

Example Drug Facts Label for Clemastine Fumerate 1.34 mg in a Tablet Dosage Form

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**Drug Facts**

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<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Clemastine fumerate 1.34 mg (equivalent to 1 mg clemastine).....	Antihistamine

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**Uses** temporarily relieves these symptoms of the common cold, hay fever, or other upper respiratory allergies:

# runny nose # itchy, watery eyes # sneezing # itching of the nose or throat

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**Warnings**

**Ask a doctor before use if you have**

- # glaucoma
  - # a breathing problem such as emphysema or chronic bronchitis
  - # trouble urinating due to an enlarged prostate gland
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**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

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**When using this product**

- # you may get drowsy
  - # 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
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**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.

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**Directions**

- # adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
  - # children under 12 years: ask a doctor
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**Other information**

- # optional - tamper evident statement
  - # store at 20-25<sup>0</sup> C (68-77<sup>0</sup> F)
  - # optional - see [end or side] panel for lot number and expiration date
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**Inactive ingredients** [list ingredients in alphabetical order]

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**Questions or comments?** call toll free 1-800-XXX-XXXX

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NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.