

LINKUS LOZENGES COUGH SUPPRESSANT/ORAL ANESTHETIC- menthol lozenge
Herbion Pakistan (Pvt.) Ltd.

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.

Menthol 5.2mg

Cough Suppressant, Oral Anesthetic

Uses:

- Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
- For temporary relief of occasional minor irritation, pain, sore mouth and sore throat

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. These may be serious.

Stop use and ask a doctor if:

- Cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persisted headache. These could be signs of a serious condition
- Sore throat symptoms do not improve in 7 days
- Irritation, pain or redness persists or worsens

Ask a doctor before use if you have:

- A persistent or chronic cough such as occurs with smoking, asthma, emphysema
- A cough that is accompanied by excessive phlegm (mucus)

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

Keep out of reach of children.

Directions

Adults and children 12 years and over
lozenges in 24 hours

Take 1-2 lozenges every 2 to 3 hours not more than 8

Children 6 years to under 12 years
lozenges in 24 hours

Take 1 lozenge every 5 to 6 hours not more than 4

Children under 6 years of age

Consult your doctor

Other Information:

- store in a cool, dry place, below 25 degrees C
- Protect from heat and light
- Diabetic patients should not use linkus lozenges without the advice of physician and they should monitor glucose levels closely while taking lozenges as it may alter blood glucose levels

Manufactured for:

Herbion USA Inc.

Williamsville NY 14221

1-888-(OK-HERBION)-654-3724

info.us@herbion.com
www.herbion.com

Ascorbic Acid, Aspartame, Colorants Red No. 40, Eucalyptus Oil, Hyssop, Large leaf Geiger Tree, Lesser Galangal, Licorice, Liquid Glucose, Long Pepper, Malabar Nut, Strawberry Flavor, Sweet Violet

Questions or comments:

1-888-654-3724 Monday thru Friday, 9am-5pm or visit www.Herbion.com

Linkus Lozenges

Sugar Free

Cough Suppressant Oral Anesthetic

Relieves Cough and Soothes Sore Throat

Strawberry



Drug Facts:

Active Ingredient (in each lozenge): Menthol, 5.2 mg. Purpose: Cough Suppressant, Oral Anesthetic

Uses:

- Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold.
- For temporary relief of occasional minor irritation, pain, sore mouth and sore throat.

Warnings:

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. These may be serious.

Ask a doctor before use if you have:

- A persistent or chronic cough such as occurs with smoking, asthma, emphysema.
- A cough that is accompanied by excessive phlegm (mucus).

Stop use and ask a doctor if:

- Cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- Sore throat symptoms do not improve in 7 days.
- Irritation, pain or redness persists or worsens.

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

Keep out of reach of children

Directions

| | |
|---------------------------------------|---|
| Adults and children 12 years and over | Take 1-2 lozenges every 2 to 3 hours not more than 8 lozenges in 24 hours |
| Children 6 year to under 12 years | Take 1 lozenge every 5 to 6 hours not more than 4 lozenges in 24 hours |
| Children under 6 years of age | Consult your doctor |

Other information

- store in a cool, dry place, below 25°C.
- Protect from heat and light
- Diabetic patients should be not use linkus lozenges without the advice of physician and they should monitor level closely while taking lozenges as it may alter blood glucose levels

INACTIVE INGREDIENTS:

Ascorbic Acid, Aspartame, Citric Acid, Colorants (FD&C Red No 40), Eucalyptus Oil, Hyssop, Isomalt, Large leaf Geiger Tree, Lesser Galangal, Licorice, Long Pepper, Malabar Nut, Strawberry Flavor, Sweet Violet.

Questions or comments:

1-888-654-3724 Monday through Friday, 9am-5pm or visit: www.herbion.com



Batch No:
Mfg. Date:
Exp. Date:

Manufactured for:
Herbion USA Inc.
Williamsville, NY 14221
1-888 (OK-HERBION)-654-3724
info.us@herbion.com
www.herbion.com

LINKUS LOZENGES COUGH SUPPRESSANT/ORAL ANESTHETIC

menthol lozenge

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:44237-006 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 mg |

Product Characteristics

| | | | |
|--------|------------|--------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 17mm |
| Flavor | STRAWBERRY | Imprint Code | NONE |

| Contains | | | | |
|------------------------------|--|----------------------|----------------------|--------------------|
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:44237-006-08 | 8 in 1 BOX | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part341 | 04/01/2010 | | |

Labeler - Herbion Pakistan (Pvt.) Ltd. (645482936)

Registrant - Herbion Pakistan (Pvt.) Ltd. (645482936)

| Establishment | | | |
|------------------------------|---------|-----------|----------------------|
| Name | Address | ID/FEI | Business Operations |
| Herbion Pakistan (Pvt.) Ltd. | | 645482936 | relabel, manufacture |