

**FAST DISSOLVING DAYTIME - NIGHTTIME COLD AND FLU- acetaminophen,
dextromethorphan hbr, guaifenesin, phenylephrine hcl, doxylamine succinate
RITE AID**

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.

630T RITE AID COLD AND FLU FAST DISSOLVING

**MAXIMUM STRENGTH DAYTIME COLD AND FLU
DRUG FACTS**

Active ingredients (in each softgel)
ACETAMINOPHEN 325MG
DEXTROMETHORHAN HBR10 MG,
GUAIFENESIN 200 MG
, PHENYLEPHRINE HCL 5 MG

- temporarily relieves common cold/flu symptoms: nasal congestion, headache, cough, minor aches and pains, sore throat
 - temporarily reduces fever
 - promotes nasal and/or sinus drainage
 - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
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Warnings

Liver warning - This product contains acetaminophen. Severe liver damage may occur if you take - more than 8 softgels

This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 8 Softgels in 24 hrs, which is the maximum daily amount for this product
- 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.

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

Do not take more than directed (See Overdose warning section) - do not exceed 12 Softgels per 24

hr period

- adults & children 12 yrs & over 2 Softgels every 4 hrs
 - children 4 to under 12 yrs: Do not use
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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. (1800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

PAIN RELIEVER-FEVER REDUCER

COUGH SUPPRESSANT

MINOR ACHES AND PAINS

CHEST CONGESTION

Maximum Strength Nighttime Cold and Flu Drug Facts

(in each softgel)

Acetaminophen 325mg

Dextromethorphan HBR 10 mg

Doxylamine Succinate 6.25 mg

PhenylephrineHCl 5mg

Purpose

- Pain reliever/Fever reducer
 - Cough suppressant
 - Antihistamine
 - Nasal decongestant
-

MINOR ACHES AND PAINS, FEVER

NASAL CONGESTION AND SINUS PRESSURE

SNEEZING, RUNNY NOSE

COUGH

PAIN RELIEVER-FEVER REDUCER

COUGH SUPPRESSANT

MINOR ACHES AND PAINS

NASAL DECONGESTION

Warnings

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

- more than 8 softgels in 24 hrs, which is the maximum daily amount for this product -
- 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.

Directions

take only as directed - do not exceed 8 softgels per 24 hours -

adults & children 12 yrs & over 2 softgels with water every 6 hrs -

children 4 to under 12 yrs ask a doctor -

children under 4 yrs do not use

FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Keep out of reach of children.

Overdose warning

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

NDC 11822-7855-0

Compare to the active ingredients of
**Mucinex® Fast-Max® Day Cold & Flu,
& Night Cold & Flu**

COLD & FLU

FAST DISSOLVING SOFTGELS

 DAYTIME	 NIGHTTIME
ACETAMINOPHEN DEXTROMETHORPHAN HBr GUAFENESIN PHENYLEPHRINE HCl	ACETAMINOPHEN DEXTROMETHORPHAN HBr DOXYLAMINE SUCCINATE PHENYLEPHRINE HCl
PAIN RELIEVER / FEVER REDUCER COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT	PAIN RELIEVER / FEVER REDUCER COUGH SUPPRESSANT / ANTI-HISTAMINE NASAL DECONGESTANT
Relieves aches, fever & sore throat Controls cough Relieves nasal & chest congestion Thins & loosens mucus For ages 12 & over	Relieves aches, fever & sore throat Controls cough Relieves nasal congestion Relieves runny nose & sneezing For ages 12 & over
 ACTUAL SIZE	 ACTUAL SIZE



16 8
DAYTIME NIGHTTIME
SOFTGELS SOFTGELS
24 TOTAL SOFTGELS

FAST DISSOLVING DAYTIME - NIGHTTIME COLD AND FLU

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7859
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7859-0	24 in 1 CARTON	08/18/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

DAY COLD AND FLU FAST DISSOLVING

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

Product Information

Item Code (Source)	NDC:11822-3685
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Route of Administration	ORAL
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	78
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 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 final	part341	08/18/2020	

Part 2 of 2

NIGHT COLD AND FLU FAST DISSOLVING

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

Product Information

Item Code (Source)	NDC:11822-3684
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	24mm
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 final	part341	07/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2020	

Labeler - RITE AID (014578892)

Registrant - TIME CAP LABS INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11822-7859)

Revised: 8/2020

RITE AID