

TBX-FREE- laburnum anagyroides strip
Aavishkar Oral Strips Pvt. Ltd.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

TBX-Free

Active ingredient - Laburnum anagyroides 1x

PURPOSE

Homeopathic treatment of chronic nicotism

Directions and Use

- For adults 18 years or older
- For best results use TBX-FREE on your quit day
- It is important to complete treatment. If you feel you need to use TBX-FREE for a longer period to keep from smoking, talk to your health care provider.
- Reduce nicotine cravings associated with smoking cessation
- If you smoke over 20 cigarettes a day, take 4 strips a day as needed
- If you smoke under 20 cigarettes a day, use TBX-FREE as recommended below.

Do not use: In conjunction with another smoking cessation product; if you are taking prescription medication for depression or asthma; If you are taking prescription medication for depression or asthma; If you have ever had an allergic reaction to this product or any of its ingredients

Ask doctor of pharmacist before use if you have: heart disease or an irregular heartbeat; high blood pressure; stomach ulcers; diabetes; allergies to other medications

Stop use and speak to a doctor: If any of the following occur - mouth, teeth or jaw problems, irregular heartbeat or palpitations, you develop symptoms of an allergic reaction (such as difficulty breathing or a rash).

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

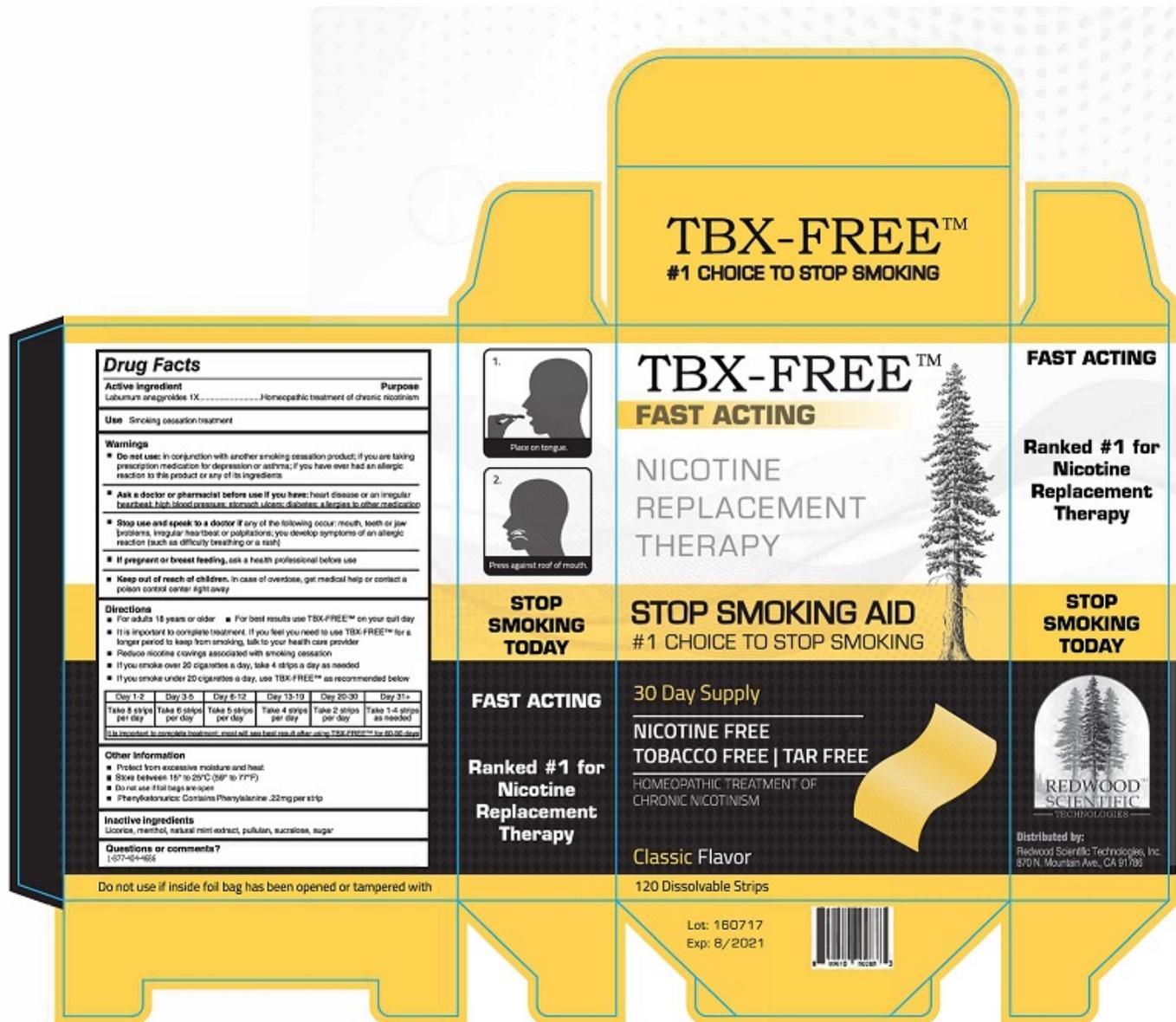
Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.

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Smoking cessation treatment

INACTIVE INGREDIENTS

Licorice, menthol, natural mint extract, pullulan, sucralose, sugar



TBX-FREE

laburnum anagyroides strip

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71750-001 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|----------|
| LABURNUM ANAGYROIDES POLLEN (UNII: JX345H5MPP) (LABURNUM | LABURNUM ANAGYROIDES | 1.00 mg |

| | | | | |
|---------------------------------------|------------------|---|-----------------------------|---------------------------|
| ANAGYROIDES POLLEN - UNII:JX345H5MPP) | | POLLEN | 1100_~J | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| MINT (UNII: FV98Z8G1TP) | | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | | |
| MENTHOL (UNII: L7T10EIP3A) | | | | |
| SUCROSE (UNII: C151H8M554) | | | | |
| PULLULAN (UNII: 8ZQ0AYU1TT) | | | | |
| LICORICE (UNII: 61ZBX54883) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71750-001-01 | 120 in 1 BOX; Type 0: Not a Combination Product | 01/12/2018 | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic | | | 01/11/2018 | |

Labeler - Aavishkar Oral Strips Pvt. Ltd. (872196103)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|------------------------|
| Aavishkar Oral Strips Pvt. Ltd. | | 872196103 | manufacture(71750-001) |

Revised: 1/2018

Aavishkar Oral Strips Pvt. Ltd.