SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl
Wal-Mart Stores 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.

Equate 44-042011

Active ingredients (in each 20 mL)
(Daytime)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Active ingredients (in each 20 mL)
(Nighttime)

Acetaminophen 650 mg
Diphenhydramine HCl 25 mg
Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer
Antihistamine/cough suppressant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - sore throat
  - nasal congestion
  - minor aches and pains
  - headache
  - runny nose and sneezing ***(Nighttime only)***
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ***(Daytime only)***
- controls cough to help you get to sleep ***(Nighttime only)***

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
- with other drugs containing acetaminophen
- more than 4,000 mg of acetaminophen in 24 hours
- 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
- 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.
- 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 have ever had an allergic reaction to this product or any of its ingredients
- with any other product containing diphenhydramine, even one used on skin ***(Nighttime only)***

Ask a doctor before use if you have
- heart disease
- diabetes
- thyroid disease
- liver disease
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis ***(Nighttime only)***
- glaucoma ***(Nighttime only)***

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(Nighttime only)***

When using this product
- **do not exceed recommended dosage**
- excitability may occur, especially in children ***(Nighttime only)***
- marked drowsiness may occur ***(Nighttime only)***
- avoid alcoholic beverages ***(Nighttime only)***
- alcohol, sedatives, and tranquilizers may increase drowsiness ***(Nighttime only)***
- use caution when driving a motor vehicle or operating machinery ***(Nighttime only)***

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.

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing. Do not take DAY & NIGHT at the same time.

Directions

- **do not take more than directed**
- do not take more than 6 doses in any 24-hour period
- mL = milliliter; FL OZ = fluid ounce
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

Other information

- **each 20 mL contains:** sodium 10 mg ***(Daytime only)***, sodium 9 mg ***(Nighttime only)***
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients (Daytime only)

anhydrous citric acid, disodium edetate, FD&C blue #1, FD&C red #40, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum

Inactive ingredients (Nighttime only)

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sodium metabisulfite, sorbitol, sucralose, xanthan gum

Questions or comments?

1-888-287-1915

Principal display panel

Equate™

Compare to Maximum Strength Mucinex® FAST-MAX® Day Time Severe Cold and Night Time Cold & Flu Active Ingredients†

NDC 49035-945-02

Maximum Strength Daytime **Severe Cold** **ACETAMINOPHEN** - Pain Reliever/Fever Reducer DEXTROMETHORPHAN HBr - Cough Suppressant GUAIFENESIN - Expectorant PHENYLEPHRINE HCl - Nasal Decongestant **Multi-Symptom Relief** • Relieves aches, fever & sore throat • Controls cough • Relieves nasal & chest congestion • Thins & loosens mucus Ages 12+	Maximum Strength Nighttime **Cold & Flu** **ACETAMINOPHEN** - Pain Reliever/Fever Reducer DIPHENHYDRAMINE HCl - Antihistamine/Cough Suppressant PHENYLEPHRINE HCl - Nasal Decongestant **Multi-Symptom Relief** • Relieves aches, fever & sore throat • Controls cough • Relieves nasal congestion •Relieves runny nose & sneezing Ages 12+

TWO - 6 FL OZ (177 mL) BOTTLES TOTAL - 12 FL OZ (354 mL)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

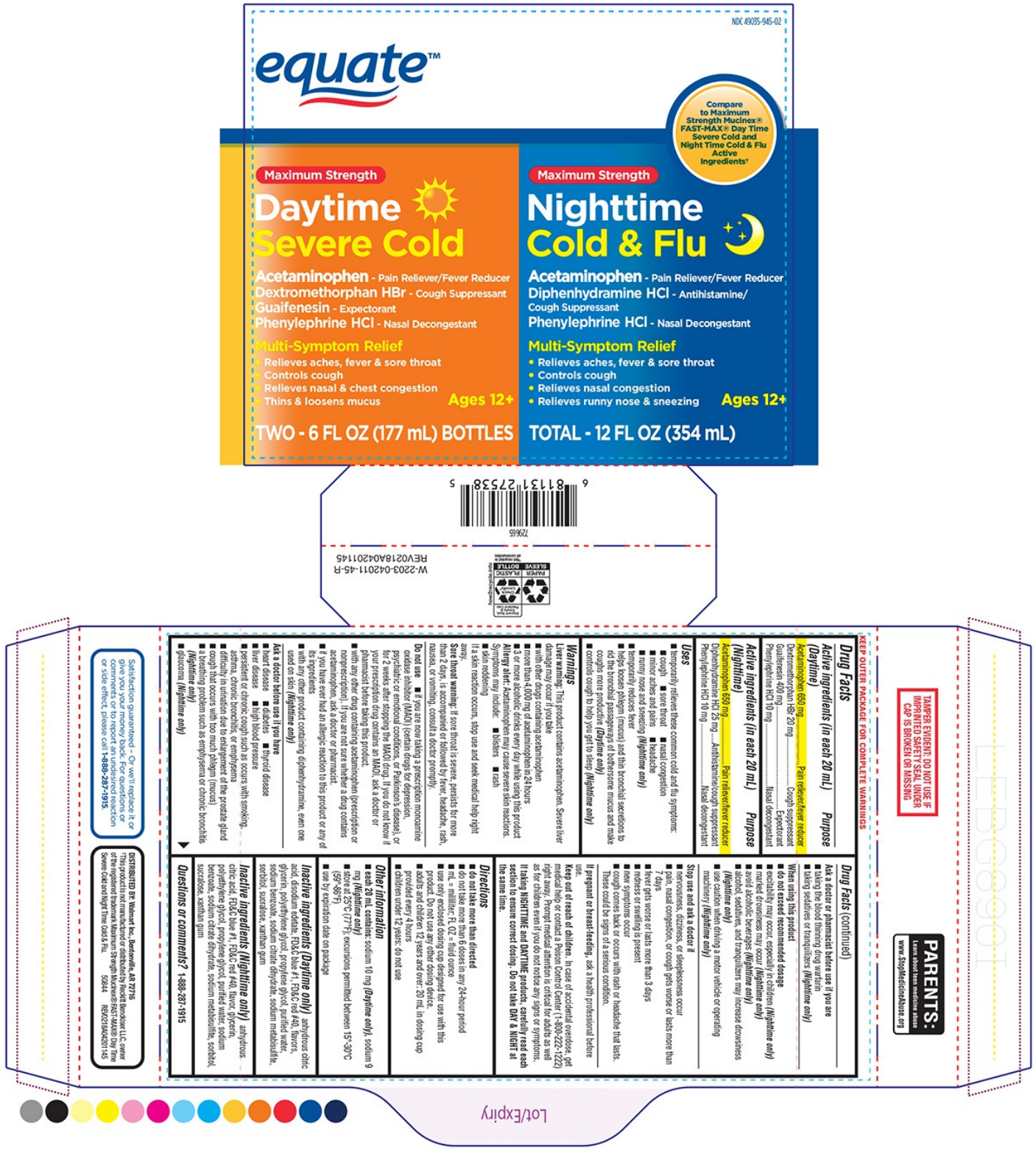
PARENTS:
Learn about teen medicine abuse:
www.StopMedicineAbuse.org

Distributed by:Walmart Inc., Bentonville, AR 72716

†This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® Day Time Severe Cold and Night Time Cold & Flu.

50844 REV0218A04201145

Satisfaction guaranteed – Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.



Equate 44-042011

SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-945

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-945-02	1 in 1 PACKAGE; Type 0: Not a Combination Product	08/15/2018	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	177 mL
Part 2	1 BOTTLE	177 mL

Part 1 of 2

COLD AND FLU NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information	
Item Code (Source)	NDC:49035-811
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	BLUE	**Score**	
Shape		**Size**	
Flavor	BERRY (Mixed)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49035-811-45	177 mL in 1 BOTTLE; 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	08/15/2018	

Part 2 of 2

SEVERE COLD DAYTIME

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information	
Item Code (Source)	NDC:49035-842
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	**Score**	
Shape		**Size**	
Flavor	BERRY (Mixed)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-842-45	177 mL in 1 BOTTLE; 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	08/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/15/2018	

Labeler - Wal-Mart Stores Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	MANUFACTURE(49035-945) , PACK(49035-945)

Revised: 8/2019 Wal-Mart Stores Inc