

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

LOT

EXP

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:
WOLSTEEL MEDICINE COMPANY
美國蘇武藥業有限公司
215 W. Aliso Street
Los Angeles, CA 90012 U.S.A.
Tel: (818) 221-3406
Fax: (323) 221-2448
www.wolsteel.com



Pharma code

Drug Facts (continued)

When using this product

- do not exceed recommended dosage
- do not exceed recommended dosage in children
- 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:

- nasal congestion is accompanied by fever
- severe sore throat
- any of the following occurs (these could be signs of a serious condition):
- fever that persists for more than 3 days
- cough that persists for more than 7 days (adults)
- sore throat (children) or 7 days (adults)
- pain, cough or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults)

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.

Do not give to children under 6 years of age unless directed by a doctor.

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- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount for this product
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- 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 before taking this product.
- 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 the user has:

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- liver disease
- high blood pressure
- diabetes
- glaucoma
- 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 tranquilizers or sedatives
- taking the blood thinning drug warfarin

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, polyvinyl K30, sodium starch glycolate

Inactive ingredients colloidal silicon dioxide, corn starch, D&C yellow no. 10 aluminum lake, magnesium stearate, polyvinyl 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

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Manufactured by:
FORTUNE PHARMACEUTICAL CO., LTD.
香港福壽有限公司
Hong Kong

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.

Cold & Cough Formula
COLTALIN[®]-DM

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
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.
香港藥業有限公司
Made in China

<p>Drug Facts</p> <p>Active Ingredients (in each tablet)</p> <p>Acetaminophen 325 mg Chlorpheniramine maleate 2 mg Dextromethorphan hydrobromide 10 mg Phenylephrine hydrochloride 5 mg</p> <p>Purposes</p> <p>Pain reliever-fever reducer Antihistamine Cough suppressant Nasal decongestant</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves these symptoms due to a cold, the flu, or hay fever: minor aches and pains nasal congestion runny nose sinus congestion and pressure cough due to minor throat and bronchial irritation itching of the nose or throat, and itchy, watery eyes temporarily reduces fever promotes nasal and/or sinus drainage <p>Warnings</p> <p>Liver Warning: This product contains acetaminophen. Severe liver damage may occur if:</p> <ul style="list-style-type: none"> 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 adult has 3 or more alcoholic drinks everyday while using this product taken with other drugs containing acetaminophen <p>Do not use</p> <ul style="list-style-type: none"> 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, Parkinson's disease, or for 2 weeks after stopping MAOI) or if you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. <p>Ask a doctor before use if the user has</p> <ul style="list-style-type: none"> heart disease high blood pressure diabetes glaucoma liver disease thyroid disease a high fever difficulty in urination due to enlargement of the prostate gland a breathing problem such as emphysema or chronic bronchitis a persistent cough <p>Ask a doctor or pharmacist before use if the user is</p> <ul style="list-style-type: none"> taking tranquilizers or sedatives taking the blood thinning drug warfarin 	
<p>Drug Facts (continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> do not exceed recommended dosage may cause drowsiness, 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> blunt 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 nasal congestion is accompanied by fever any of the following occurs (these could be signs of a serious condition): fever gets worse or lasts more than 3 days fever that is accompanied or followed by high fever, headache, sore throat new symptoms occur redness or swelling is present cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache <p>Do not give to children under 6 years of age unless directed by a doctor.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical help attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Directions</p> <p>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</p> <p>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</p> <p>children under 6 years of age consult a doctor</p> <p>Other Information</p> <ul style="list-style-type: none"> Keep tightly sealed store below 25°C (77°F) in a dry place, away from direct sunlight <p>Inactive ingredients</p> <p>coloidal silicon dioxide, magnesium stearate, povidone, D & C yellow no. 10 aluminum lake, aluminum starch glycolate, K50, sodium starch glycolate</p> <p>Questions or comments? (888) 221-3496 M-F 9 am to 5 pm</p> <p>*You may also report serious side effects to this phone number</p>	

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: 9D2RT19KYH) (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: 70097M6I30)	
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	M	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: 2/2024

FORTUNE PHARMACAL COMPANY LIMITED