PAREGORIC- paregoric liquid
Hi-Tech Pharmacal Co., Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Paregoric, USP

***each 5 mL contains 2 mg of anhydrous morphine**

Rx Only

DESCRIPTION

Each 5 mL contains:

Anhydrous Morphine ..... 2 mg

(from opium tincture)

Alcohol 45%

Inactive Ingredients: anise oil, benzoic acid, camphor, alcohol, glycerin, and purified water.

CLINICAL PHARMACOLOGY

Morphine produces its major effects on the central nervous system (CNS) and on the bowel.

INDICATIONS AND USAGE

Paregoric is useful for the treatment of diarrhea.

CONTRAINDICATIONS

Hypersensitivity to morphine. Because of its stimulating effect on the spinal cord, morphine should not be used in convulsive states, such as those occurring in status epilepticus, tetanus, and strychnine poisoning.

This preparation should not be used in diarrhea caused by poisoning until the toxic material is eliminated from the gastrointestinal tract.

PRECAUTIONS

General

Head Injury and Increased Intracranial Pressure - The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal-fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a preexisting increase in intracranial pressure. Furthermore, narcotics produce additional effects that may obscure the clinical course in patients with head injuries.

Acute Abdominal Conditions - The administration of morphine or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Special-Risk Patients - Morphine should be given with caution to certain patients, such as the elderly or debilitated and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

Morphine should be used with extreme caution in patients with disorders characterized by hypoxia, since even usual therapeutic doses of narcotics may decrease respiratory drive to the point of apnea while simultaneously increasing airway resistance.

Hypotensive Effect - The administration of morphine may result in severe hypotension in the postoperative patient or any individual whose ability to maintain blood pressure has been compromised by a depleted blood volume or the administration of such drugs as the phenothiazines or certain anesthetics.

Supraventricular Tachycardias - Because of a possible vagolytic action that may produce a significant increase in the ventricular response rate, morphine should be used with caution in patients with atrial flutter and other supraventricular tachycardias.

Convulsions - Morphine may aggravate preexisting convulsions in patients with convulsive disorders. If dosage is escalated substantially above recommended levels because of tolerance development, convulsions may occur in individuals without a history of convulsive disorders.

Information for Patients

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

Interactions

Drug Interactions

Morphine in combination with other narcotic analgesics, general anesthetics, phenothiazines, tranquilizers, sedative/hypnotics, or other CNS depressants (including alcohol) has additive depressant effects, and the patient should be so advised. When such combination therapy is contemplated, the dosage of one or both agents should be reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Paregoric has no known carcinogenic or mutagenic potential. However, no long-term animal studies are available to support this observation.

Usage in Pregnancy

Pregnancy Category C – Animal reproduction studies have not been conducted with morphine. It is not known whether morphine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Paregoric should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Morphine appears in the milk of nursing mothers. Caution should be exercised when paregoric is administered to a nursing woman.

ADVERSE REACTIONS

The most frequent adverse reactions include lightheadedness, dizziness, sedation, nausea, and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1- 800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

Paregoric is a Schedule lll narcotic.

Dependence

Morphine can produce drug dependence and, therefore, has the potential for being abused. Patients receiving therapeutic dosage regimens of 10 mg every 4 hours for 1 to 2 weeks have exhibited mild withdrawal symptoms. Development of the dependent state is recognizable by an increased tolerance to the analgesic effect and the appearance of purposive phenomena (complaints, pleas, demands, or manipulative actions) shortly before the time of the next scheduled dose. A patient in withdrawal should be treated in a hospital environment. Usually, it is necessary only to provide supportive care with administration of a tranquilizer to suppress anxiety. Severe symptoms of withdrawal may require administration of a replacement narcotic.

OVERDOSAGE

Signs and Symptoms

Serious overdosage of morphine is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and, sometimes, bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest, and death may occur.

Treatment

Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote against the respiratory depression that may result from overdosage or unusual sensitivity to narcotics. Therefore, an appropriate dose of the antagonist should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of morphine may exceed that of the antagonist, the patient should be kept under continued surveillance, and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated.

DOSAGE AND ADMINISTRATION

Usual Pediatric Dosage

0.25 to 0.5 mL/kg of body weight 1 to 4 times a day or as directed by a physician.

Usual Adult Dosage

5 to 10 mL 1 to 4 times a day or as directed by a physician.

HOW SUPPLIED

Paregoric, USP 2 mg*/5 mL, *each 5 mL contains 2 mg of anhydrous morphine (from opium tincture); alcohol 45% and is available in 16 fl. oz (473 mL) bottles.

RECOMMENDED STORAGE

Store at controlled room temperature, 15°-30°C (59°-86°F) [see USP].

PROTECT FROM LIGHT

AVOID EXCESSIVE HEAT

SHAKE WELL BEFORE USING

NOTE: This product may deposit a sediment if exposed to low temperatures. Filter if necessary.

Dispense in a tight, light-resistant container as defined in the USP. Use safety closures when dispensing this product unless otherwise directed by a physician or requested by the purchaser.

Rx Only

Manufactured By:

HI-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev. 855:05 03/16

Package/Label Display Panel

Paregoric, USP

2 mg*/5 mL

***each 5 mL contains 2 mg of anhydrous morphine**

DO NOT USE THIS PRODUCT IF THE SAFETY SEAL AROUND THE CAP IS BROKEN OR MISSING.

BULK CONTAINER-

NOT FOR HOUSEHOLD USE

Each 5 mL contains:

Anhydrous Morphine …….2 mg

Alcohol ……...45%

USUAL USAGE: See accompanying package insert.

WARNING: KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Store at controlled room temperature, 15° - 30°C (59°-86°F) [see USP]. PROTECT FROM LIGHT. AVOID EXCESSIVE HEAT. SHAKE WELL BEFORE USING.

Dispense in a tight, light-resistant container as defined in the USP. Use safety closures when dispensing this product unless otherwise directed by a physician or requested by the purchaser.

Rx Only

16 fl oz (473 mL)

HI-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev.855:06 07/16

PAREGORIC

paregoric liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50383-855
Route of Administration	ORAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MORPHINE (UNII: 76I7G6D29C) (MORPHINE - UNII:76I7G6D29C)	MORPHINE	2 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
ANISE OIL (UNII: 6Y89129C8H)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	

Product Characteristics			
Color	YELLOW (light yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-855-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/06/2012	

Labeler - Hi-Tech Pharmacal Co., Inc. (101196749)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co., Inc.		101196749	MANUFACTURE(50383-855)

Revised: 12/2018 Hi-Tech Pharmacal Co., Inc.