

HANDY SOLUTIONS SINUS CONGESTION AND PAIN RELIEF- acetaminophen, guaifenesin, phenylephrine hydrochloride tablet
Navajo Manufacturing Company 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.

Handy Solutions Sinus Congestion & Pain Relief

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 325 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purposes

Pain Reliever/Fever Reducer
Expectorant
Decongestant

Uses

- relieves nasal congestion associated with sinusitis
 - relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
 - relieves sinus congestion and pressure, helps decongest sinus openings and passages
 - restores free breathing
 - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive
- Temporarily relieves minor aches, pains and fever associated with:
- headache • common cold • toothache • backache • muscular aches • menstrual cramps

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 tablets in 24 hours
- with other drugs containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 3 or more alcoholic drinks every day while using this product

Do not use

- with any other product containing acetaminophen. This will provide more than the recommended dose (overdose) of acetaminophen and could cause serious health concerns
- 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 MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.

- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- when using this product do not exceed the recommended dose

Ask a doctor before use if you have:

- heart disease • high blood pressure
- thyroid disease • diabetes
- difficulty in urination due to enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus)

Stop use and ask a doctor if:

- symptoms do not improve
- pain or fever persists or gets worse
- 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 a fever, rash, or persistent headache. A persistent cough may be a sign 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

Adults and children 12 years of age and older: Take 2 tablets every 4 to 6 hours as needed; do not exceed 8 tablets in 24 hours, or as directed by a doctor.

Children under 12 years of age: consult a doctor.

Other information

- Avoid excessive heat and humidity.
- Store at controlled room temperatures 15° to 30°C (59° to 86°F).
- Tamper evident. Do not use if packet is torn, cut or opened.

Inactive ingredients

FD&C Red #40, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

Questions or comments?

Call 1-800-525-5097

Package Labeling:



HANDY SOLUTIONS SINUS CONGESTION AND PAIN RELIEF

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-178
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	FR14
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-178-02	2 in 1 POUCH; Type 0: Not a Combination Product	10/22/2016	
2	NDC:67751-178-03	3 in 1 CARTON	10/22/2016	
2		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/22/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	pack(67751-178)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-178) , repack(67751-178)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(67751-178)

Revised: 11/2019

Navajo Manufacturing Company Inc.