PENTREXCILINA- acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet
OPMX LLC

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.

PENTREXCILINA

Drug Facts

Active Ingredients (in each tablet)

Acetaminophen USP 325mg.....Pain reliever/fever reducer

Guaifenesin USP 200mg.....Expectorant

Phenylephrine HCL USP 5mg.....Decongestant

Dextromethorphan HBr USP 15mg.....Antitussive

Purpose

Pain reliever/ fever reducer

Expectorant

Decongestant

Antitussive

Uses

Temporarily

- 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 freer breathing
- Helps loosen bothersome mucus, drain bronchial tubes, and make coughs more productive
- Suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants
- 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

Allergy alert:

Acetaminophen may cause severe skin reactions. Symproms may include: skin reddening, blisters, rash if a skin reaction occurs, stop use and seek medical help right away.

Warning: A persistent cough may be a sign of a serious condition

Do not

- use with any other product containing acetaminophen this will provide more than the recommended dose (overdose) of acetaminophen and cold cause serious health concerns.
- use more than the recommended dose
- 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 recommended dose
- if you are now taking a presription 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
- take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema or where cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

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, 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

Ask a doctor before use if you have:

heart disease, high blood pressure, thyroid disease, diabetes, difficulty in urination due to enlargement of the prostate gland, liver disease

Ask a doctor or pharmacist if you are

taking the blood thinning drug warfarin.

Do not exceed recommended dosage

if nervousness, dizziness, or sleeplessness occur, discontinue use consult a doctor.

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 nnotice any signs or symptoms

Directions:

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

Other Inforamtion:

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

Inactive Ingredients

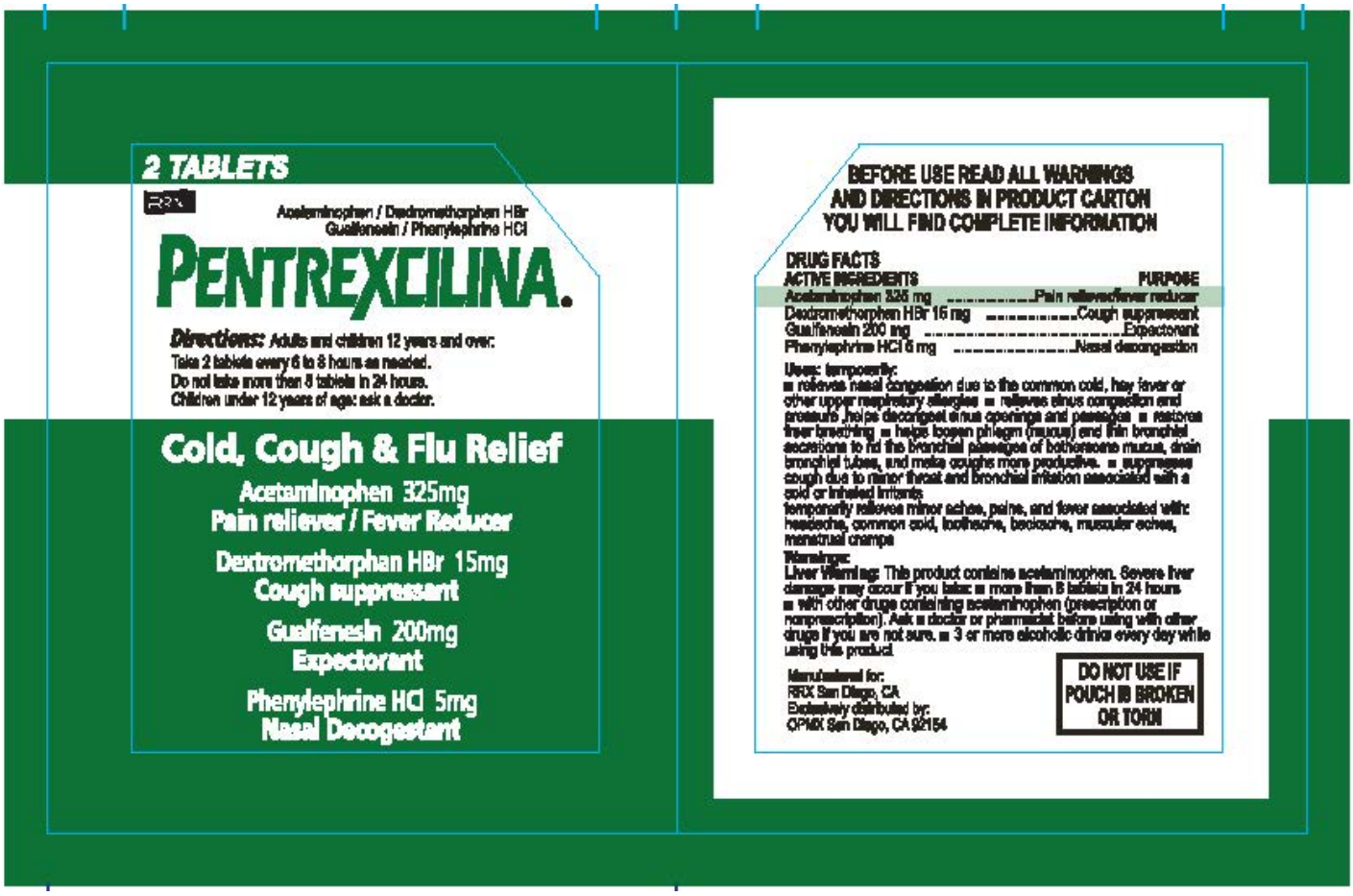
maltodextrin, microcrystalline cellulose, povidone, silicon dioxide*, sodium starch glycolate, starch, stearic acid

(*may contain)

Questions or comments?

Call: 619-600-5632 (Mon-Fri 9am - 5pm EST)

Pentrexcilina
2 Tablets in a pouch



PENTREXCILINA

acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-155
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 - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

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

Product Characteristics

Color	white	**Score**	2 pieces
Shape	capsule	**Size**	16mm
Flavor		**Imprint Code**	A15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-155-06	6 in 1 PACKAGE	01/05/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69729-155-72	72 in 1 PACKAGE	01/05/2018	
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	01/05/2018	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Centurion Laboratories Pvt Ltd		873229784	manufacture(69729-155) , analysis(69729-155) , pack(69729-155)