DAY TIME PE COLD AND FLU RELIEF- acetaminohpen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
McKesson (Sunmark)

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.

DRUG FACTS

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethoprhan HBr 10 mg

Phenlyephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - fever
  - cough due to minor throat and bronchial irritation

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, 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 exceed recommended dosage.

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with 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 can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. 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 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 4 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- **when using other day time or nite time products, carefully read each label to insure correct dosing**

Other information

- store at room temperature 15º-30ºC (59º-86ºF)
- avoid excessive heat

Inactive ingredients

butylated hydroxyanisole, butylated hydroxytoluene, edible white ink, FD&C red #40*, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan,

sorbitol

*may contain this ingredient

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

COMPARE TO VICKS® DAYQUIL® LIQUICAPS® ACTIVE INGREDIENTS†

Day Time PE

Cold & Flu Relief

Relieves major cold and flu symptoms

Non-drowsy

Pain reliever, Fever reducer, Cough suppressant, Nasal decongestant

aches, fever, sore throat...**ACETAMINOPHEN**

cough...DEXTROMETHORPHAN HBr

nasal congestion...PHENYLEPHRINE HCl

MULTI-SYMPTOM

SOFTGELS

Another Quality Product Distributed by McKesson

One Post Street, San Francisco, CA 94104

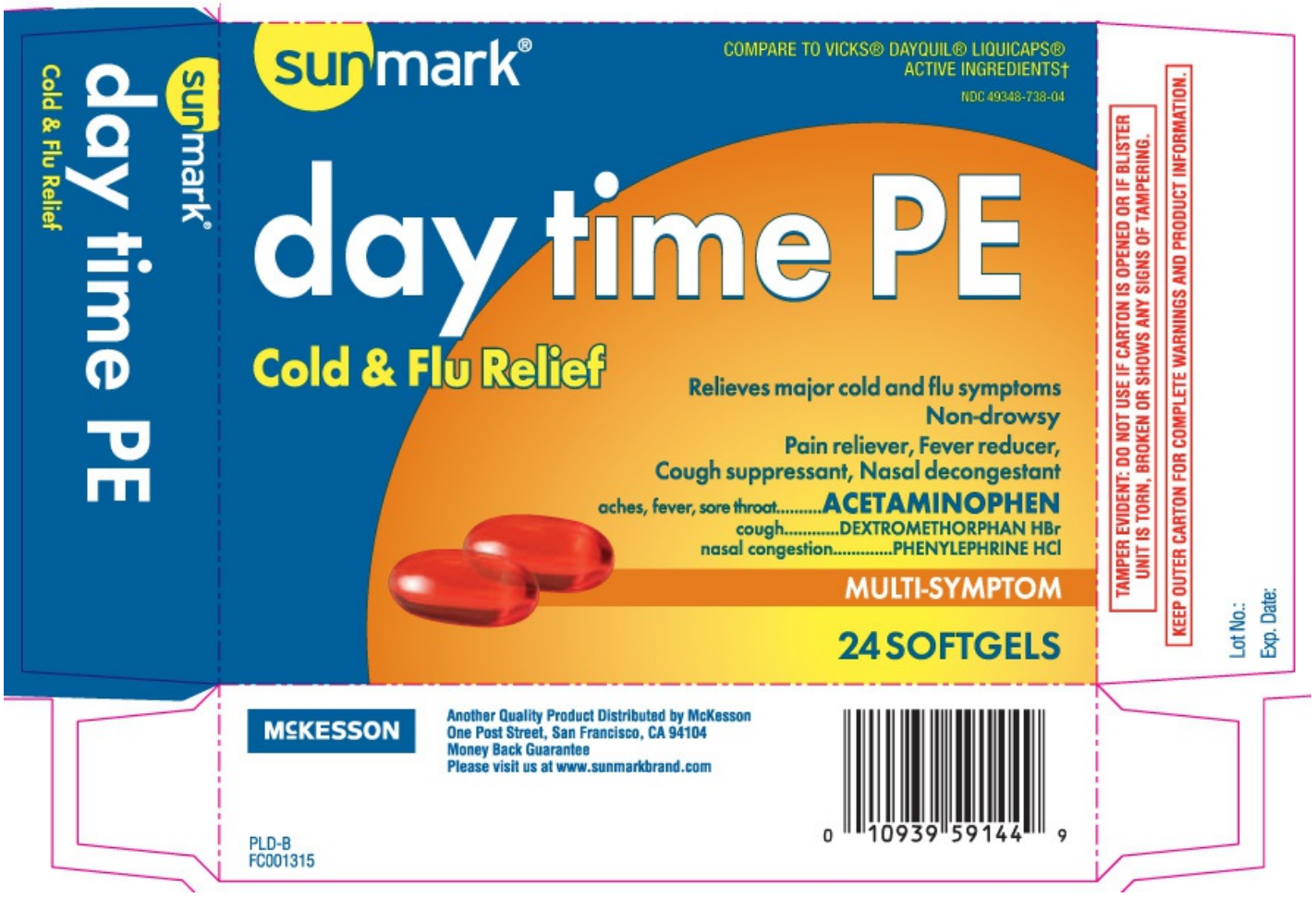
www.sunmarkbrand.com

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

†This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil® LiquiCaps®.

Package Label



Sunmark DayTime Cold & Flu Softgel

DAY TIME PE COLD AND FLU RELIEF

acetaminohpen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-738
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

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	ORANGE (red)	**Score**	no score
Shape	CAPSULE (Oblong)	**Size**	19mm
Flavor		**Imprint Code**	P19;36A;95A
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49348-738-02	1 in 1 CARTON	07/09/2010	12/31/2020
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49348-738-47	2 in 1 CARTON	07/09/2010	12/31/2020
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:49348-738-04	2 in 1 CARTON	07/09/2010	12/31/2020

3		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 FINAL	part341	07/09/2010	12/31/2020

Labeler - McKesson (Sunmark) (177667227)

Revised: 12/2018 McKesson (Sunmark)