

NICOTINE- nicotine patch
TYA Pharmaceuticals

Drug Facts

Active ingredient (in each patch)

Nicotine, 14 mg delivered over 24 hours

Purpose

Stop smoking aid

Uses

Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Warnings

Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known. **If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider.**

Do not use

- If you continue to smoke, chew tobacco, use snuff, use nicotine gum, or use nicotine patch or other nicotine-containing products

Ask a doctor before use if you have

- Heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- High blood pressure not controlled with medication. Nicotine can increase your blood pressure.
- An allergy to adhesive tape or skin problems because you are more likely to get rashes

Ask a doctor or pharmacist before use if you are

- Using a non-nicotine stop smoking drug
- Taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

When using this product

- Do not smoke even when not wearing the patch. The nicotine in your skin will still be entering your bloodstream for several hours after you take off the patch.
- If you have vivid dreams or other sleep disturbances, remove this patch at bedtime

Stop use and ask a doctor if

- Skin redness caused by the patch does not go away after four days, or your skin swells, or you get a rash
- Irregular heartbeat or palpitations occur
- You get symptoms of nicotine overdose, such as nausea, vomiting, dizziness, weakness, and rapid heartbeat

Keep out of reach of children and pets

Used patches have enough nicotine to poison children and pets. If swallowed, get medical help or

contact a Poison Control Center right away. Save pouch to use for patch disposal. Dispose of used patch by folding sticky ends together and putting in pouch.

Directions

- **If you are under 18 years of age, ask a doctor before use**
- Before using this product, read the enclosed self-help guide for complete directions and other information
- Stop smoking completely when you begin using the patch
- If you smoke more than 10 cigarettes per day, use the following schedule:

Weeks 1 thru 4	Weeks 5 and 6	Weeks 7 and 8
STEP 1 use one 21 mg patch/day	STEP 2 use one 14 mg patch/day	STEP 3 use one 7 mg patch/day

- If you smoke 10 or start with for 6 weeks, then for 2 weeks and then stop **less cigarettes per day, Step 2 Step 3**
- Apply one new patch every 24 hours on skin that is dry, clean, and hairless
- Remove backing from patch and immediately press onto skin. Hold for 10 seconds.
- Wash hands after applying or removing patch. Save pouch to use for patch disposal. Dispose of used patch by folding sticky ends together and putting in pouch.
- The used patch should be removed and a new one applied to a different skin site at the same time each day
- If you have vivid dreams, you may remove the patch at bedtime and apply a new one in the morning
- Do not wear more than one patch at a time
- Do not cut patch in half or into smaller pieces
- Do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- Stop using the patch at the end of 8 weeks. If you still feel the need to use the patch talk to your doctor.

Other information

- Store at 20°-25°C (68°-77°F)

Inactive ingredients

acrylate adhesive, polyester, silicone adhesive

Comments or questions?

Call-1-877-440-7867 8 AM - 8PM ET, Monday-Friday

This product is not affiliated with Novartis Consumer Health, Inc.

NICOTINE TRANS.SYS. 14MG PATCH(14CT BOX)

0536-5895-88

LOT: XXXX

EXP: XX-XX-XX

MFR: AVEVA

REPACKAGED BY: T.Y.A. PHARMACEUTICALS

2930 CRESCENT DR.

TALLAHASSEE, FL 32301

(850) 385-0228



DOSE: SEE PACKAGE INSERT

NICOTINE

nicotine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64725-5895(NDC:0536-5895)
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nicotine (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R)	Nicotine	14 mg in 24 h

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64725-5895-1	14 h in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA074612	10/20/1997	
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Labeler - TYA Pharmaceuticals (938389038)

Registrant - TYA Pharmaceuticals (938389038)

Establishment

Name	Address	ID/FEI	Business Operations
TYA Pharmaceuticals		938389038	RELABEL(64725-5895) , REPACK(64725-5895)

Revised: 8/2011

TYA Pharmaceuticals