

NIGHTTIME COLD AND COUGH SUGAR-FREE- acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder
Cellchem Pharmaceuticals 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.

Nighttime Cold and Cough Sugar-Free

Drug Facts

Active Ingredients (in each packet)	Purpose
Acetaminophen 650 mg.....	Pain reliever/Fever reducer
Diphenhydramine Hydrochloride 25 mg.....	Antihistamine/Cough Suppressant
Phenylephrine Hydrochloride 10 mg.....	Nasal decongestant

Uses

- Temporarily relieves these symptoms due to cold:
 - minor aches and pains
 - headache
 - minor sore throat pain
 - nasal and sinus congestion
 - cough due to minor throat and bronchial irritation
 - runny nose
 - sneezing
 - itchy, watery eyes due to hay fever
 - itchy nose or throat
- Temporarily reduces fever

Relieve:

- nasal congestion
- sore throat pain
- Cough
- Headache
- Bodyaches
- Fever
- runny nose
- sneezing

Warnings

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

- more than 6 packets 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.

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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- in a child under 12 years of age
- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription and non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on the skin
- 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema, asthma, or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

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

When using this product

- do not exceed recommended dosage
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious

condition.

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.

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.

KEEP CARTON FOR REFERENCE.

DO NOT DISCARD.

DO NOT USE IF SEALED PACKET IS TORN OR BROKEN

Directions

- do not use more than directed
- take every 4 hours, while symptoms persist.

Do not take more than 6 packets in 24 hours unless directed by a doctor.

Age	Dose
adults and children 12 years and over	one packet
children under 12 years	do not use

- dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water; stir briskly before and after heating. Do not overheat.

Other Information

- **each packet contains:** potassium 10 mg, sodium 23 mg.
- **phenylketonurics:** contains phenylalanine 10 mg per packet.
- store at controlled room temperature 20-25°C (68 -77°F). Protect from heat and moisture.

Inactive ingredients

Acesulfame potassium, aspartame, calcium phosphate dibasic, citric acid, D&C Yellow #10, maltodextrin, flavors, silicon dioxide, sodium citrate dihydrate.

Questions, Comments or Adverse Reactions?

You may report serious side effects to: +1 844-481-8884

Serious side effects can also be reported to: drugsafety@cellchempharma.ca

Distributed by:

CellChem Pharmaceuticals Inc.

Unit 1, 30 Concourse Gate

Nepean, Ontario K2E 7V7

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

SEAL AREA
INK FREE AREA
ZONE DE COLLAGE
ZONE SANS ENCRE

Drugs Facts

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Diphenhydramine Hydrochloride 25 mg Antihistamine / Cough Suppressant
Phenylephrine Hydrochloride 10 mg Nasal decongestant

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Drug Facts (continued)

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- phenylephrine: contains phenylalanine 10 mg per packet.
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Inactive ingredients:

Acetosulfate potassium, aspartame, calcium phosphate dibasic, citric acid, D&C Yellow #10, maltodextrin, flavors, silicon dioxide, sodium citrate dihydrate.

NDC 73147-3111-6

Nighttime Cold and Cough Sugar-Free

Acetaminophen - Pain reliever / Fever reducer
Diphenhydramine HCl - Antihistamine / Cough Suppressant
Phenylephrine HCl - Nasal decongestant

Relieves:
 Nasal congestion
 Sore throat pain
 Cough
 Headache
 Body ache
 Fever
 Runny nose
 Sneezing



6 Packets

honey lemon flavor

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 Nepean, Ontario K2E 7V7

SEAL AREA
INK FREE AREA
ZONE DE COLLAGE
ZONE SANS ENCRE

LOT & EXP DD-MM-YYYY



TO OPEN: FOLD CORNER & TEAR AT SLIT OR CUT ALONG DOTTED LINE WITH SCISSORS, DO NOT USE IF SEALED PACKET IS TORN OR BROKEN.



Nighttime Cold and Cough Sugar-Free

honey lemon flavor

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Acetaminophen 650 mg Pain reliever/fever reducer
Diphenhydramine HCl 25 mg Antihistamine/cough suppressant
Phenylephrine hydrochloride 10 mg Nasal decongestant

SEE ALLERGY AND LIVER

WARNINGS ON OTHER SIDE

**THIS PACKET DOES NOT CONTAIN
FULL PRODUCT INFORMATION.
SEE CARTON FOR COMPLETE
LABELLING INFORMATION. READ
ALL WARNINGS AND DIRECTIONS
ON CARTON BEFORE USE.
DO NOT DISCARD CARTON.**

1 SINGLE DOSE
0.09 oz Powder

PC-3111-GENERIC-3

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Nepean, Ontario K2E 7V7

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

honey lemon flavor

**Nighttime
Cold and Cough
Sugar-Free**

NIGHTTIME COLD AND COUGH SUGAR-FREE

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73147-3111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor	HONEY (honey lemon flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73147-3111-6	6 in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2019	

Labeler - Cellchem Pharmaceuticals Inc (11518618)

Registrant - Cellchem Pharmaceuticals Inc (11518618)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Confab Inc		241754217	manufacture(73147-3111)

Revised: 1/2021

Cellchem Pharmaceuticals Inc