

**TBX-FREE- cytisine strip**  
**Dalian Jixin Electronic Information Co., 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.*

-----

Active Ingredient

Cytisine 8mg

Purpose

Treatment of chronic nicotineism

**KEEP OUT OF REACH OF CHILDREN**

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

**Use**

Smoking cessation treatment

**DIRECTIONS**

Adults 18 years or over

Begin using TBX-Free on your quit day

It is important to complete treatment. If you feel you need to use TBX-Free to keep from smoking, talk to your health care provider.

**Warnings**

Do not use: in conjunction with another smoking cessation product; 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 a doctor or pharmacist before use if you have: heart disease or an irregular heartbeat; high blood pressure; stomach ulcers; diabetes; allergies to other medication

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)

**Inactive Ingredients**

pullulan, natural mint extract, sugar, menthol, licorice, aspartame

**OTHER SAETY INFORMATION**

Protect from excessiv moisture and heat

Store between 15° and 25° C (59° to 77 ° F)

**QUESTIONS OR COMMENTS**

1-800-965-1594

**TBX-FREE**  
STRIP DELIVERY TECHNOLOGY

# Drug Facts

**Active ingredient****Purpose**

Cytisine 8mg ..... Treatment of chronic nicotineism

**Use** Smoking cessation treatment

**Warnings**

■ **Do not use:** in conjunction with another smoking cessation product; 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 a doctor or pharmacist before use if you have:** heart disease or an irregular heartbeat; high blood pressure; stomach ulcers; diabetes; allergies to other medication

■ 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)

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

**Directions**

- Adults 18 years or older
- Begin using 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

**Other Information**

- protect from excessive moisture and heat
- store between 15° to 25° C (59° to 77° F)

**Inactive ingredients**

pullulan, natural mint extract, sugar, menthol, licorice, aspartame

# Questions or comments?

1-800-965-1594

## TBX-FREE

cytisine strip

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69461-001
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYTISINE (UNII: 53S5U404NU) (CYTISINE - UNII:53S5U404NU)	CYTISINE	8 mg in 1 mg

### Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
MENTHOL (UNII: L7T10EP3A)	
LICORICE (UNII: 61ZBX54883)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
MINT (UNII: FV98Z8G1TP)	
ASPARTAME (UNII: Z0H242BBR1)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69461-001-01	110 mg in 1 BOX; Type 0: Not a Combination Product	11/20/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/20/2015	

**Labeler** - Dalian Jixin Electronic Information Co., Ltd. (544903951)

### Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Dalian Jixin Electronic Information Co., Ltd.		544903951	manufacture(69461-001)
---	--	-----------	------------------------

Revised: 11/2015

Dalian Jixin Electronic Information Co., Ltd.