

CHLORESIN- acetaminophen, dextromethorphan, guaifenesin, phenylephrine tablet
Affasco Inc.

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.

Active Ingredients (In Each Tablet)

Acetaminophen 325 mg, Dextromethorphan HBr 15 mg, Guaifenesin 200 mg, Phenylephrine HCl 5 mg
Pain reliever/fever reducer, Cough suppressant, Expectorant, Nasal decongestant

Uses: For temporary relief of:

- cough • sore throat • minor aches • pain
- headaches • nasal congestion • fever
- helps loosen phlegm (mucus), thin bronchial secretions to make coughs more productive

Warnings:

Liver Warning:

This product contains acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, if you take with other drugs containing acetaminophen (prescription or nonprescription), or if you have 3 or more alcoholic drinks every day while using this product.

Ask a doctor before use if you have: heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland, cough that occurs with too much phlegm (mucus), chronic cough that lasts such as occurs with smoking, asthma, or emphysema or chronic bronchitis.

Stop use and ask a doctor if: you get nervous, dizzy or sleepless, cough lasts more than 7 days, comes back or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

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 for children even if you do not notice any signs or symptoms.

Directions: Do not use more than directed.

Adults and children: (12 years and older) Take 2 tablets with water every 6-8 hours as needed. Do not take more than 8 tablets in 24 hours, or as directed by doctor.

Children: (under 12 years) Do use unless directed by a doctor.

SEE ORIGINAL BOX FOR COMPLETE PRODUCT INFORMATION

Afassco

Made in
USA

CHLORESIN

2 Tablets

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Acetaminophen 325 mgPain reliever/fever reducer
Dextromethorphan HBr 15 mgCough suppressant
Guaifenesin 200 mgExpectorant
Phenylephrine HCl 5 mgNasal decongestant

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Questions? Contact Afassco Minden, NV 89423
Store at room temperature
Tamper evident: Do not use packet if torn or cut.

Warnings (continued)

Ask a doctor before use if you have: heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland, cough that occurs with too much phlegm (mucus), chronic cough that lasts such as occurs with smoking, asthma, or emphysema or chronic bronchitis. **Stop use and ask a doctor if:** you get nervous, dizzy or sleepless, cough lasts more than 7 days, comes back or occurs with fever, rash or headache that lasts. These could be signs of a serious condition. **If pregnant or breast-feeding,** ask a health care 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 for children even if you do not notice any signs or symptoms.

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PRODUCT INFORMATION**

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CHLORESIN

acetaminophen, dextromethorphan, guaifenesin, phenylephrine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51532-0107
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51532-0107-2	2 in 1 PACKET; Type 0: Not a Combination Product	10/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/25/2016	

Labeler - Affasco Inc. (609982723)**Registrant** - ULTRAtab laboratories, Inc. (151051757)

Establishment			
Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(51532-0107)

Establishment			
Name	Address	ID/FEI	Business Operations
ULTRAtab LABORATORIES, INC.		151051757	manufacture(51532-0107)

Revised: 9/2019

Affasco Inc.