

**SHOPRITE DAY CALM SEVERE- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution**  
**Wakefern Food Corporation**

*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.*

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**ShopRite Day-Calm Severe Drug Facts**

**Active ingredients (in each 15 mL)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- 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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen

- adult has 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.

#### **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
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

#### **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**

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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.**

**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.

**Directions**

- take only as directed – see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

**Other information**

- each 15 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

**Questions?**

1-800-SHOPRITE

**Package/Label Principal Display Panel**

Compare to: Active Ingredients in Vicks® DayQuil® Severe

SEE NEW WARNINGS

MAXIMUM STRENGTH

DAY-CALM

SEVERE

PAIN RELIEVER/FEVER REDUCER

Acetaminophen – Aches/Fever/Sore Throat

COUGH SUPPRESSANT

Dextromethorphan HBr – Cough

EXPECTORANT

Guaifenesin – Chest Congestion

NASAL DECONGESTANT

Phenylephrine HCl – Nasal/Sinus Congestion & Sinus Pressure

Multi-symptom

ALCOHOL FREE

Non-Drowsy

12 FL OZ (355 mL)

**Drug Facts** (continued)

■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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 ■ pain, nasal congestion, or cough gets worse or lasts more than 5 days (children) or 7 days (adults) ■ you get nervous, dizzy or sleepless ■ 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.

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**Questions? 1-800-SHOPRITE** \*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® DayQuil® Severe.

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 Wakefern Food Corp.  
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 Keasbey, NJ 08832 ©2016

**PARENTS:**  
 Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



Compare to: Active Ingredients in Vicks® DayQuil® Severe\*

SEE NEW WARNINGS

**ShopRite** MAXIMUM STRENGTH

**DAY-CALM SEVERE**

PAIN RELIEVER/FEVER REDUCER  
 Acetaminophen ... Aches/Fever/Sore Throat  
 COUGH SUPPRESSANT  
 Dextromethorphan HBr ... Cough  
 EXPECTORANT  
 Guaifenesin ... Chest Congestion  
 NASAL DECONGESTANT  
 Phenylephrine HCl ... Nasal/Sinus Congestion & Sinus Pressure

Multi-symptom • ALCOHOL FREE

Non-Drowsy 12 FL OZ (355 mL)

**Drug Facts** **DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

Active ingredients (in each 15 mL)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses** temporarily relieves common cold/flu symptoms: ■ sore throat ■ nasal congestion ■ sinus congestion and pressure ■ cough due to minor throat and bronchial irritation ■ minor aches and pains ■ fever ■ headache ■ reduces swelling of nasal passages ■ temporarily restores freer breathing through the nose ■ 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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 ■ liver disease ■ heart disease ■ diabetes  
 ■ thyroid disease ■ high blood pressure  
 ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus)

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**SHOPRITE DAY CALM SEVERE**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-603
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	10 mg	

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 15 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	ORANGE (clear)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT, MENTHOL	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-603-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/03/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/03/2014	

**Labeler** - Wakefern Food Corporation (069722418)