

**NICOTINE- nicotine patch**  
**TYA Pharmaceuticals**

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**Drug Facts**

**Active ingredient (in each patch)**

Nicotine, 21 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<br>use one 21 mg patch/day | STEP 2<br>use one 14 mg patch/day | STEP 3<br>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. 21MG PATCH(14CT BOX)**

**0536-5896-88**

**LOT: XXXX**

**EXP: XX-XX-XX**

**MFR: AVEVA**

**REPACKAGED BY: T.Y.A. PHARMACEUTICALS**

**2830 CRESCENT DR.**

**TALLAHASSEE, FL 32301**

**(850) 385-0228**



**DOSE: SEE PACKAGE INSERT**

**NICOTINE**

nicotine patch

**Product Information**

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:64725-5896(NDC:0536-5896) |
| <b>Route of Administration</b> | TRANSDERMAL    |                           |                               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>                                   | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| Nicotine (UNII: 6M3C89ZY6R) (Nicotine - UNII:6M3C89ZY6R) | Nicotine                 | 21 mg in 24 h   |

**Inactive Ingredients**

| <b>Ingredient Name</b>         | <b>Strength</b> |
|--------------------------------|-----------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) |                 |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1        | NDC:64725-5896-1 | 14 h in 1 BOX              |                             |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| ANDA                      | ANDA074612                                      | 10/20/1997                  |                           |

**Labeler** - TYA Pharmaceuticals (938389038)

**Registrant** - TYA Pharmaceuticals (938389038)

**Establishment**

| Name                | Address | ID/FEI    | Business Operations                      |
|---------------------|---------|-----------|--|
| TYA Pharmaceuticals |         | 938389038 | RELABEL(64725-5896) , REPACK(64725-5896) |

Revised: 8/2011

TYA Pharmaceuticals