

BIOVANTA TRIP ACTION TART CHERRY AND HONEY- acetylsalicylic acid, menthol lozenge

Applied Biological Laboratories 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.

biovanta Tart Cherry

Drug Facts

Drug Facts

Active Ingredient

Active Ingredient (in each lozenge):

Menthol 5mg.....Antitussive

Acetyl Salicylic Acid* (NSAID)* 6 mg.....Analgesic

*nonsteroidal anti-inflammatory drug

Purpose

Antitussive and Analgesic

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants.
- For the temporary relief of minor aches and pains associated with a sore throat.

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy Alert: Aspirin may cause a severe allergic reaction, which may include:

- Asthma (wheezing) ■ Hives ■ Facial swelling ■ Shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if the user:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug

- takes other drugs containing prescription or nonprescription NSAIDs (e.g. aspirin, ibuprofen, naproxen, or others)
- takes more than directed or for a longer time than directed
- is age 60 or older
- has 3 or more alcoholic drinks per day while using this product

Ask a doctor before use

Ask a doctor before use if you have:

- a history of stomach problems, such as heartburn
- high blood pressure, heart disease, liver cirrhosis, or kidney disease
- taken a diuretic ■ not been drinking fluids ■ lost a lot of fluid due to vomiting or diarrhea

Stop use

Stop use of this product and ask a healthcare provider if user experiences any of the following signs or stomach bleeding:

- feels faint ■ vomits blood ■ has bloody or black stools ■ has stomach pain that does not get better

If pregnant or breast-feeding

Pregnancy: If pregnant or breast-feeding, always ask your healthcare provider before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless directed to do so by a doctor as it may cause problems in the unborn child or complications during delivery.

Do not use

Do not use:

- If you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor.
- If allergic to milk and/or egg white, or have ever had an allergic reaction to this product or any of its ingredients.

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult your healthcare provider.

Keep out of the reach of children

Children Warning: Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Dissolve 1 lozenge slowly in mouth.
- Repeat every 30 minutes as needed or as directed by health care provider.
- Children under 6 consult health care provider.

Other Information

- Store at room temperature.
- Check expiration date before using.
- Tamper Evident: Do not use if tamper seal is broken or missing.
- Do not give lozenges to children younger than age 4.
- Actual lozenge color may vary slightly due to the natural ingredients.

Inactive Ingredients

Aloe, Honey, Isomalt, Lactoferrin, Lysozyme, Natural Colors, Natural Cherry Flavor, Sodium Chloride, Stevia Rebaudiana, Water

biovanta Tart Cherry

biovanta™

(NSAID*)

TRIPLE ACTION LOZENGES

- Fights Colds
- Soothes Sore Throats
- Relieves Coughs

Tart Cherry

Non-Drowsy

24 Lozenges

NDC 73678-460-24

Questions or Comments? 866-889-3959

info@appliedbioinc.com

Distributed by:

Applied Biological Laboratories

760 Parkside Ave., 317

Brooklyn, New York 11226



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Acetylsalicylic Acid (NSAID)* 6 mg
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bio vanta™

Scientifically proven formula

Works in a whole new way by reducing the inflammation that causes cold symptoms

Triple action lozenges relieve sore throat, cough and cold symptoms in one remedy

The naturally derived ingredients in Biovanta maximize impact while minimizing side effects.

Questions or Comments?
866-880-3959
info@appliedbioinc.com

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*www.biovanta.com to learn more

MADE FROM 100% NATURAL INGREDIENTS

SUGAR FREE

NEW!

bio vanta™
(NSAID*)

TRIPLE ACTION LOZENGES

- Fights Colds
- Soothes Sore Throats
- Relieves Coughs

Non-Drowsy

TART CHERRY

24 LOZENGES

NDC-73678-460-24

Every ingredient in Biovanta is derived from natural sources.

| | |
|-------------------------------------|----------------------------|
| ACETYLSALICYLIC ACID Plant-Based | MENTHOL |
| HONEY | STEVIA |
| LACTOFERRIN From milk | LYSOZYME From egg white |
| ISOMALT Found in sugar beets | ALOE From the plant |
| CHERRY | NATURAL FLAVORS |

BIOVANTA TRIP ACTION TART CHERRY AND HONEY

acetylsalicylic acid, menthol lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73678-460 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 6 mg |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ISOMALT (UNII: S870P55O2W) | |
| HONEY (UNII: Y9H1V576FH) | |
| LACTOFERRIN, BOVINE (UNII: KG21X1090A) | |
| LYSOZYME (UNII: 968JKA7T33) | |
| ALOE (UNII: V5VD430YW9) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| WATER (UNII: 059QF0KO0R) | |
| STEVIA REBAUDIANA WHOLE (UNII: 6U422Y08O2) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 17mm |
| Flavor | CHERRY, HONEY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:73678-460-24 | 24 in 1 BOX | 08/15/2020 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 08/15/2020 | |

Labeler - Applied Biological Laboratories Inc. (080512733)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Lozy's Pharmaceuticals SL. | | 466116516 | manufacture(73678-460) |

