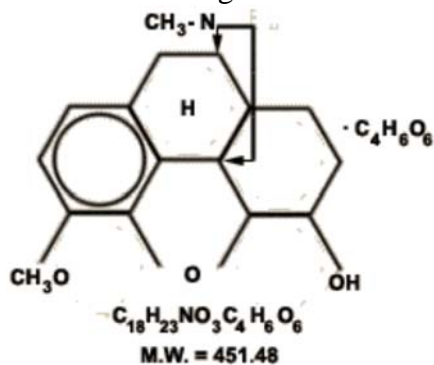
Caffeine (1,3,7-trimethylxanthine), a bitter, white crystalline powder, is a central nervous system stimulant.

It has the following structural formula:



Dihydrocodeine Bitartrate (4,5a-epoxy-3-methoxy-17-methylmorphinan-6a-ol (+)-tartrate), an odorless, fine white powder is an opioid analgesic.

It has the following structural formula:



In addition, each capsule also contains the following inactive ingredients: alginic acid, microcrystalline

cellulose and stearic acid. The capsule is composed of: FD&C Blue #1, FD&C Red #40, gelatin, silicon dioxide, sodium lauryl sulfate, and titanium dioxide. Imprinting ink composed of: ammonium hydroxide, isopropyl alcohol, n-butyl alcohol, pharmaceutical glaze (modified) in SD-45, propylene glycol, simethicone, and titanium dioxide.



Clinical Pharmacology

PANLOR® DC capsules contain dihydrocodeine which is a semi-synthetic narcotic analgesic related to codeine, with multiple actions qualitatively similar to those of codeine; the most prominent of these involve the central nervous system and organs with smooth muscle components. The principal action of therapeutic value is analgesia. This combination product also contains acetaminophen, a non-opiate, non-salicylate analgesic and anti-pyretic. This combination product contains caffeine as an analgesic adjuvant. Caffeine is also a CNS and cardiovascular stimulant.

Indications and Usage

PANLOR® DC capsules are indicated for the relief of moderate to moderately severe pain.

Contraindications

This combination product is contraindicated in persons with hypersensitivity to dihydrocodeine, codeine, acetaminophen, caffeine, or the other components noted above.

Warnings

Dihydrocodeine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery.

Precautions

General:

PANLOR® DC capsules should be given with caution to certain patients such as the elderly or debilitated. Acetaminophen is relatively non-toxic at therapeutic doses, but should be used with caution in patients with severe renal or hepatic disease. Caffeine in high doses may produce CNS and cardiovascular stimulation and GI irritation.

Information for Patients:

Dihydrocodeine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using PANLOR® DC capsules should be cautioned accordingly.

Drug Interactions

Dihydrocodeine

Patients receiving other narcotic analgesics, general anesthetics, tranquilizers, sedative-hypnotics, or other CNS depressants (including alcohol) concomitantly with PANLOR® DC capsules may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

Caffeine

Caffeine may enhance the cardiac inotropic effects of beta-adrenergic stimulating agents. Co-administration of caffeine and disulfiram may lead to a substantial decrease in caffeine clearance. Caffeine may increase the metabolism of other drugs such as phenobarbital and aspirin. Caffeine accumulation may occur when products or foods containing caffeine are consumed concomitantly with quinolones such as ciprofloxacin.

Pregnancy: Teratogenic Effects - Pregnancy Category C

Animal reproduction studies have not been conducted with PANLOR® DC capsules. It is also not known whether this product can cause fetal harm when administered to pregnant women or can affect reproduction capacity in males and females. This product should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Because of the potential for serious adverse reactions in nursing infants from this product, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:

Since there is no experience in pediatric patients who have received this drug, safety and efficacy in pediatric patients have not been established.

Adverse Reactions

The most frequently observed reactions include lightheadedness, dizziness, drowsiness, sedation, nausea, vomiting, constipation, pruritus, and skin reactions.

Drug Abuse and Dependence

This combination product is subject to the provisions of the Controlled Substance Act, and has been placed in Schedule III.

Dihydrocodeine can produce drug dependence of the codeine type and therefore has the potential of being abused. Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of dihydro-codeine, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic containing medications.

Prolonged, high intake of caffeine may produce tolerance and habituation. Physical signs of withdrawal, such as headaches, irritation, nervousness, anxiety, and dizziness may occur upon abrupt discontinuation.

Overdosage

Following an acute overdosage with PANLOR® DC capsules, toxicity may result from the dihydrocodeine, acetaminophen, or, less likely, caffeine component. An overdose is a potentially lethal polydrug overdose situation, and consultation with a regional poison control center is recommended. A listing of the poison control centers can be found in standard references such as the Physician's Desk Reference®

Signs and Symptoms and Laboratory Findings:

Toxicity from dihydrocodeine is typical of opiates and includes pinpoint pupils, respiratory depression, and loss of consciousness. Convulsions, cardiovascular collapse, and death may occur. With acetaminophen, dose-dependent hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may occur. Early symptoms of hepatotoxicity include nausea, vomiting,

diaphoresis, and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams or fatalities with less than 15 grams. Acute caffeine poisoning may cause insomnia, restlessness, delirium, tachycardia, extrasystoles, and seizures.

Because overdose information on this combination product is limited, it is unclear which of the signs and symptoms of toxicity would manifest in any particular overdose situation.

Treatment:

Immediate treatment includes support of cardiorespiratory function and measures to reduce drug absorption. Vomiting should be induced with syrup of ipecac, if the patient is alert and has adequate laryngeal reflexes. Oral activated charcoal should follow. The first dose should be accompanied by an appropriate cathartic. Gastric lavage may be necessary. Hypotension is usually hypovolemic and should be treated with fluids. Endotracheal intubation and artificial respiration may be necessary. Peritoneal or hemodialysis may be necessary. If hypoprothrombinemia occurs, Vitamin K should be administered.

The pure opioid antagonist, naloxone, is a specific antidote against respiratory depression which results from opioid overdose. Naloxone hydrochloride (usually 0.4 to 2.0 mg) should be administered intravenously; however, because its duration of action is relatively short, the patient must be carefully monitored until spontaneous respiration is reliably re-established. Re-administration may be necessary. Naloxone should not be given in the absence of clinically significant respiratory or circulatory depression secondary to opioid overdosage.

In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time since ingestion. Do not await the plasma concentration determination of acetaminophen before administering acetylcysteine. Serum liver enzyme levels should be quantitated. Therapy in children involves a similar treatment scheme; however, a regional Poison Control Center should be contacted.

No specific antidote is available for caffeine. In addition to the supportive measures above, administration of demulcents such as aluminum hydroxide gel may diminish GI irritation. Seizures may be treated with intravenous diazepam or a barbiturate.

Dosage and Administration

The usual adult dosage is two (2) PANLOR® DC capsules orally every four (4) hours. Dosage should be adjusted according to the severity of the pain and the response of the patient. No more than ten (10) capsules should be taken in a 24-hour period.

How Supplied

PANLOR® DC capsules, containing acetaminophen 356.4 mg, caffeine 30 mg and dihydrocodeine bitartrate* 16 mg (*Warning: May be habit forming), are supplied in bottles of 100 capsules (NDC# 0525-0016-01). Capsules are red, body and cap, and are imprinted with "PAL" on the cap and "0016" on the body in white ink.

Store at controlled room temperature, 20°C - 25°C (68°F - 77°F).

Protect from moisture.

Dispense in a tight, light-resistant container with a child-resistant closure.

Rx only

Manufactured for:

Pan American Laboratories, Inc.
Covington, LA 70433

Manufactured by:

MIKART, INC.
Atlanta, GA 30318