

Nicorette® Invisi Transdermal Patch

Nicotine (10mg/16hr, 15mg/16hr and 25mg/16hr)

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What Nicorette® Invisi Transdermal Patch is used for

Nicorette® Invisi Transdermal Patch is used to relieve withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking, or when you are cutting down the number of cigarettes you smoke while trying to stop smoking.

How Nicorette® Invisi Transdermal Patch works

When you stop smoking, or cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke (craving). This indicates you were dependent on nicotine.

When you apply Nicorette® Invisi Transdermal Patch to the skin, nicotine is released and passes into your body. The nicotine released from the patch is sufficient to relieve the unpleasant withdrawal

symptoms such as irritability, restlessness, anxiety, and frustration. It will also help to relieve the sudden intense urge to smoke, but Nicorette® Invisi Transdermal Patch will not give you the “buzz” you get from smoking a cigarette.

Before you use Nicorette® Invisi Transdermal Patch

- When you must not use it

Do not use

- If you have an allergy to nicotine or any of the other ingredients.
- If you are pregnant, trying to get pregnant or think you may be pregnant.
- If you are breast-feeding. Ask your doctor or pharmacist for advice.

- Before you start to use it

Talk to your doctor or pharmacist

- If you have experienced a serious cardiovascular event (heart disease), or hospitalization for a cardiovascular complaint, in the previous 4 weeks (e.g. Stroke, myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft and angioplasty) or if you suffer from uncontrolled hypertension (high blood pressure).
- If you have liver or kidney disease.
- If you have an overactive thyroid gland or have a pheochromocytoma (a tumour of the adrenal gland that can affect blood pressure).
- If you have a skin disorder such as psoriasis, eczema or

hives (urticaria) covering large area of your skin.

- If you have acute stomach or duodenal ulcer.
- If you have diabetes, because smoking cessation may lead to changes in insulin or medication requirements.
- If you have experience of epilepsy and seizures.
- Tell your doctor or pharmacist if the above symptoms persist or worsen, or if you experience new symptoms.

Young people under the age of 18 should only use Nicorette® Invisi Transdermal Patch if recommended by doctor. Nicorette® Invisi Transdermal Patch should not be used by non-smokers.

- Taking other medicines

Talk to your doctor or pharmacist if you are taking other medicines such as theophylline, clozapine or ropinirole. Stopping smoking or cutting down may require the dose of these medicines to be adjusted.

How to use Nicorette® Invisi Transdermal Patch

How much to use

- Use one new patch per day.
- Wash your hands before applying the patch.
- Each Nicorette® Invisi Transdermal Patch comes with a child resistant sachet which can be opened by cutting along the edge with a pair of scissors.
- Remove the patch from its sachet and then peel one part of the silvery aluminium backing away.

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Avoid touching the sticky surface of the patch with your fingers. Carefully apply the sticky part of the patch to the chosen area of skin and then peel off the remaining half of the silvery backing foil.

- Press the patch firmly onto the skin with your palm or fingertips.
- Run your fingers around the edge to ensure it sticks firmly.

- When to use it

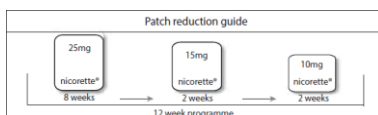
Apply when you wake up (usually in the morning) and remove 16 hours later (usually at bedtime). On the day of starting the treatment, you should stop smoking completely, so the last cigarette is the day before using the patch. Do not smoke during treatment.

- How long to use it

Heavy smokers (those smoking 15 or more cigarettes in a 24-hour period) are recommended to start at Step 1 with the 25mg/16 hours patch and use one patch daily for 8 weeks.

Gradual weaning from the patch should then be initiated. One 15mg/16 hours patch should be used daily for 2 weeks followed by one 10mg/16 hours patch daily for 2 weeks.

Light smokers (those smoking less than 15 cigarettes in a 24-hour period) are recommended to start at Step 2 (15mg/16 hours) for 8 weeks and decrease the dose to Step 3 (10mg/16hours) for the final 4 weeks.



Heavy smoker		Light smoker	
Dose regimen	Duration	Dose regimen	Duration
Step 1 Nicorette® Invisi Transdermal Patch 25mg/16 Hour	First 8 weeks		
Step 2 Nicorette® Invisi Transdermal Patch 15mg/16 Hour	Next 2 weeks	Step 2 Nicorette® Invisi Transdermal Patch 15mg/16 Hour	First 8 weeks
Step 3 Nicorette® Invisi Transdermal Patch 10mg/16 Hour	Last 2 weeks	Step 3 Nicorette® Invisi Transdermal Patch 10mg/16 Hour	Last 4 weeks

Nicorette® Invisi Transdermal Patch is usually not recommended for use over a period in excess of 6 months but some people may need longer treatment in order to avoid getting into a smoking habit again.

Combination therapy

Highly dependent smokers, smokers who experience “breakthrough” cravings or those who failed with single NRT treatment, can use a flexible smoking cessation format, in combination with patch for fast relief of cravings. Use same dosing recommendation for both patch and gum as per monotherapy. Upon control of cravings, start with tapering patch and gum as directed in monotherapy.

Do not administer to persons under 18 years of age without recommendation from a health care professional. There is insufficient clinical data from controlled trials to recommend routine use in adolescents’ under age of 18.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

If you have used more than the recommended dosage, left the patch on for too long or have smoked while using Nicorette® Invisi Transdermal Patch, you may experience nausea, vomiting, salivation, pain in your abdomen, diarrhea, sweating,

headache, dizziness, hearing disturbance or weakness. At higher dose, you will experience low blood pressure, weak and irregular pulse, difficult to breath, collapse and spasm.

In case of high doses, the above symptoms can be followed by hypotension (decreased blood pressure), weak and irregular pulse, breathing difficulties, sudden weakness, fainting and generalized seizures. If you do get any of these effects, administration of nicotine must be stopped immediately, and the patient must be treated symptomatically. Remove patch and rinse application site with water. Seek medical treatment immediately.

Dosage of nicotine that is normally tolerated by adult smokers during their treatment can cause severe poisoning in young children and can even result in their death. Please bear in mind that used patches still contain residual levels of nicotine, which can be harmful for children. Therefore, store both new and used patches out of reach of children. In the event of overdose, get medical help immediately.

While you are using it

- Things you must do

Before applying Nicorette® Invisi Transdermal Patch,

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choose completely clean, dry area of hairless skin on the front or side of the chest, upper arm or hip.

- Things you must not do

Do not use more than one patch at a time. If you lose a patch while swimming, bathing, or showering you can replace it with another patch.

Do not apply oil, lotion, or talcum powder to the skin before putting on the patch as this may prevent it from sticking properly.

The patch should not be kept on at night while sleeping as it may cause nicotine-induced sleep disturbance. If you forget to remove the patch the night before, continue treatment the following morning by removing the old patch and applying the new one.

- Things to be careful of

Avoid placing the patch onto any area of skin that is red, cut or irritated. Do not use the same area on two consecutive days to help avoid skin irritation.

Remove the patch before undergoing any Magnetic Resonance Imaging (MRI) procedures to prevent the risk of burns.

Side effects

Like all medicines, Nicorette® Invisi Transdermal Patch can cause side effects, although not everybody gets them.

As many of the effects are due to nicotine, they can also occur when nicotine is obtained through smoking.

Effects related to smoking (nicotine withdrawal)

- Dizziness
- Headache
- Irritability or aggression
- Feeling low
- Anxiety
- Restlessness
- Poor concentration
- Increased appetite or weight gain
- Urge to smoke (craving)
- Nighttime awakening or sleep disturbance
- Lowering of heart rate

Effects of too much nicotine

You may also get these effects:

- Feeling faint
- Feeling sick (nausea)
- Headache

Side effects of Nicorette® Invisi Transdermal Patch

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of Nicorette® Invisi Transdermal Patch.

About 20% of users experienced mild local skin reactions during the first weeks of treatment.

The commonly reported side-effects are rash and hives. Uncommonly reported side effects include fast heartbeat, application site reactions, body weakness, chest discomfort and pain, general feeling of being unwell, muscle pain, abnormal dream, shortness of breath, increase sweating, flushing, high blood pressure.

If you notice these or any other unwanted effects not listed in this leaflet, tell your doctor or pharmacist.

When you stop smoking you may develop mouth ulcers. The reason why this happens is unknown.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Nicorette® Invisi Transdermal Patch

- Storage

Keep out of the reach and sight of children. Store below 30°C.

Do not use Nicorette® Invisi Transdermal Patch after the expiry date which is stated on the pouch and on the carton.

- Disposal

After removal, fold the patch into half which sticky side inwards and place inside the opened sachet or a piece of aluminium foil. Dispose the used patch carefully in the household rubbish, away from reach of children and animals. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

- What it looks like

Semi-transparent, beige, imprinted, rectangular transdermal patch, with rounded corners. It consists of pre-

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coated backing layer, nicotine source layer, and a skin contact adhesive layer on a pre-coated aluminized and siliconized release liner.

Serial Number

NPRA(R2/3)230503/1057

Each strength of the patch has a different size:

10mg: 9.0 cm²

15mg: 13.5 cm²

25mg: 22.5 cm²

- Ingredients

- Active ingredient:

Nicotine

- Inactive ingredients:

Medium chain triglycerides,

basic butylated methacrylate

copolymer,

polyethyleneterephthalate film

(PET), acrylic adhesive solution,

potassium hydroxide,

croscarmellose sodium,

aluminium acetylacetonate,

siliconized PET release liner

with aluminized single side.

MAL Number:

10mg: MAL14035012XCZ

15mg: MAL14035008XCZ

25mg: MAL14035009XCZ

Manufacturer

LTS Lohmann Therapie-

Systeme AG, Lohmannstr.2, D-

56626 Andernach, Germany.

Product Registration Holder

JNTL (MALAYSIA) SDN. BHD.

Lot 3 & 5, Jalan Tandang,

46050 Petaling Jaya, Selangor,

Malaysia.

Consumer Care Centre

Toll Free Number:

1-800-222-565

Date of revision

28 Feb 2024 (CCDS V3.0 19

Apr 2022)