ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM 7 IN 1 RELIEF NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

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 liquid-filled capsule)

Acetaminophen, USP 325 mg

Dextromethorphan HBr, USP 15 mg

Doxylamine Succinate, USP 6.25 mg

Purposes

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves these symptoms occurring with a cold or flu, hay fever, or other upper respiratory allergies:
    - headache
    - sore throat
    - cough
    - minor aches and pains
    - runny nose
    - sneezing
    - itchy, watery eyes
    - itching of the nose or throat
- temporarily reduces fever

Warnings

Liver warning

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

- more than 8 capsules in any 24-hour period, which is the maximum daily amount
- 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:

- 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

- to sedate a child or to make a child sleepy
- 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.

Ask a doctor before use if you have

- liver disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or 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
- taking any other pain reliever/fever reducer
- taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- 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.

- new symptoms occur

If pregnant or breast-feeding, ask a health 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 take more than 8 capsules in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage.
- this adult product is not intended for use in children under 12 years of age

age	**dose**
adults and children 12 years and over	2 capsules every 6 hours
children under 12 years	do not use

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).

Inactive ingredients

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, mineral oil, pharmaceutical ink, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

Call weekdays from 9 AM to 5 PM EST at **1 800-762-4675**

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL

ADULT

Robitussin®

MAXIMUM
STRENGTH
SEVERE
Multi-Symptom
7 in 1 Relief

ACETAMINOPHEN (Pain Reliever/Fever Reducer)
DEXTROMETHORPHAN HBr (Cough Suppressant)
DOXYLAMINE SUCCINATE (Antihistamine)

CF
NIGHTTIME
MAX

1. Cough, Sore Throat
2. Body Aches, Fever

3. Runny Nose, Sneezing
4. Itchy Throat

For Ages 12 & Over

10
LIQUID-FILLED
CAPSULES

ROBITUSSIN MAXIMUM STRENGTH SEVERE MULTI-SYMPTOM 7 IN 1 RELIEF NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8744
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	R
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8744-10	5 in 1 CARTON	07/01/2018	
1		2 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	07/01/2015	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 11/2020 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC