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

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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

	1 tablet every 4 hours, not

Adults and children 12 years of age and over:	to exceed 6 tablets in 24 hours or as directed by a doctor
Children under 12 years of age	½ tablet every 4 hours, 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?

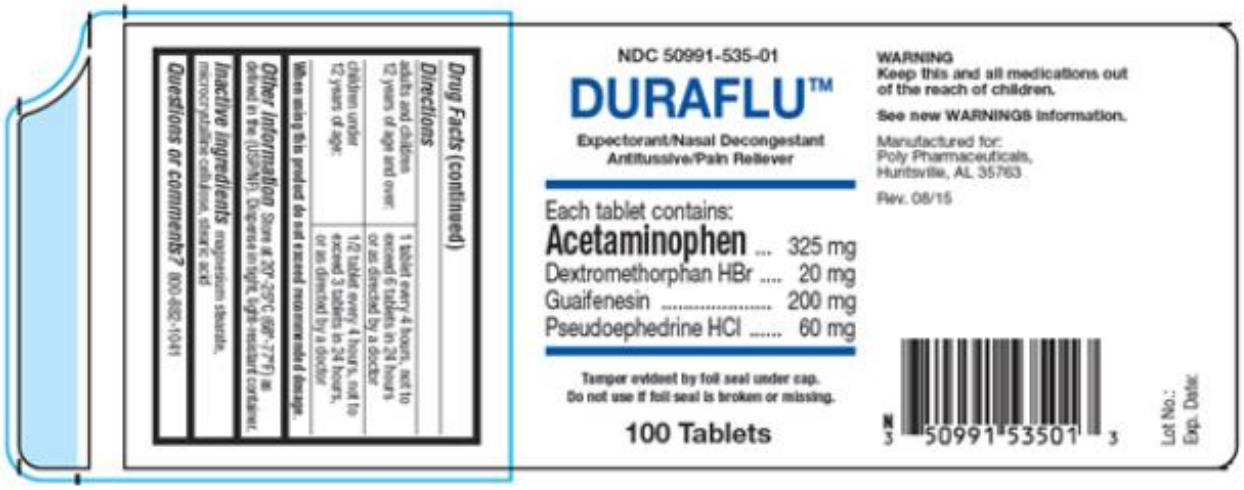
800-882-1041

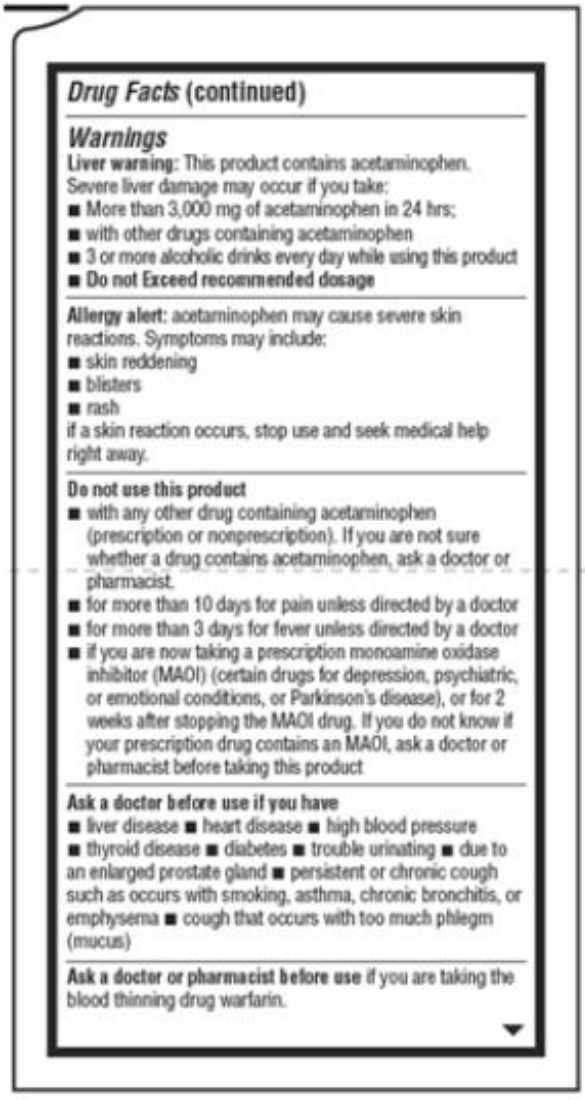
Manufactured For:
Poly Pharmaceuticals, Inc.
Huntsville, AL 35763

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
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
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 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
unapproved drug other		10/01/2015	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024 Poly Pharmaceuticals, Inc.