BELLADONNA ALKALOIDS WITH PHENOBARTBITAL- belladonna alkaloids with phenobartbital tablet
Rebel Distributors Corp

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.

BELLADONNA
ALKALOIDS WITH
PHENOBARBITAL
TABLETS
Rx Only
Rev. 04/05

DESCRIPTION:

Each Tablet contains:

Atropine Sulfate, USP.....0.0194 mg
Hyoscyamine Sulfate, USP.....0.1037 mg
Scopolamine Hydrobromide, USP.....0.0065 mg
Phenobarbital, USP.....16.2 mg

Inactive ingredients: Anhydrous Lactose, Calcium Stearate, Colloidal Silicon Dioxide, Corn Starch, and Microcrystalline Cellulose.

CLINICAL PHARMACOLOGY:

This drug combination provides natural belladonna alkaloids in a specific, fixed ratio combined with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation.

INDICATIONS AND USAGE:

Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the following indications as “possibly” effective:

For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

May also be useful as adjunctive therapy in the treatment of duodenal ulcer. IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS.

CONTRAINDICATIONS:

Glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis especially if complicated by toxic magacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Belladonna alkaloids with phenobarbital tablets are contraindicated in patients with known hypersensitivity to any of the ingredients. Phenobarbital is contraindicated in acute intermittent porphyria

and in those patients in whom phenobarbital produces restlessness and/or excitement.

WARNINGS:

In the presence of a high environmental temperature, heat prostration can occur with belladonna alkaloids (fever and heatstroke due to decreased sweating).

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Belladonna alkaloids with phenobarbital tablets may produce drowsiness or blurred vision. The patient should be warned, should these occur, not to engage in activities requiring mental alertness, such as operating a motor vehicle or other machinery, and not to perform hazardous work.

Phenobarbital may decrease the effect of anticoagulants, and necessitate larger doses of the anticoagulant for optimal effect. When the phenobarbital is discontinued, the dose of the anticoagulant may have to be decreased.

Phenobarbital may be habit forming and should not be administered to individuals known to be addiction prone or to those with a history of physical and/or psychological dependence upon drugs.

Since barbiturates are metabolized in the liver, they should be used with caution and initial doses should be small in patients with hepatic dysfunction.

PRECAUTIONS:

Use with caution in patients with: autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia, and hypertension.

Belladonna alkaloids may produce a delay in gastric emptying (antral stasis) which would complicate the management of gastric ulcer.

Theoretically, with overdosage, a curare-like action may occur.

Carcinogenesis, mutagenesis.

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy Category C.

Animal reproduction studies have not been conducted with belladonna alkaloids with phenobarbital tablets. It is not known whether belladonna alkaloids with phenobarbital tablets can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Belladonna alkaloids with phenobarbital tablets should be given to a pregnant woman only if clearly needed.

Nursing mothers.

It is not know whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when belladonna alkaloids with phenobarbital tablets are administered to a nursing mother.

ADVERSE REACTIONS:

Adverse reactions may include xerostomia, urinary hesitancy and retention; blurred vision; tachycardia; palpitation; mydriasis; cycloplegia; increased ocular tension; loss of taste sense; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; musculoskeletal pain; severe allergic reaction or drug idiosyncrasies, including anaphylaxis, urticaria and other dermal manifestations; and decreased

sweating. Elderly patients may react with symptoms of excitement, agitation, drowsiness, and other untoward manifestations to even small doses of the drug. Phenobarbital may produce excitement in some patients, rather than a sedative effect. In patients habituated to barbiturates, abrupt withdrawal may produce delirium or convulsions.

DOSAGE AND ADMINISTRATION:

The dosage of belladonna alkaloids with phenobarbital tablets should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

Adults: One or two tablets three or four times a day according to condition and severity of symptoms.

OVERDOSAGE:

The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of the mouth, difficulty in swallowing, CNS stimulation.
Treatment should consist of gastric lavage, emetics and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride, should be added.

HOW SUPPLIED:

Belladonna Alkaloids with Phenobarbital Tablets are supplied as; White, round, scored, compressed tablets imprinted “West-ward 140”.

Bottles of 30 NDC 21695-890-30

Store at 20 – 25° C (68- 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

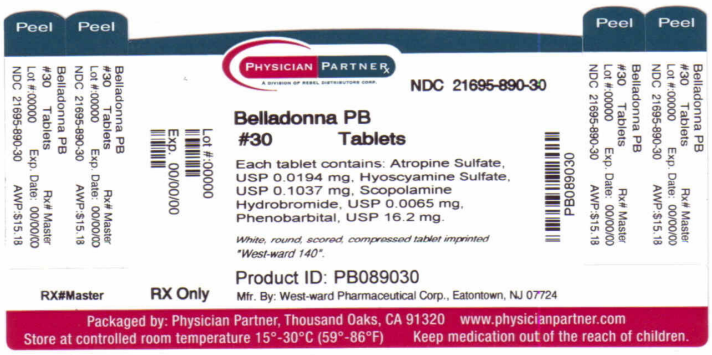
Manufactured by:
West-ward Pharmaceutical Corp.
Eatontown, NJ 07724
Revised April 2005

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



BELLADONNA ALKALOIDS WITH PHENOBARTBITAL

belladonna alkaloids with phenobartbital tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-890(NDC:0143-1140)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.0194 mg
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.1037 mg
SCOPOLAMINE HYDROBROMIDE (UNII: 451IFR0GXB) (SCOPOLAMINE - UNII:DL48G20X8X)	SCOPOLAMINE HYDROBROMIDE	0.0065 mg
PHENOBARBITAL (UNII: YQE403BP4D) (PHENOBARBITAL - UNII:YQE403BP4D)	PHENOBARBITAL	16.2 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	West;ward;140
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-890-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		08/31/2004	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 1/2011 Rebel Distributors Corp