

**RELIEF-PE - acetaminophen, phenylephrine, chlorpheniramine tablet, coated
NorMed**

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.

Relief-PE

Temporarily relieves nasal congestion, sinus pressure, and minor aches and pains due to:

- the common cold
- hay fever
- upper respiratory allergies
- headache
- itchy/watery eyes
- runny nose
- muscular aches

Temporarily reduces fever

Liver warning: this product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcohol drinks every day while using this product

Do not use:

- with any other drug containing acetaminophen (prescription or non-prescription)
- 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, or if you do not know if your prescription drug contains an MAOI

Ask a doctor or pharmacist before use if

- you are taking sedatives or tranquilizers
- you are taking the blood thinning drug warfarin
- you do not know if other drugs you are taking contain acetaminophen

Ask a doctor before use if you have

- heart, liver, or thyroid disease
- high blood pressure
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

When using this product to not use more than directed. This product may cause excitability or drowsiness. Alcohol, sedatives and tranquilizers may increase the drowsiness effect. Use caution when driving a motor vehicle or operating machinery.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- new symptom occur
- fever worsens or lasts for more than 3 days
- pain or nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present

These could be signs of serious condition

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

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222.

Directions: Do not take more than directed. Adults and children 12 years of age and over:

- take 1 to 2 tablets every 6 hours while symptoms persist
- do not take more than 8 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: **do not use**; this will provide more than the recommended dose (overdose) and may cause liver damage

Active Ingredients (in each tablet)

Acetaminophen 325mg...pain reliever/fever reducer

Phenylephrine 5mg...nasal decongestant

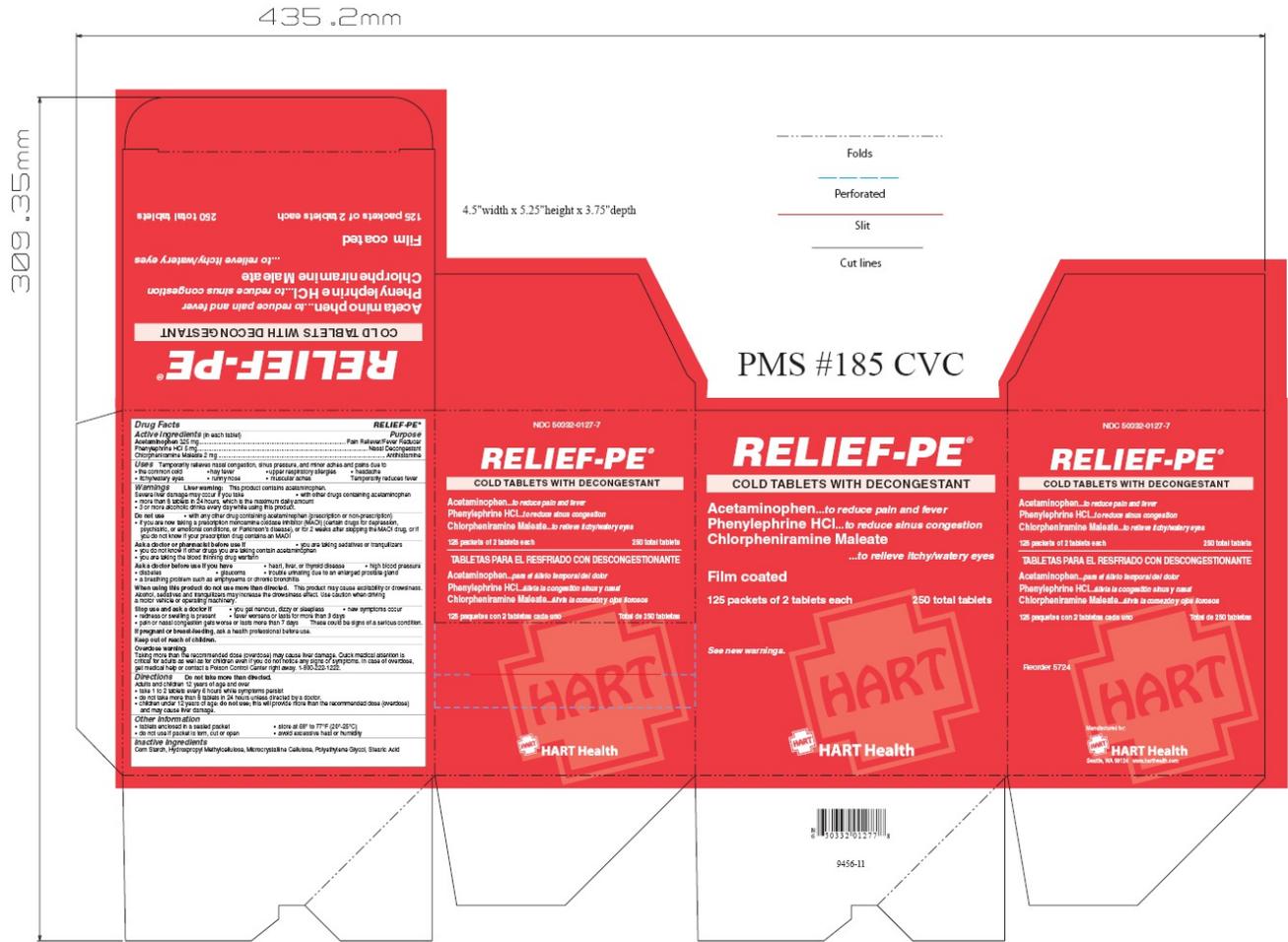
chlorpheniramine maleate 2mg...antihistamine

Pain Reliever/Fever Reducer

Nasal Decongestant

Antihistamine

corn starch, hydroxypropyl methylcellulose, microcrystalline cellulose, polyethylene glycol, stearic acid



RELIEF-PE

acetaminophen, phenylephrine, chlorpheniramine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 332-0127
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -		DIPHENYLDIMINE	5 mg

UNII:1WS297W6MV)	FINENTLEPHIRINE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE	2 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	AZ275
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0127-4	100 in 1 BOX, UNIT-DOSE		
2	NDC:50332-0127-7	250 in 1 BOX, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/16/2012	

Labeler - NorMed (069560969)