Example Drug Facts Label for Doxylamine Succinate 25 mg Tablet Dosage Form

Drug Facts

Active ingredient (in each tablet)

Purpose

Doxylamine succinate 25 mg......Nighttime sleep-aid

Use helps to reduce difficulty in falling asleep

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

Ask a doctor or pharmacist before use if you are taking any other drugs

When using this product

- # you may get drowsy. Use only at bedtime.
- # avoid alcoholic drinks

Stop use and ask a doctor if

sleeplessness does not go away for more than 2 weeks. This could be a sign of a serious condition.

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.

Directions

adults and children 12 years and older: 1 tablet 30 minutes before bedtime; not more than 1 tablet each day

children under 12 years: do not use

Other information

- # optional tamper evident statement
- # store at 20-25°C (68-77°F)
- # optional see [end or side] panel for lot number and expiration date

Inactive ingredients [list ingredients in alphabetical order]

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

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