

PHENOBARBITAL WITH BELLADONNA ALKALOIDS- phenobarbital with belladonna alkaloids elixir

AvKARE

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.

PHENOBARBITAL with BELLADONNA ALKALOIDS ELIXIR

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ⓂRx Only

DESCRIPTION:

Each 5 mL (teaspoonful) of elixir contains:

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

Inactive ingredients:

Ethyl Alcohol, Purified Water, Glycerin, Methylparaben Sodium, Propylparaben Sodium, Saccharin Sodium, Xylitol, Citric Acid, Stevia Reb-A, Natural and Artificial Grape Flavor

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:

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 A 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 megacolon; myasthenia gravis; hiatal hernia associated with reflux esophagitis.

Phenobarbital with Belladonna Alkaloids Elixir is 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.

Phenobarbital with Belladonna Alkaloids Elixir 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:

General

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, Impairment of Fertility

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

Pregnancy Category C

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

Nursing mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when *Phenobarbital* with *Belladonna Alkaloids Elixir* is 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.

To report SUSPECTED ADVERSE REACTIONS, contact AvKARE at 1-855-361-3993 or FDA

at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION:

The dosage of *Phenobarbital with Belladonna Alkaloids Elixir* should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

Adults:

One or two teaspoonfuls of elixir three or four times a day according to conditions and severity of symptoms.

Pediatric patients:

may be dosed every 4 to 6 hours.

Starting Dosage:

Body Weight q4h q6h

10 lb. (4.5 kg) 0.5 mL 0.75 mL

20 lb. (9.1 kg) 1.0 mL 1.5 mL

30 lb. (13.6 kg) 1.5 mL 2.0 mL

50 lb. (22.7 kg) 1/2 tsp 3/4 tsp

75 lb. (34 kg) 3/4 tsp 1 tsp

100 lb. (45.4kg) 1 tsp 1 1/2 tsp

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:

Phenobarbital with Belladonna Alkaloids Elixir is supplied as a purple colored, grape flavored liquid.

4 oz. bottles

NDC: 42291-205-04

16 oz. (Pint) bottles

NDC: 42291-205-16

AVOID FREEZING

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.

All prescriptions using this product shall be pursuant to State statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on the therapeutic equivalence.

WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR

CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Manufactured for:

AvKARE

Pulaski, TN 38478

Mfg. Rev. 01/18

AV 05/20 (P)

Principal Display Panel

AVKARE.
NDC 42291-205-04

**PHENOBARBITAL
with
BELLADONNA
ALKALOIDS
ELIXIR**

Each 5 mL (1 teaspoonful) contains:
Phenobarbital, USP 16.2 mg
Hyoscyamine Sulfate, USP 0.1037 mg
Atropine Sulfate, USP 0.0194 mg
Scopolamine Hydrobromide, USP 0.0065 mg

USUAL ADULT DOSAGE
See accompanying product literature for complete information.

Store at 20° - 25°C (68° - 77°F) (See USP Controlled Room Temperature). Protect from light and avoid freezing.

Keep container tightly closed.

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

WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured for:
AvKARE
Pulaski, TN 38478
Mfg. Rev. 01/18

4 oz. Bottle Rx Only AV 05/20 (P)

N 3 42291 20504 8

AVKARE.
NDC 42291-205-16

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Manufactured for:
AvKARE
Pulaski, TN 38478
Mfg. Rev. 01/18

16 oz. Bottle Rx Only AV 05/20 (P)

N 3 42291 20516 1

PHENOBARBITAL WITH BELLADONNA ALKALOIDS

phenobarbital with belladonna alkaloids elixir

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42291-205
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL (UNII: YQE403BP4D) (PHENOBARBITAL - UNII:YQE403BP4D)	PHENOBARBITAL	16.2 mg in 5 mL
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.1037 mg in 5 mL
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.0194 mg in 5 mL
SCOPOLAMINE HYDROBROMIDE (UNII: 451IFR0GXB) (SCOPOLAMINE - UNII:DL48G20X8X)	SCOPOLAMINE HYDROBROMIDE	0.0065 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-205-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2020	
2	NDC:42291-205-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/05/2020	

Labeler - AvKARE (796560394)

