Duraflu Tablets

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**

<table>
<thead>
<tr>
<th>Adults and children 12 years of age and over:</th>
<th>1 tablet every 4 hours, not to exceed 6 tablets in 24 hours or as directed by a doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children under 12 years of age</td>
<td>½ tablet every 4 hours, not to exceed 3 tablets in 24 hours, or as directed by a doctor</td>
</tr>
</tbody>
</table>

**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**
DURAFLU
acetaminophen, dextromethorphan hbr, guaifenesin, pseudoephedrine hcl tablet

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:50991-535</th>
</tr>
</thead>
</table>

WARNING
Keep this and all medications out of the reach of children.
See new WARNING information.
Manufactured for:
Poly Pharmaceuticals,
Huntsville, AL 35763
Rev. 08/15

Each tablet contains:
Acetaminophen ... 325 mg
Dextromethorphan HBr ... 20 mg
Guaifenesin ............... 200 mg
Pseudoephedrine HCl ...... 60 mg

Tempor overdures by foil sheet under cap. Do not use if foil seal is broken or missing.

100 Tablets

Drug Facts (continued)

When using this product do not exceed recommended dosage.

Stop use and ask a doctor if:
- nervousness, dizziness, or sleeplessness occurs
- 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
- This could be a sign of a serious condition

Drug Facts

Active Ingredients

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<tr>
<th>Purpose</th>
<th>Acetaminophen 325 mg</th>
<th>Pain Reliever</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dextromethorphan 20 mg</td>
<td>Antitussive</td>
</tr>
<tr>
<td></td>
<td>Guaifenesin 200 mg</td>
<td>Nasal Decongestant</td>
</tr>
<tr>
<td></td>
<td>Pseudoephedrine 60 mg</td>
<td></td>
</tr>
</tbody>
</table>

Drug Facts (continued)

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
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- 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 or pharmacist before use:
- 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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.
### Route of Administration
ORAL

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)</td>
<td>ACETAMINOPHEN</td>
<td>325 mg</td>
</tr>
<tr>
<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
<td>DEXTROMETHORPHAN HYDROBROMIDE</td>
<td>20 mg</td>
</tr>
<tr>
<td>GUAIFFENESIN (UNII: 495W7451VQ) (GUAIFFENESIN - UNII:495W7451VQ)</td>
<td>GUAIFFENESIN</td>
<td>200 mg</td>
</tr>
<tr>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F)</td>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td>60 mg</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)</td>
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</tr>
<tr>
<td>STEARIC ACID (UNII: 4ELV7Z65AP)</td>
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</table>

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Imprint Code</th>
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</thead>
<tbody>
<tr>
<td>white</td>
<td>2 pieces</td>
<td>OVAL</td>
<td>20 mm</td>
<td>PE;723</td>
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### Packaging

<table>
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<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>1</td>
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<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>10/01/2015</td>
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### Marketing Information

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<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph final</td>
<td>part341</td>
<td>10/01/2015</td>
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**Labeler** - Poly Pharmaceuticals, Inc. (198449894)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>TG United</td>
<td>172837085</td>
<td>manufacture(50991-535)</td>
<td></td>
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</tbody>
</table>

Revised: 1/2020

Poly Pharmaceuticals, Inc.