DAYTIME AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr,guaifenesin, phenylephrine hcl / acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
Walgreens

630T Walgreens 0363-0775 Maximum Strength Daytime & Nighttime Cold and Flu

DRUG FACTS - Nighttime Cold & Flu

Active ingredients (in each softgel)
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purposes
Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses
• temporarily relieves these common cold and flu symptoms:
sinus congestion and pressure
cough
minor aches and pains
headache
nasal congestion
sore throat
runny nose
sneezing
itching of the nose or throat

itchy, watery eyes due to hay fever
• controls cough to help you get to sleep
• temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
• more than 12 softgels in 24 hours, which is the maximum daily amount
• 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult 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
• heart disease
• diabetes
• high blood pressure
• thyroid disease
• trouble urinating due to enlarged prostate gland
• glaucoma
• a breathing problem such as emphysema or chronic bronchitis
• persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
• cough that occurs with too much phlegm (mucus)

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

When using this product
• do not use more than directed
• excitability may occur, especially in children
• marked drowsiness may occur
• alcohol, sedatives, and tranquilizers may increase drowsiness
• avoid alcoholic drinks
• be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
• nervousness, dizziness, or sleeplessness occur
• pain, nasal congestion, 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 fever, 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
• do not take more than directed (see Overdose warning)
• do not take more than 12 softgels in any 24-hour period
• adults and children 12 years of age and older: take 2 softgels every 4 hours.
• children under 12 years of age: do not use

Other information

• store at 20-25°C (68-77°F)
• avoid excessive heat

Inactive ingredients
FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or Comments?
Call **1-877-290-4008**

DRUG FACTS - Daytime Cold & Flu

Active ingredients (in each softgel)
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purposes
Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses
• temporarily relieves common cold and flu symptoms:
sinus congestion and pressure
cough
minor aches and pains
headache
nasal congestion
sore throat

• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
• controls cough to help you get to sleep
• temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
• more than 12 softgels in 24 hours, which is the maximum daily amount
• 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult 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
• heart disease
• diabetes
• high blood pressure
• thyroid disease
• trouble urinating due to enlarged prostate gland
• persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
• cough that occurs with too much phlegm (mucus)

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

When using this product do not use more than directed

Stop use and ask a doctor if

• nervousness, dizziness, or sleeplessness occur
• pain, nasal congestion, 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 fever, 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: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
• do not take more than directed (see Overdose warning)
• do not take more than 12 softgels in any 24-hour period
• adults and children 12 years of age and older: take 2 softgels every 4 hours.
• children under 12 years of age: do not use

Other information
• store at 20-25°C (68-77°F)
• avoid excessive heat

Inactive ingredients FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or Comments?
Call **1-877-290-4008**

PRINCIPAL DISPLAY PANEL

DAYTIME AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr,guaifenesin, phenylephrine hcl / acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-0775

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0775-24	3 in 1 CARTON	06/01/2022	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity

Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

DAYTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr,guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source)	NDC:0363-0750
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	21mm
Flavor		**Imprint Code**	78
Contains			

Packaging

	Item		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	06/01/2022	

Part 2 of 2

NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source)	NDC:0363-1011
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 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 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	21mm
Flavor		**Imprint Code**	72
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	06/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2022	

Labeler - Walgreens (008965063)

Registrant - TIME CAP LABORATORIES INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(0363-0775)