NITE TIME SEVERE COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated
Meijer Distribution Inc

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.

Meijer 44-677

Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
  - minor aches and pains
  - sinus congestion and pressure
  - sore throat
  - fever
  - headache
  - nasal congestion
  - cough due to minor throat and bronchial irritation
  - runny nose and sneezing
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- diabetes
- thyroid disease
- heart disease
- glaucoma
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or chronic cough that lasts or 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 sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

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 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.

In case of accidental 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

- **do not take more than directed**
- do not take more than 8 caplets in 24 hours
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

black iron oxide, corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

NDC 41250-877-08

meijer®

Compare to Vicks® NyQuil® Severe Cold & Flu
active ingredients*

MAXIMUM STRENGTH

NiteTime
Severe Cold & Flu

Acetaminophen
Dextromethorphan HBr
Doxylamine Succinate
Phenylephrine HCl

Pain Reliever/Fever Reducer / Cough Suppressant
Antihistamine / Nasal Decongestant

Relieves: Headache, Fever,
Sore Throat, Minor Aches & Pains,
Nasal/Sinus Congestion & Sinus Pressure,
Sneezing, Runny Nose, Cough

24 CAPLETS

Actual Size

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks® NyQuil® Severe Cold & Flu.
50844 REV0519B67708

DIST. BY MEIJER
DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com

MEIJER PHARMACIST RECOMMEND
MONEY BACK GUARANTEE

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


meijer
NDC 41250-877-08
Compare to Vicks® NyQuil® Severe Cold & Flu active ingredients*
MAXIMUM STRENGTH
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Acetaminophen | Dextromethorphan HBr
Doxylamine Succinate | Phenylephrine HCl
Pain Reliever/Fever Reducer | Cough Suppressant
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24 Caplets
Actual Size
Relieves: Headache, Fever, Sore Throat, Minor Aches & Pains, Nasal/Sinus Congestion & Sinus Pressure, Sneezing, Runny Nose, Cough
Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
Active ingredients (in each caplet) Purpose
Acetaminophen 325 mg ..... Pain reliever/fever reducer
Dextromethorphan HBr 10 mg ..... Cough suppressant
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Uses
■ temporarily relieves common cold and flu symptoms:
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■ sore throat ■ fever ■ headache ■ nasal congestion
■ cough due to minor throat and bronchial irritation
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■ reduces swelling of nasal passages
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Drug Facts (continued)
■ cough that occurs with too much phlegm (mucus)
Ask a doctor or pharmacist before use if you are
■ taking sedatives or tranquilizers
■ taking the blood thinning drug warfarin
When using this product
■ do not exceed recommended dosage
■ excitability may occur, especially in children
■ marked drowsiness may occur ■ avoid alcoholic beverages
■ be careful when driving a motor vehicle or operating machinery
■ alcohol, sedatives, and tranquilizers may increase drowsiness
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 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. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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
■ do not take more than directed
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■ adults and children 12 years and over: take 2 caplets with water every 4 hours
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Drug Facts (continued)
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■ if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor before use if you have
■ liver disease ■ diabetes ■ thyroid disease
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Inactive ingredients black iron oxide, corn starch,
Drug Facts (continued)
croscarmellose, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide
Questions or comments? 1-800-426-9391
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING
No print/No varnish
Lot & Exp date
PID 3723192
DIST. BY MEIJER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544
www.meijer.com
OUR QUALITY GUARANTEE
The Pleasure of Pleasing
WWW.MEIJER.COM/SATISFACTION
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50844
REV0519867708
B-1214-677-08-R
REV0519867708

Meijer 44-677

NITE TIME SEVERE COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41250-877
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**
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CROSPOVIDONE (UNII: 2S7830E561)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;677
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-877-08	2 in 1 CARTON	08/01/2015	
1		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	08/01/2015	

Labeler - Meijer Distribution Inc (006959555)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(41250-877)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(41250-877)

Revised: 5/2020 Meijer Distribution Inc