PENTREXCILINA NIGHT TIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled
OPMX LLC

Pentrexcilina Night Time

Drug Facts

Active ingredients (in each Softgels)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

Temporarily relieves common cold/flu symptoms:

- Cough due to minor throat & bronchial irritation
- Sore throat
- Headache
- Minor aches & pains
- Fever
- Runny nose & sneezing

Warnings

Liver warning

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy Alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

• skin reddening • blisters • rash • If a skin reaction occurs, stop use and seek medical help right away

Sore throat warning

If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). • If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

When using this product

- Excitability may occur, especially in children
- Marked drowsiness may occur
- Avoid Alcoholic drinks
- Be careful when driving a motor vehicle or operating machinery
- Alcohol, sedatives, & tranquilizers may increase drowsiness

Stop use and ask a doctor if

- Pain or cough gets worse or lasts more than 7 days
- Fever gets worse or lasts more than 3 days
- Redness or swelling is present
- New symptoms occur
- Cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions

- Take only as directed
- Do not exceed 4 doses per 24 hrs

Adults & children 12 yrs & over	2 softgels with water every 6 hrs
Children 4 to under 12 yrs	Ask a doctor

Children under 4 yrs	Do not use

Other information

- Store at room temperature

Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, titanium dioxide

Questions?

Call toll free 619-600-5632 Monday through Friday 9AM - 5PM EST

Made for:

RRX

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

PRINCIPAL DISPLAY PANEL

NDC 69729-041-10

Pentrexcilina Night-Time

EXTRA STRENGH

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

- COLD, FLU & COUGH
- TOS, GRIPE Y RESFRIADO

10 Softgels

PENTREXCILINA NIGHT TIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69729-041
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	AP02
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-041-10	10 in 1 CARTON	05/23/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/23/2022	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
SOFTECH PHARMA PRIVATE LIMITED		677111277	manufacture(69729-041) , pack(69729-041) , label(69729-041)

Revised: 4/2024 OPMX LLC