

HISTENOL FORTE II - phenylephrine hcl, acetaminophen, 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
Multi-Symptom Cold Tablets

Acetaminophen / Guaifenesin / Phenylephrine
Acetaminofen / Guafenesina / Fenilefrina
Pain Reliever / Expectorant / Nasal Decongestant
Alivia el dolor / Expectorante / Descongestionante nasal
NON-DROWSY
TABLETAS CONTRA LOS MÚLTIPLES SÍNTOMAS DEL RESFRÍADO
NO PRODUCE SOMNOLENCIA

Drug Facts
Active ingredients (in each tablet): Acetaminophen 325 mg, Guaifenesin 100 mg, Phenylephrine HCl 3 mg.
Purposes: Pain relief, Expectorant, Nasal decongestant.

Warnings
Liver warning: The product contains acetaminophen. Severe liver damage may occur if you take more than 12 tablets in 24 hours, which is the maximum daily amount. Do not take more than 12 tablets every day while using this product.

Directions
Adults: Take 2 tablets every 4 hours, not more than 12 tablets in 24 hours. Children under 12 years: Ask a doctor.

Other information
Store at 19-27°C (68-77°F). Avoid excessive heat above 40°C (104°F).

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

Questions? 1-800-841-9417 or zee-medical.com

Datos farmacéuticos (continúa)
Si está embarazada o lactando consulte a un médico antes de usarlo. Mantenga fuera del alcance de los niños. En caso de una sobredosis, obtenga ayuda médica o llame inmediatamente a un centro de control de envenenamiento. No use más de 12 tabletas en 24 horas.

Indicaciones
Alivia el dolor / Expectorante / Descongestionante nasal.

Información adicional
Conservar a 19-27°C (68-77°F). Evitar el calor excesivo 40°C (104°F).

Ingredientes inactivos
FDC rojo 40, almidón, celulosa microcristalina, povidona, sílice, glicolato de sodio de almidón, malto dextrina, sílice, povidona.

Preguntas? 1-800-841-9417 o zee-medical.com

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MEKESSON

1

HISTENOL FORTE II			
phenylephrine hcl, acetaminophen, guaifenesin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35418-111
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	100 mg
Inactive Ingredients			
Ingredient Name			Strength

FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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)