

**DEFENSOL D (MULTI SYMPTOM EFFERVESCENT TABLETS)- acetaminophen 250mg, chlorpheniramine maleate 2mg, dextromethorphan hydrobromide 10mg, phenylephrine hydrochloride 5mg tablet, effervescent
Menper Distributors Inc.**

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.

Defensol D (Multi Symptom Effervescent Tablets)

Active Ingredients

Active Ingredients (in each tablet) Purposes

Acetaminophen 250 mg.....Pain Relieve/fever reducer
Chlorpheniramine maleate 2mgAntihistamine
Dextromethorphan hydrobromide 10mg.....Cough suppressant
Phenylephrine hydrochloride 5mg.....Nasal decongestant

☐Purposes

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Uses: Temporarily relieves these symptoms due to a cold or flu:

- Minor aches and pains
- Headache
- Cough
- Sore throat
- Runny nose
- Nasal and sinus congestion
- Temporarily reduces fever

☐Warnings:

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

- More than 8 tablets in 24 hours, which is the maximum daily amount for this product
- With other drugs containing acetaminophen
- 3 or more alcoholic drinks while using this product

Sore Throat Warning: If sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. **Do not use to sedate children.**

Do not use:

- 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 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.**

- If you have ever had an allergic reaction to this product or any of its ingredients
- In children under 12 years of age

Ask a doctor before use if you have:

- Liver disease
- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes
- Glaucoma
- Cough with excessive phlegm (mucus)
- A breathing problem such as emphysema or chronic bronchitis
- Difficulty in urination due to enlargement of the prostate gland
- Persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- A sodium restricted diet

Ask a doctor or pharmacist before use if you are:

- Taking the blood thinning medicine warfarin
- Taking sedatives or tranquilizers

When using this product:

- Do not exceed the recommended dosage
- May cause marked drowsiness
- 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, 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.**
- Nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

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Keep out of reach of children

- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick 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 the recommended dose
- Adults and children 12 years and over: take 2 tablets fully dissolved in 4oz. of water every four hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor
- Children under 12 years: do not use

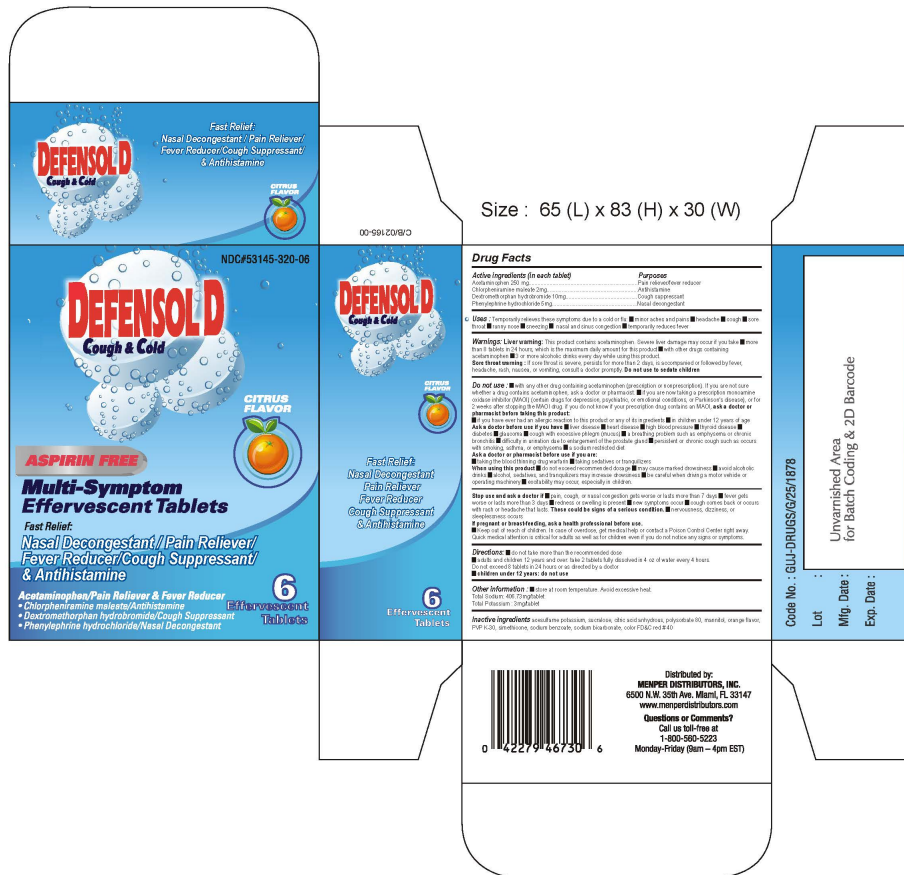
Other Information:

- Store at room temperature. Avoid excessive heat
- Total Sodium: 406.73mg/tablet
- Total Potassium: 3mg/tablet

Inactive Ingredients

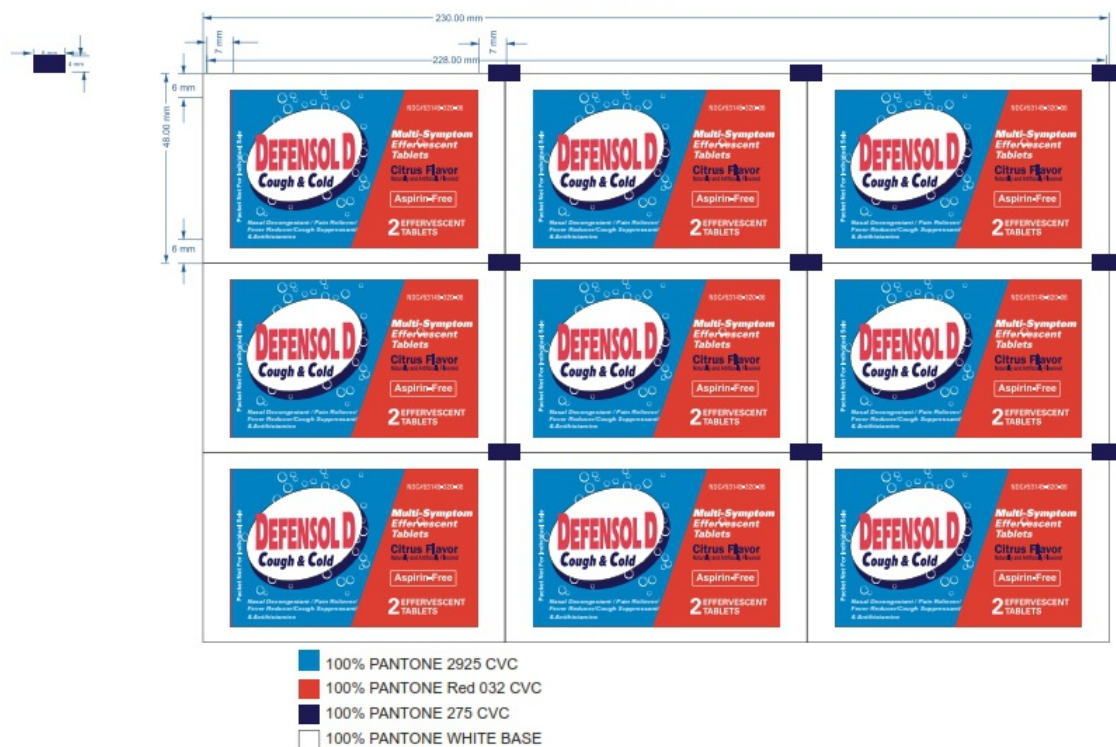
Acesulfame potassium, sucralose, citric acid anhydrous, polysorbate 80, mannitol, orange flavor, PVP K-30, simethicone, sodium benzoate, sodium bicarbonate, color FD&C red #40

Defensol D Effervescent - Outer Carton.jpg



Defensol D Effervescent Pouch.jpg

Front Foil



DEFENSOL D (MULTI SYMPTOM EFFERVESCENT TABLETS)

acetaminophen 250mg, chlorpheniramine maleate 2mg, dextromethorphan hydrobromide 10mg, phenylephrine hydrochloride 5mg tablet, effervescent

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53145-320 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|------------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg in 250 |
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 2 mg in 250 |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg in 250 |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE | 5 mg in 250 |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

MANNITOL (UNII: 3OWL53L36A)

POVIDONE K30 (UNII: U725QWY32X)

PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)

SODIUM BENZOATE (UNII: OJ245FE5EU)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

FD&C RED NO. 40 (UNII: WZB9127XOA)

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 30mm |
| Flavor | ORANGE | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53145-320-06 | 6 in 1 BOX | 12/01/2015 | |
| 1 | NDC:53145-320-02 | 2 in 1 POUCH; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 12/01/2015 | |

Labeler - Menper Distributors Inc. (101947166)

Revised: 1/2016

Menper Distributors Inc.