

COLTALIN-DM- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet
FORTUNE PHARMACAL COMPANY LIMITED

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever-fever reducer
Antihistamine
Cough suppressant
Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold, the flu, or hay fever:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - runny nose
 - sinus congestion and pressure
 - cough due to minor throat and bronchial irritation
 - sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever
- temporarily reduces fever
- promotes nasal and/or sinus drainage

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount for this product
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

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 the user is 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 the user has

- heart disease
- high blood pressure
- diabetes
- glaucoma
- liver disease
- thyroid disease
- a high fever
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- a persistent cough

Ask a doctor or pharmacist before use if the user is

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

When using this product

- **do not exceed recommended dosage**
- may cause excitability especially in children
- do not drive or operate machinery
- avoid alcoholic beverages
- may cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect

Stop use and ask a doctor if

- pain or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)
- sore throat persists for more than 2 days
- nasal congestion is accompanied by fever
- nervousness, dizziness, or sleeplessness occur
- any of the following occurs (these could be signs of a serious condition):
 - fever gets worse or lasts more than 3 days
 - a severe sore throat
 - sore throat is accompanied or followed by fever, headache, rash, nausea or vomiting
 - redness or swelling is present
 - new symptoms occur
 - cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache

Do not give to children under 6 years of age unless directed by 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 notice any signs or symptoms.

Directions

- adults and children 12 years of age and over: 2 tablets every 4 hours, while symptoms persist, not to exceed 6 doses (12 tablets) in 24 hours, or as directed by a doctor
- children 6 to under 12 years of age: 1 tablet every 4 hours, while symptoms persist, not to exceed 5 doses (5 tablets) in 24 hours, or as directed by a doctor
- children under 6 of age : consult a doctor

Other information

- keep tightly sealed
- store between below 25 C (77 F) in a dry place, away from direct sunlight

Inactive ingredients colloidal silicon dioxide, corn starch, D&C yellow no. 10 aluminum lake, magnesium stearate, povidone K30, sodium starch glycolate

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

- you may also report serious side effects to this phone number

COLTALIN-DM

Safely Sealed

NDC 51467-007-01

Acetaminophen - Pain Reliever-Fever Reducer

Chlorpheniramine Maleate - Antihistamine

Dextromethorphan Hydrobromide - Cough Suppressant

Phenylephrine Hydrochloride - Nasal Decongestant

Cough, Cold & Flu Multi-Symptom Relief

- Minor Aches & Pain, Sore Throat
- Headache, Fever
- Nasal Congestion, Sinus Pressure/Drainage
- Cough
- Sneezing, Runny Nose
- Itchy, Watery Eyes

24 Tablets

In Individually Sealed Strip

Aspirin Free

Product code

SAFELY SEALED • NDC 51467-007-01

COLTALIN[®]-DM

幸福傷風咳素-DM

Acetaminophen - Pain Reliever - Fever Reducer
Chlorpheniramine Maleate - Antihistamine
Dextromethorphan Hydrobromide - Cough Suppressant
Phenylephrine Hydrochloride - Nasal Decongestant

Cough, Cold & Flu Multi-Symptom Relief

咳嗽、傷風、流感 舒緩各種症狀

- Minor Aches & Pain, Sore Throat 輕微疼痛、喉嚨痛
- Headache, Fever 發熱、頭痛
- Nasal Congestion, Sinus Pressure/Drainage 鼻塞、鼻竇充血
- Cough 咳嗽
- Sneezing, Runny Nose 打噴嚏、流鼻涕
- Itchy, Watery Eyes 眼睛發癢、淚眼

24
Tablets

In Individually Sealed Strip
獨立鋁箔密封包裝

ASPIRIN FREE



PRINTED WITH SOY INK

24 Tablets/H



幸福傷風咳素-DM

傷風感冒止咳配方

Please refer to enclosed package insert for Chinese translation of drug facts.

請參閱內附之說明書以查看中文藥品資料。



Distributed by:
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Fax: (323) 221-2448
www.kolstee.com



Pharma code

Drug Facts (continued)

When using this product
• do not exceed recommended dosage
• do not drink alcoholic beverages
• may cause marked drowsiness, alcohol, sedatives, and tranquilizers
• may increase the drowsiness effect

Stop use and ask a doctor if:
• pain, cough or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)
• sore throat persists for more than 2 days
• nervousness, dizziness, or sleepiness occur
• any of the following occurs (these could be signs of a serious condition):
• fever gets worse or lasts more than 3 days
• a severe sore throat
• nausea or vomiting
• redness or swelling is present
• new symptoms occur

• cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache
Do not give to children under 6 years of age unless directed by a doctor.
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Directions
adults and children 12 years of age and over
take 2 tablets every 4 hours, while symptoms persist, not to exceed 6 doses (12 tablets) in 24 hours, or as directed by a doctor

children 6 to under 12 years of age
take 1 tablet every 4 hours, while symptoms persist, not to exceed 5 doses (5 tablets) in 24 hours, or as directed by a doctor
consult a doctor
children under 6 years of age

Other information
• store tightly sealed
• store below 25°C (77°F) in a dry place, away from direct sunlight
D&C yellow no. 10 aluminum lake, magnesium stearate, povidone, KCl, sodium starch glycolate

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Phenylephrine hydrochloride 5 mg

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• temporarily relieves these symptoms due to a cold, the flu, or hay fever:
• minor aches and pains • headache • sore throat
• nasal congestion • runny nose • sinus congestion and pressure
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Ask a doctor before use if the user has
• diabetes • glaucoma • heart disease • high blood pressure • a high fever • liver disease • thyroid disease • a breathing problem such as emphysema or chronic bronchitis • difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if the user is
• taking tranquilizers or sedatives
• taking the blood thinning drug warfarin

COLTALIN[®]-DM
Cold & Cough Formula
Do not use if individually sealed foil unit dose pouches are torn, broken, or show evidence of being opened.
Keep outer carton for complete warnings and product information.

Manufactured by:
FORTUNE PHARMACEUTICAL CO., LTD.
香港福隆有限公司
Made in China

Version no.

COLTALIN-DM

Safely Sealed

NDC 51467-007-02

Acetaminophen - Pain Reliever-Fever Reducer

Chlorpheniramine Maleate - Antihistamine

Dextromethorphan Hydrobromide - Cough Suppressant

Phenylephrine Hydrochloride - Nasal Decongestant

Cough, Cold & Flu Multi-Symptom Relief

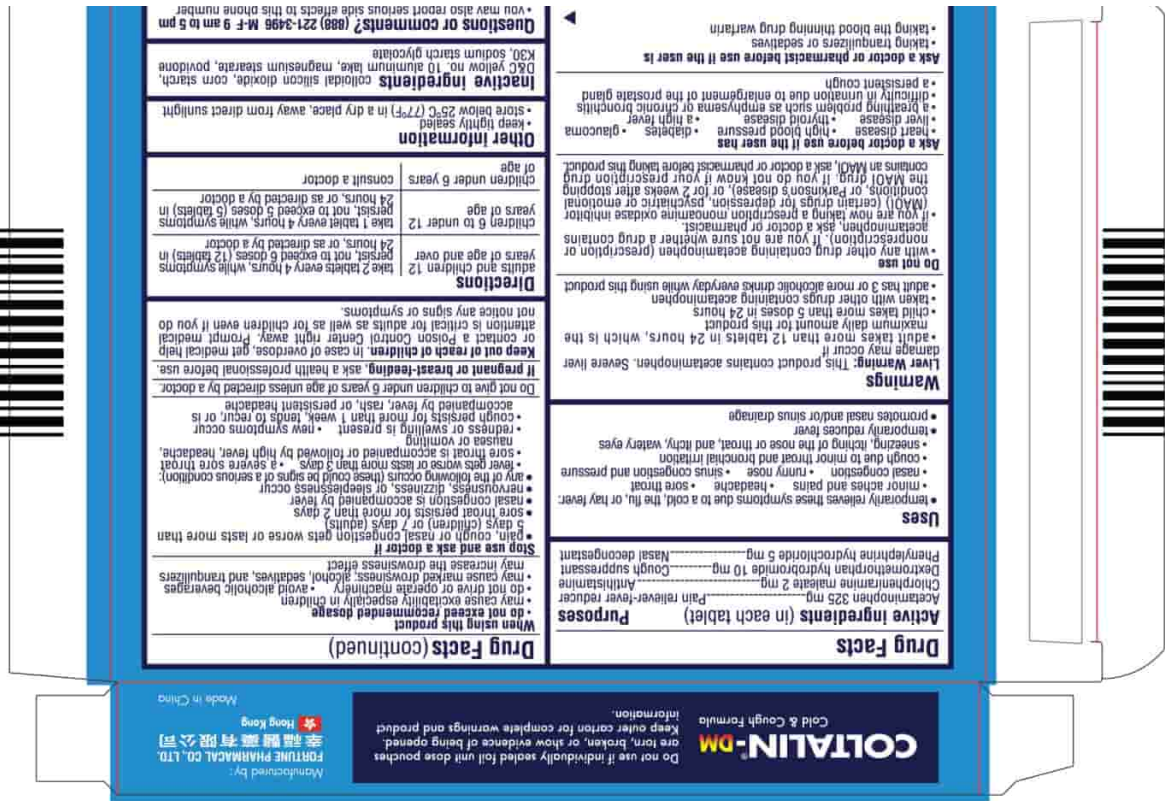
- Minor Aches & Pain, Sore Throat
- Headache, Fever
- Nasal Congestion, Sinus Pressure/Drainage
- Cough
- Sneezing, Runny Nose
- Itchy, Watery Eyes

36 Tablets

In Individually Sealed Strip

Aspirin Free





COLTALIN-DM

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-007
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)		CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg
Inactive Ingredients			
Ingredient Name			Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

STARCH, CORN (UNII: 08232NY3SJ)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
MAGNESIUM STEARATE (UNII: 70097M6I3O)				
POVIDONE K30 (UNII: U725QWY32X)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	FORTUNE	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-007-01	2 in 1 BOX	03/01/2004	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51467-007-02	3 in 1 BOX	04/26/2016	
2		12 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	part341		03/01/2004	

Labeler - FORTUNE PHARMACAL COMPANY LIMITED (686280561)

Establishment

Name	Address	ID/FEI	Business Operations
FORTUNE PHARMACAL COMPANY LIMITED		686280561	manufacture(51467-007)

Revised: 11/2024

FORTUNE PHARMACAL COMPANY LIMITED