DURAFLU- acetaminophen, dextromethorphan hbr, guaifenesin, pseudoephedrine hcl tablet
Poly Pharmaceuticals, Inc.

Duraflu Tablets

DurafluTablets

Rev. 08/15

Drug Facts

Active Ingredients

Acetaminophen 325 mg
Dextromethorphan HBr 20 mg
Guaifenesin 200 mg
Pseudoephedrine HCl 60 mg

Purpose

Pain Reliever
Antitussive
Expectorant
Nasal Decongestant

Temporarily relieves

- minor aches and pains
- fever
- headache
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- nasal congestion due to the common cold

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take:

- More than 3,000 mg of acetaminophen in 24 hrs;
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product
- **Do not Exceed recommended dosage**

■ KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN

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.

Do not use 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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor
- 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 ■ persistent or chronic cough such 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 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 occur
- pain, cough, or nasal congestion 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

Directions

Adults and children 12 years of age and over:	1 tablet every 4 hours, not to exceed 6 tablets in 24 hours or as directed by a doctor
	½ tablet every 4 hours,

Children under 12 years of age	not to exceed 3 tablets in 24 hours, or as directed by a doctor

When using this product do not exceed recommended dosage.

Other information

Store at 20°- 25° Celsius (68° – 77° Fahrenheit) as defined in the (USP/NF). Dispense in tight, light-resistant container.

Inactive ingredients

magnesium stearate, microcrystalline cellulose, stearic acid

Questions or comments?

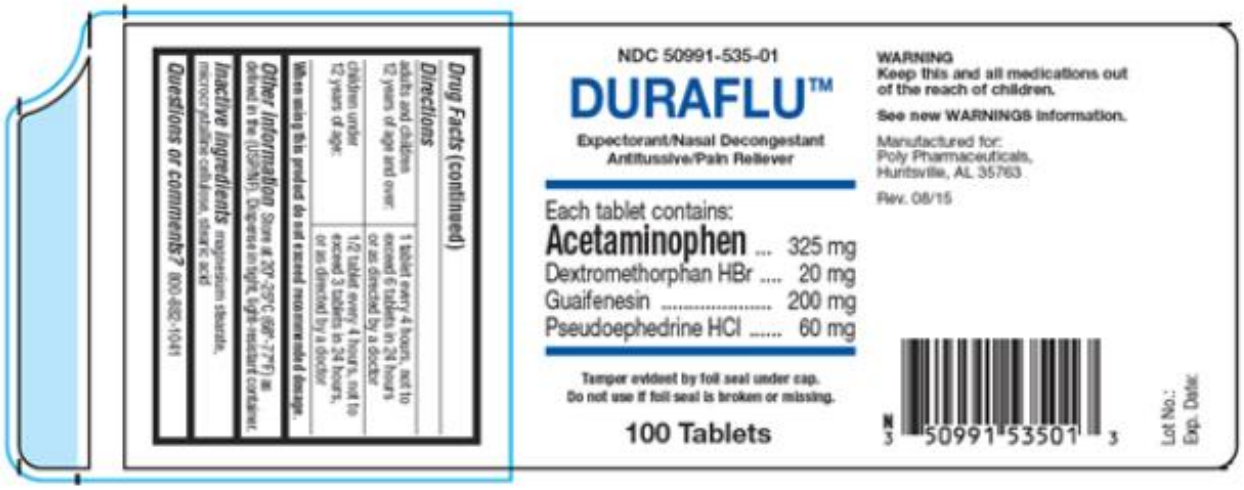
800-882-1041

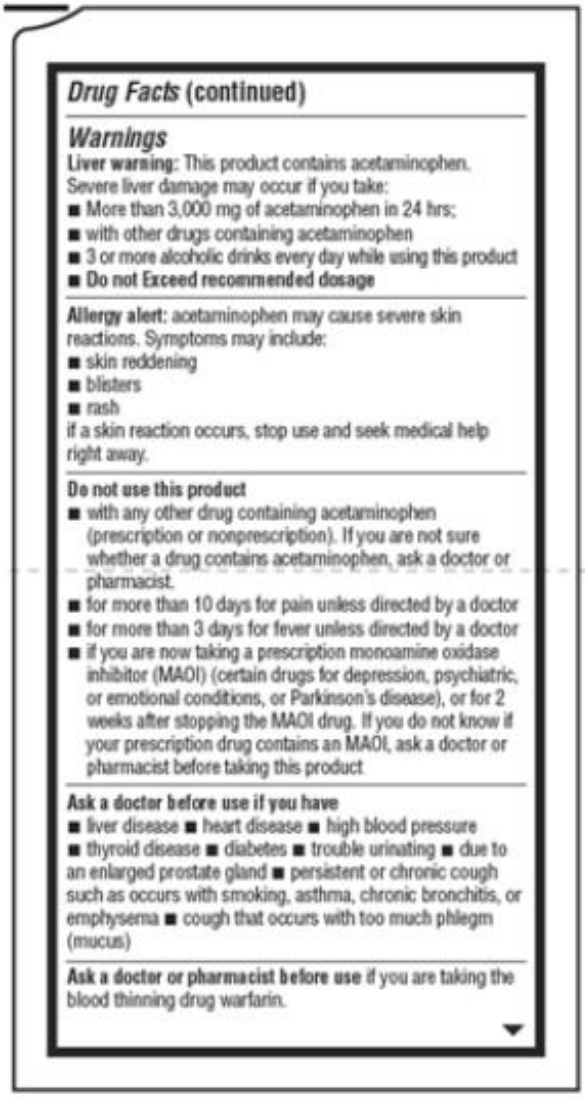
Manufactured For:
Poly Pharmaceuticals, Inc.
Huntsville, AL 35763

Rev. 08/15

PRINCIPAL DISPLAY PANEL

NDC 50991-535-01
DURAFLU™
Expectorant/ Nasal Decongestant
Antitussive/Pain Reliever
100 Tablets





DURAFLU

acetaminophen, dextromethorphan hbr, guaifenesin, pseudoephedrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50991-535

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	PE;723
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-535-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2015	
2	NDC:50991-535-02	6 in 1 CARTON	10/01/2015	
2		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 Drug	M012	10/01/2015	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 11/2024 Poly Pharmaceuticals, Inc.