RITE AID DAYTIME SEVERE COLD AND COUGH RELIEF- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride powder, for solution
Rite Aid 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.

Rite Aid® Daytime Severe Cold & Cough Relief

Drug Facts

Active ingredients (in each packet)	*Purposes*
Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan hydrobromide 20 mg	Cough suppressant
Phenylephrine hydrochloride 10 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold:
  - minor aches and pains
  - minor sore throat pain
  - headache
  - nasal and sinus congestion
  - cough due to minor throat and bronchial irritation
- temporarily reduces fever

Warnings

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.

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

- in a child under 4 years of age
- if you are allergic to acetaminophen
- 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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

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
- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- 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 care professional before use.

Keep out of reach of children.

In case of 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 use more than directed**
- take every 4 hours, while symptoms persist. Do not take more than 5 packets in 24 hours unless directed by a doctor

Age	Dose
children under 4 years of age	**do not use**
children 4 to under 12 years of age	do not use unless directed by a doctor
adults and children 12 years of age and over	one packet

- dissolve contents of one packet into 8 oz. hot water: sip while hot. Consume entire drink within 10-15 minutes.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after

heating. Do not overheat.

Other information

- **each packet contains:** potassium 4 mg, sodium 27 mg
- **phenylketonurics:** contains phenylalanine 34 mg per packet
- store at controlled room temperature 20°-25°C (68°-77°F). Protect product from heat and moisture.

Inactive ingredients

acesulfame potassium, aspartame, citric acid anhydrous, FD&C blue no. 1, FD&C red no. 40, flavors, maltodextrin, sodium citrate anhydrous, sucrose, and pregelatinized starch.

Questions or Comments?

Call **1-866-923-4914**

DISTRIBUTED BY: RITE AID
30 HUNTER LANE, CAMP HILL, PA 17011

PRINCIPAL DISPLAY PANEL - 6 Packet Carton

RITE
AID®
PHARMACY

SEE NEW WARNINGS INFORMATION & DIRECTIONS

***Compare to the active ingredients in**
Theraflu® Severe Cold & Cough

daytime
severe cold
& cough relief

acetaminophen 650 mg
dextromethorphan HBr 20 mg
phenylephrine HCl 10 mg

pain reliever/fever reducer
cough suppressant &
nasal decongestant

relieves:
nasal & sinus congestion
cough
body ache
sore throat pain
headache
fever

berry infused
with menthol &
green tea flavors

6 PACKETS

severe cold & cough relief

acetaminophen 650 mg
dextromethorphan HBr 20 mg
phenylephrine HCl 10 mg

pain reliever/fever reducer/cough suppressant & nasal decongestant

RITE AID PHARMACY

SEE NEW WARNINGS INFORMATION & DIRECTIONS

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daytime severe cold & cough relief

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relieves:
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6 PACKETS

TAMPER EVIDENT INNER PACKET
DO NOT USE IF SEALED PACKET
IS TORN OR BROKEN

*This product is not manufactured or distributed by Novartis Consumer Health, Inc. or their affiliates, owner of the registered trademark Theraflu®.

DISTRIBUTED BY: RITE AID
30 HUNTER LANE, CAMP HILL, PA 17011

MADE IN ISRAEL

SATISFACTION GUARANTEE

IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

ITEM 393460

0 11822 04693 0

20497-1014-1
800

daytime

RITE AID PHARMACY

READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE.
KEEP CARTON FOR REFERENCE. DO NOT DISCARD.

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Drug Facts (continued)

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

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acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-2112
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	650 mg
Dextromethorphan hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan hydrobromide	20 mg
Phenylephrine hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine hydrochloride	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
acesulfame potassium (UNII: 23OV73Q5G9)	
aspartame (UNII: Z0H242BBR1)	
anhydrous citric acid (UNII: XF417D3PSL)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C red no. 40 (UNII: WZB9127XOA)	
maltodextrin (UNII: 7CVR7L4A2D)	
anhydrous trisodium citrate (UNII: RS7A450LGA)	
sucrose (UNII: C151H8M554)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11822-2112-7	6 in 1 CARTON; 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	06/28/2013	

Labeler - Rite Aid Corporation (014578892)

Revised: 4/2015 Rite Aid Corporation