

THROAT COAT - menthol pastille
Phytoneering Extract Solutions GmbH

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.

Warnings

Sore throat warning: If sore throat is severe, accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly. Do not exceed recommended dosage.

If pregnant or breastfeeding, ask a health professional before use.

Keep this and all drugs out of the reach of children.

| Active Ingredient (in each pastille) | Purpose |
|--------------------------------------|--------------------|
| Menthol 2.5 mg | Oral pain reliever |

Uses: temporarily relieves occasional minor irritation, pain, sore mouth, sore throat

Directions For adults and children 2 to 12 years of age: Allow 1 pastille to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor. Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients

Organic gum arabic, organic raw cane sugar, Throat Coat® herbal extract (extractive obtained from a mixture of: licorice root, organic wild cherry bark, organic bitter fennel fruit, organic cinnamon bark, organic sweet orange peel, organic slippery elm bark, organic marshmallow root, and licorice root dry extract), organic maltose syrup, honey, organic peppermint leaf essential oil, organic sweet orange peel essential oil, organic fennel fruit essential oil, organic cinnamon bark essential oil, natural vegetable and beeswax glaze.

Other Information

Tamper-evident: Each pastille is individually enclosed in a sealed, imprinted blister. Do not use if the blister unit is open or torn.

Enter section text here

Traditional  Medicinals®

Throat Coat® Herbal Pastilles

Oral Pain Reliever
For the Temporary Relief of
Sore Throat Pain

NEW



Not Just an Ordinary Lozenge!

24 Herbal Pastilles

Net Wt. 48g

Traditional Medicinals®

Throat Coat® Herbal Pastilles

Adults and children 2 to 12 years of age:
Allow 1 pastille to dissolve slowly in mouth.
May be repeated every 2 hours as needed.
Do not chew.

Look for other Traditional Medicinals® Products:
Herbal Syrups
Throat Coat®
Herbal Lozenges
Elderberry
Herbal Tea®
Over 45 herbal tea choices

Look for other Traditional Medicinals® Products:
Herbal Pastilles
Herba Tussine
Echinacea Plus®
Herbal Teas
Over 45 herbal tea choices

Kunden-Info: 1-800-775-5554
Kontakt: 1-800-775-5554
Fax: 1-800-775-5554
Tel: 1-800-775-5554
Date: 12/05/07
Dosen: 21/05/07
Hersteller: 79183 Waldkirch
R. Falter KG

FRISERLEITUNG

Not Just an Ordinary Lozenge!
Cough drops, lozenges and pastilles may appear similar, but there are important differences. Like candy, ordinary drops and lozenges are made from sugar, or the sugar free chemical aspartame, with colors and flavors added. Often produced in candy factories, these products are usually wrapped in paper, if at all, rather than preserved in protective pharmaceutical packaging. Our medicated pastilles contain the active ingredient menthol, made from organic mint essential oil, concentrated medicinal herb extracts and essential oils. These ingredients are then compressed into an organic gum Arabic base (extracted from the Acacia tree) providing you with healing and soothing anesthetic, antitussive and demulcent effects. Our herbal pastilles are true herbal medicine!

Traditional Medicinals®

Throat Coat® Herbal Pastilles

Oral Pain Reliever
For the Temporary Relief of
Sore Throat Pain



Safe & Effective
Throat Coat® Herbal Pastilles contain menthol for effective temporary relief of minor irritation, pain, sore mouth and sore throat, as well as a concentrated extract of our clinically-tested Throat Coat® tea formula.

All Natural Soothing Relief
A combination of organic herbs, essential oils and natural sweeteners, these pastilles offer an effective dose of natural relief.

Convenient and Natural
Perfect for on-the-go, take these pastilles with you for convenient relief wherever you are. No artificial flavors or colors.

For more information visit:
www.TraditionalMedicinals.com

Not Just an Ordinary Lozenge!
24 Herbal Pastilles Net Wt. 48g

These pastilles are made in partnership with Bionorica® of Germany, blending the ancient wisdom of herbal medicine with modern scientific methods.

Drug Facts

| Active Ingredient (in each pastille) | Purpose |
|--------------------------------------|--------------------|
| Menthol 2.5 mg | Oral pain reliever |

Uses temporarily relieves occasional
 minor irritation pain sore mouth sore throat

Warnings
Sore throat warning: If sore throat is severe, accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly. Do not exceed recommended dosage.
 If pregnant or breastfeeding, ask a health professional before use. Keep this and all drugs out of the reach of children.

Directions For adults and children 2 to 12 years of age:
 Allow 1 pastille to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a dentist or doctor.
 Children under 2 years of age: Consult a dentist or doctor.

Other Information
 Tamper-evident: Each pastille is individually enclosed in a sealed, imprinted blister.
 Do not use if the blister unit is open or torn.

Inactive Ingredients
 Organic gum arabic, organic raw cane sugar, Throat Coat® herbal extract (extractive obtained from a mixture of licorice root, organic wild cherry bark, organic bitter fennel fruit, organic cinnamon bark, organic sweet orange peel, organic slippery elm bark, organic marshmallow root, and licorice root dry extract), organic maltose syrup, honey, organic peppermint leaf essential oil, organic sweet orange peel essential oil, organic fennel fruit essential oil, organic cinnamon bark essential oil, natural vegetable and beeswax glaze.

70% organic ingredients NDC# 13340-5624-4

Throat Coat®

Traditional Medicinals Sebastopol, California 95472
 Certified by the California Certified Organic Farmers (CCOF).



LOT#: _____
 EXP. DATE: _____
 Distributed by:
 Traditional Medicinals
 4515 Ross Road, Sebastopol, CA 95472
 www.TraditionalMedicinals.com
 ©2005 051005, PFC100805
 70-90% recycled board



Carton image

THROAT COAT

menthol pastille

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13340-5624 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A) | Menthol | 2.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Acacia (UNII: 5C5403N26O) | |
| Raw Sugar (UNII: 8M707QY5GH) | |
| Maltose Syrup (UNII: 00JKR0NZ8O) | |
| Honey (UNII: Y9H1V576FH) | |
| Fennel Oil (UNII: 59AAO5F6HT) | |
| Cinnamon Bark Oil (UNII: XE54U569EC) | |
| Orange Oil (UNII: AKN3KSD11B) | |
| Peppermint Oil (UNII: AV092KU4JH) | |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|----------|
| Color | brown | Score | no score |
| Shape | ROUND (T) | Size | 18mm |
| Flavor | | Imprint Code | T |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------|----------------------|--------------------|
| 1 | NDC:13340-5624-4 | 24 in 1 BLISTER PACK | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 01/26/2005 | |

Labeler - Phytoneering Extract Solutions GmbH (344281931)

Revised: 6/2010

Phytoneering Extract Solutions GmbH