AQUANAZ PSE- dextromethorphan hbr, guafenesin, pseudoephedrine hcl tablet
Capital Pharmaceutical, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Aquanaz PSE

Active Ingredients

Dextromethorphan HBr 20mg

Guaifenesin 375mg

Pseudoephedrine HCl 60mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Uses

Temporarily relieves these symptoms occurring with a cold nasal decongestion:
▪ cough due to minor throat and bronchial irritation
▪ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes.

Warnings

▪ **When using this product do not exceed recommended dosage.**

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs

for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Stop use and ask doctor if

▪ symptoms do not improve
▪ new symptoms occur
▪ redness or swelling is present
▪ nervousness, dizziness, or sleeplessness occur
▪ symptoms do not improve within 7 days or are accompanied by fever
▪ cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

Ask Doctor before use if you have

▪ heart disease

▪ high blood pressure
▪ thyroid disease
▪ diabetes
▪ difficulty in urinating due to enlargement of the prostate gland
▪ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema or where cough is accompanied by excessive phlegm

Directions

Adults and children 12 years of age and over	1 tablet every 4 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age	1/2 tablet every 4 hours, not to exceed 2 tablets in 24 hours, or as directed by a doctor.

Do not exceed recommended dosage.

Pregnant or Breast Feeding

If pregnant or breast feeding, ask a health professional before use.

Keep out of Reach of Children

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms

Inactive Ingredients

Carnauba Wax, FD&C Blue #1 Aluminum Lake, FD&C Yellow #5 Aluminum Lake, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polysorbate 80, Polyvinyl Alcohol, Silicon Dioxide, Talc

Other information

Store at 15°-30°C (59°-86°F).

- Aquanaz PSE is a clear coated caplet with green core, debossed with “AQ” Bisection “PSE” on

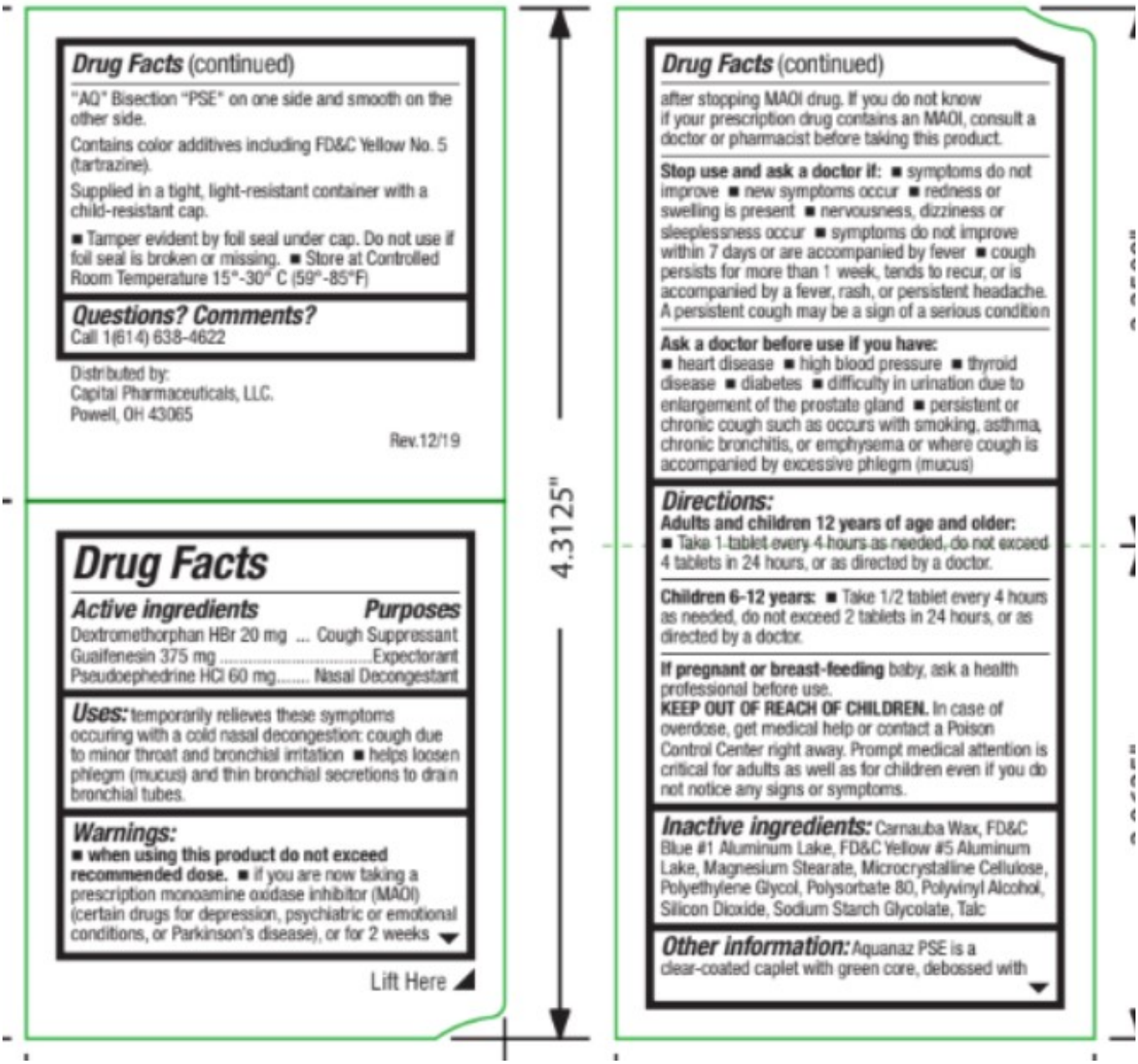
one side and smooth on the other side.
- Contains color additives including FD&C Yellow No. 5 (tartrazine).
- Supplied in a tight, light-resistant container with a child-resistant cap.
- Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
- Store at Controlled Room Temperature 15°-30°C (59°-86°F).

Questions? Comments
Call 1(614) 638-4622

Package Label

NDC 29978-588-90

Aquanaz PSE Tablets
Triple Combination Relief:
Cough Suppressant: Dextromethorphan HBr 20 mg
Expectorant: Guaifenesin 375 mg
Nasal Decongestant: Pseudoephedrine HCl 60 mg
90 tablets



AQUANAZ PSE

dextromethorphan hbr, guafenesin, pseudoephedrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:29978-588
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	375 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics			
Color	green	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	AO;PSE
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:29978-588-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2020	

Labeler - Capital Pharmaceutical, LLC (831545541)

Revised: 5/2020 Capital Pharmaceutical, LLC