MAXIMUM STRENGTH COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled TARGET CORP

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.

628T TARGET 11673-978 Maximum strength cold & flu (daytime)

Active ingredients (in each softgel)

acetamnophen 325 mg

Dextromethorphan HBr 10mg

Gualifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

- Pain reliever/fever reducer
- Cough suppressant
- Expectorant
- Nasal decongestant

Uses

temporarily relieves these common cold/flu symptoms:

- nasal congestion
- headache
- cough
- minor aches & 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

Warnings Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 softgels in 24 hrs, which is the maximum daily amount for this product
- 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 an 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 exceed 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

Questions?

Call 1-877-290-4008

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



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Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-978			
Route of Administration	ORAL					

	ent/Active Moiety			rength Streng		
	Ingredient Name Basis of Stren					
ACETAMINOPHEN (CETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN					
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)DEXTROMETHORPHAN HYDROBROMIDE(DEXTROMETHORPHAN - UNII:7355X3ROTS)HYDROBROMIDE						
•	495W7451VQ) (GUAIFENE			200 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - PHENYLEPHRINE HYDROCHLORIDE UNII:1WS297W6MV) HYDROCHLORIDE						
Inactive Ingred	lients					
	Ingred	lient Name		Strength		
GLYCERIN (UNII: PDC	•					
GELATIN (UNII: 2G86						
TITANIUM DIOXIDE						
	6 (UNII: H77VEI93A8)					
		NII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ 989GH94E)						
SHELLAC (UNII: 46N107B710) SORBITOL (UNII: 506T60A25R)						
Product Chara	cteristics					
Color	orange			no score		
Shape	pe CAPSULE Size			10mm		
Flavor		Imprint Cod	e	78		
Contains						
Packaging						
# Item Code	Package De	Package Description		Marketing End Date		
1 NDC:11673-978- 16	2 in 1 CARTON		06/08/2020			
	3 in 1 BLISTER PACK; Type Product	e 0: Not a Combination				
Marketing I	nformation					
Marketing		per or Monograph Ition	Marketing Start Date	Marketing End Date		
Category						
OTC monograph fina	l part341		06/08/2020			

Labeler - TARGET CORP (006961700)

Registrant - TIME CAP LABS INC (037052099)

Establishment								
Name	Address	ID/FEI	Business Operations					
MARKSANS PHARMA LTD		925822975	manufacture(11673-978)					

Revised: 11/2022

TARGET CORP