HISTENOL FORTE II - phenylephrine hydrochloride, acetaminophen and guaifenesin tablet
Zee Medical 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.

Drug Facts

Active Ingredient (in each tablet) Acetaminophen 325 mg, Phenylephrine HCL-5 mg, Guaifenesin-100 mg

Purpose-Pain reliever, Expectorant,Nasal Decongestant

Uses ■ temporarily relieves the following cold and flu symptoms:
■ nasal and sinus congestion ■ headache ■ minor aches and pains
■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Directions ¦ adults: take 2 tablets every 4 hours, not more than 12 tablets in 24 hours ¦ children under 12 years: ask a doctor

Warnings:Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
¦ more than 12 tablets in 24 hours, which is the maximum daily amount ¦ with other drugs containing acetaminophen
¦ 3 or more alcoholic drinks every day while using this product
Do not use
¦ 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.
¦ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains
acetaminophen, ask a doctor or pharmacist.
Ask a doctor before use if you have
¦ heart disease ¦ high blood pressure ¦ diabetes ¦ liver disease ¦ thyroid disease
¦ trouble urinating due to an enlarged prostate gland
¦ cough that occurs with too much phlegm (mucus)
¦ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin
Stop use and ask a doctor if
¦ you get nervous, dizzy or sleepless
¦ pain, nasal congestion or cough gets worse or lasts more than 7 days
¦ cough comes back or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.
¦ redness or swelling is present in the painful area ¦ any new symptoms appear

If pregnant or breast-feeding baby, 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.

Inactive ingredients
FDC red 40, maltodextrin, microcrystalline cellulose, povidone, silica, sodium starch glycolate, starch, stearic acid

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HISTENOL FORTE II

phenylephrine hcl, acetaminophen, guaifenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:35418-111
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	325 mg
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**

FD&C RED NO. 40	
MALTODEXTRIN	
CELLULOSE, MICROCRYSTALLINE	
POVIDONE K29/32	
SILICON DIOXIDE	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STARCH, CORN	
STEARIC ACID	

Product Characteristics

Color	pink (rose pink)	**Score**	no score
Shape	ROUND (ZEE;HF2)	**Size**	12mm
Flavor		**Imprint Code**	ZEE;HF2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35418-111-67	125 in 1 CARTON		
1	NDC:35418-111-68	50 in 1 CARTON		
1	NDC:35418-111-02	2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/12/2012	

Labeler - Zee Medical Inc (009645623)

Registrant - Ultra Seal Corporation (085752004)

Establishment

Name	Address	ID/FEI	Business Operations
Ultratab Laboratories, Inc.		151051757	manufacture(35418-111)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	repack(35418-111)

Revised: 11/2012 Zee Medical Inc