MULTI-SYMPTOM SEVERE COLD- acetaminophen, dextromethorphan hydrobromide, 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.

Multi-Symptom Severe Cold

Drug Facts

Active Ingredients (in each packet) **Purpose**

Acetaminophen 500 mg.....Pain reliever/Fever reducer

Dextromethorphan hydrobromide 20 mg.....Cough suppressant

Phenylephrine Hydrochloride 10 mg.....Nasal decongestant

Uses

- Temporarily relieves these symptoms due to cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - nasal and sinus congestion
  - cough due to minor throat and bronchial irritation
- Temporarily reduces fever

Relieves:

- Nasal congestion
- Sore throat pain
- Cough
- Headache
- Body ache
- Fever

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 children 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.
- 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
- 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 or emphysema

Ask a doctor or pharmacist before use if you are

- 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

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:** calcium 130 mg, potassium 10 mg, sodium 20 mg.
- phenylketonurics: contains phenylalanine 12 mg per packet.
- store at controlled room temperature 20-25°C (68 -77°F). Protect from heat and moisture.

Inactive ingredients

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

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 AERA
INK FREE AERA
ZONE DE COLLAGE
ZONE SANS ENCRE

SEAL AREA

ZONE DE COLLAGE

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE. KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

Drugs Facts

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Ask a doctor before use if you have ● liver disease ● heart disease ● high blood pressure ● thyroid disease ● diabetes ● 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 or emphysema.

Ask a doctor or pharmacist before use if you are ● taking the blood thinning drug warfarin.

When using this product ● do not exceed recommended dosage

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.

Drug Facts (continued)

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NDC 73147-3192-6

Multi-Symptom Severe Cold

Acetaminophen
- Pain reliever / Fever reducer
Dextromethorphan HBr - Cough Suppresant
Phenylephrine HCl - Nasal decongestant

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

6 Packets — Green Tea & Honey Lemon Flavors

DO NOT USE IF SEALED PACKET IS TORN OR BROKEN

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
CellChem Pharmaceuticals Inc.
Unit 1, 30 Concourse Gate
Nepean, Ontario K2E 7V7

SEAL AERA
INK FREE AERA
ZONE DE COLLAGE
ZONE SANS ENCRE

LOT & EXP DD-MM-YYYY

POSITION ONLY

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

Multi-Symptom
Severe Cold

Green Tea & Honey Lemon Flavors

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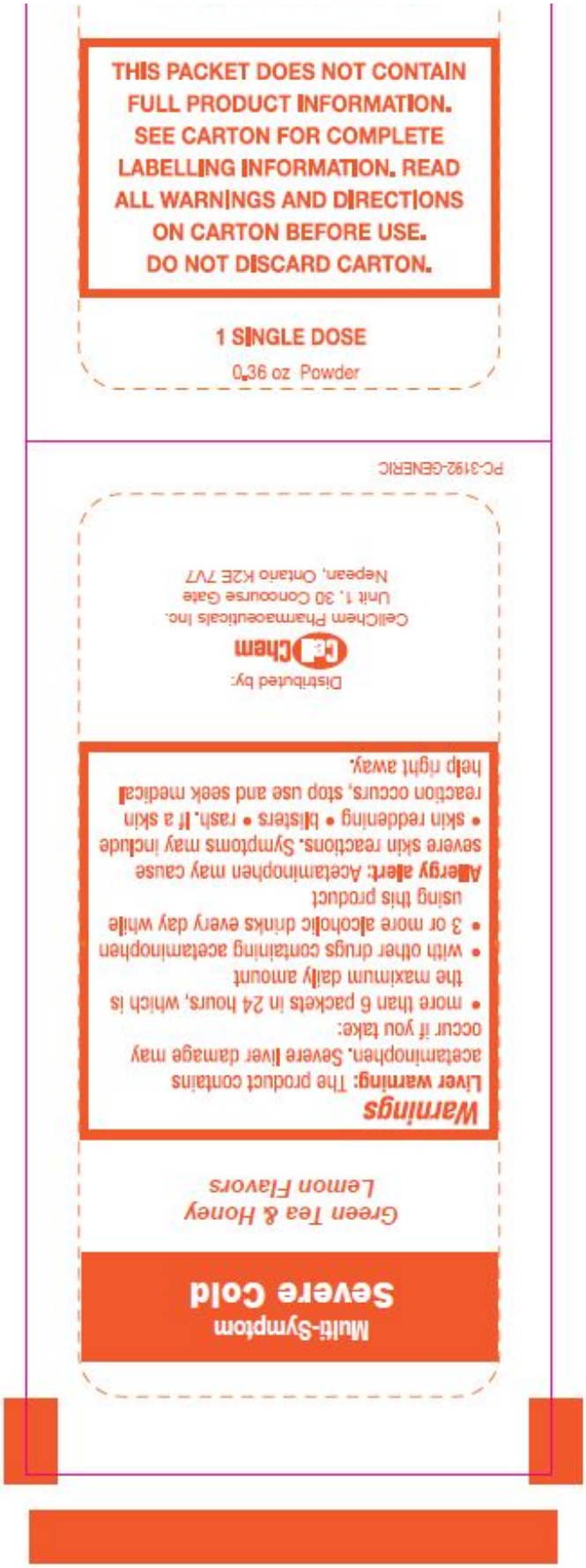
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Phenylephrine hydrochloride 10 mg	Nasal decongestant

SEE ALLERGY AND LIVER WARNINGS ON OTHER SIDE



MULTI-SYMPTOM SEVERE COLD

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73147-3192
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CARAMEL (UNII: T9D99G2B1R)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor	HONEY (Green Tea & Honey Lemon Flavors)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73147-3192-6	6 in 1 CARTON; 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 (111518618)

Registrant - Cellchem Pharmaceuticals Inc (111518618)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Confab Inc		241754217	manufacture(73147-3192)