Nicorette® Invisi Transdermal Patch

NAME OF THE PRODUCT

Nicorette® Invisi Transdermal Patch 10mg/16 Hours.

Nicorette® Invisi Transdermal Patch 15mg/16 Hours.

Nicorette® Invisi Transdermal Patch 25mg/16 Hours.

ACTIVE INGREDIENT

Nicotine 1.75mg/cm^2

INACTIVE INGREDIENTS

Medium chain triglycerides, basic butylated methacrylate copolymer, polyethylenterephthalate film (PET), acrylic adhesive solution, potassium hydroxide, croscarmellose sodium, aluminium acetylacetonate, siliconized PET release liner with aluminized single side.

PHARMACEUTICAL FORM

Transparent patch for topical application available in sizes of 22.5cm^2/ 13.5cm^2 / 9.0cm^2.

Nicorette Invisi Transdermal Patch 10 mg/15 mg/ 25 mg per 16 Hours is a semi-transparent, beige, imprinted, 9.0 cm^2 /13.5cm^2/ 22.5cm^2, rectangular Transdermal Therapeutic System (TTS), with rounded corners. It consists of pre-coated backing layer, nicotine source layer, and a skin contact adhesive layer on a pre-coated aluminized and siliconized release liner and contains 15.75 mg/ 23.62 mg/ 39.37 mg nicotine.

PHARMACOLOGY

Pharmacodynamics

Pharmacotherapeutic group: Drug used in nicotine dependence. ATC code: N07B A01

A sudden stop of smoking for long term smokers will experience the following withdrawal symptoms: urge or craving to smoke, dysphoria or depressed mood, insomnia, irritability, frustration or aggression, anxiety, difficulty in concentrating, restlessness or impatience, reduced heart rate, increased appetite or increase in weight, dizziness, cough, constipation, gum bleeding or mouth ulcers or swelling of the nasal passages and the back of the throat.

Clinical studies have shown that nicotine replacement products can help smokers quit or reduce their smoking by helping these withdrawal symptoms.

Patch treatment mimics the fluctuations of nicotine over the day in smokers, with no nicotine administration during sleep. Daytime nicotine patch treatment does not give the nicotine induced sleep disturbances seen with nicotine administration during sleep.

Pharmacokinetics

All patches are labelled by the average amount of nicotine absorbed by the average patient over 16 hours. The maximum level of plasma concentration after administration is reached after approximately 9 hours with the plasma peak is in the afternoon/evening when the risk of relapse is highest. The major eliminating organ is the liver. Progressive severity of renal impairment is associated with decreased total clearance of nicotine.

INDICATION

For the treatment of tobacco dependence by relieving nicotine craving and withdrawal symptoms thereby facilitating smoking cessation in smokers motivated to quit.

Advice and support normally improve the success rate.

DOSAGE AND ROUTE OF ADMINISTRATION

The patient should make every effort to stop smoking completely during treatment with Nicorette® Invisi Transdermal Patch. Advice and support normally improve the success rate.

Adults and the Elderly

The patch should be applied to an intact area of the skin upon waking up in the morning and removed at bedtime.

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 patch) for 8 weeks and decrease the dose to Step 3 (10mg/16 hours patch) for the final 4 weeks.

Heavy Smokers **Light Smokers**

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**

Combination therapy

Highly dependent smokers, smokers who experience “breakthrough” cravings or those who have failed with single NRT treatment, can use a flexible smoking cessation format, in combination with the 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.

Children and Adolescents

Nicorette® Invisi Transdermal Patch should not be administered to persons under 18 years of age without recommendation from a healthcare professional. There is limited experience of treating this age group with Nicorette® Invisi Transdermal Patch.

Use of the patch beyond 6 months is generally not recommended.
Some ex-smokers may need longer treatment to avoid returning to smoking.

How to apply the patches

Nicorette® Invisi Transdermal Patch should be applied to clean, dry intact areas of hairless skin, for example on the hip, upper arm, or chest. These areas should be varied each day and the same site should not be used on consecutive days.

1. Wash your hands before applying the patch.
2. Cut open the pouch with a pair of scissors along the side, as indicated. Select a clean, dry, hairless intact area of skin, such as the hip, upper arm, or chest.
3. Peel one part of the silvery aluminium backing away as far as possible. Avoid touching the sticky surface of the patch with your fingers, as much as possible.
4. Apply the sticky part of the patch carefully onto the skin and peel off the remaining half of the silvery aluminium backing.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Run your fingers firmly round the edge to ensure that the patch sticks firmly.
7. If the patch comes off, replace with a new one. Use of skin oils or talc can prevent proper adhesion of the patch.

After removal, used patches should be dispose of carefully.

The patches should be folded after use with the sticky side inwards, put back in an empty pouch and dispose of where children cannot reach it.

Administration of nicotine should be stopped temporarily if any symptoms of nicotine excess occur. Nicotine intake should be decreased by either lowering dosing frequency or strength if nicotine excess symptoms persist. Please refer to symptoms and treatment of overdose for further details.

CONTRAINDICATION

Hypersensitivity to nicotine or any excipients of the patch.

WARNING AND PRECAUTIONS

Before taking the Nicorette® Invisi Transdermal Patch, please consult with your healthcare professional if you have the following conditions:

- Serious cardiovascular event (heart disease), or recently hospitalized for a cardiovascular complaint e.g., stroke, myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft and angioplasty or suffer from uncontrolled hypertension (high blood pressure)
- Diabetes
- Severe or moderate liver disease
- Severe kidney disease
- An overactive thyroid gland
- A tumor of the adrenal gland (phaeochromocytoma)
- Stomach ulcer
- Oesophagitis
- Ever experienced of epilepsy and seizures

If symptoms persist or get worse, or if new symptoms occur, stop use and consult your healthcare professional.

Nicorette® Invisi Transdermal Patch should be removed prior to undergoing any Magnetic Resonance Imaging (MRI) procedures to prevent the risk of burns.

INTERACTION WITH OTHER MEDICAMENTS

Tell your healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important if you take medicine containing:

theophylline, tacrine, clozapine, ropinirole, imipramine, olanzapine, clomipramine, fluvoxamine, flecainide and pentazocine.

PREGNANCY AND LACTATION

Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. Therefore, the pregnant smoker should always be advised to stop smoking completely without the use of nicotine replacement therapy. The risk of continued smoking may pose greater hazard to the foetus as compared with the use of nicotine replacement products in a supervised smoking cessation programme. Use of Nicorette® Invisi Transdermal Patch by the pregnant smoker should only be initiated after advice from a healthcare professional.

Nicotine passes freely into breast milk in quantities that may affect the child, even with therapeutic doses. The use of Nicorette® Invisi Transdermal Patch should therefore be avoided when breastfeeding. Should smoking cessation not be achieved, use of the Nicorette® Invisi Transdermal Patch by breastfeeding smokers should only be initiated after advice from a healthcare professional.

SIDE EFFECTS

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.

Like all medicines, Nicorette® Invisi Transdermal Patch can cause side effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to smoking (nicotine withdrawal)

You may experience unwanted effects because you have stopped smoking, or you have reduced the amount of nicotine you are taking. These effects include:

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

Reported Side Effects

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.

Undesirable effects arise from combination therapy (use of transdermal patch and another oral format together) may differ from monotherapy whereby the undesirable effects may be attributed to the pharmaceutical form. The frequency of the undesirable effects is comparable with what is given in the package insert for the respective product.

If you notice these or any other unwanted effects not listed in this package insert, tell your healthcare professional.

SYMPTOMS AND TREATMENT OF OVERDOSE

Excessive use of nicotine from either nicotine replacement products and/or smoking might cause symptoms of an overdose.

Overdosage with nicotine can occur if many patches are used simultaneously or if the user has very low nicotine dependence or uses other forms of nicotine concomitantly, including smoking.

Symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, weak and irregular pulse, breathing difficulties, prostration, circulatory collapse, and general convulsions.

Doses of nicotine that are tolerated by adult smokers during treatment may produce severe symptoms of poisoning in small children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

Management of overdose

Administration of nicotine must be stopped immediately and the patient must be treated symptomatically. Remove patch and rinse application site with water. If excessive amount of nicotine is swallowed, activated charcoal reduces the gastrointestinal absorption of nicotine.

In the event of overdose, get medical help immediately.

Packaging:

Packs of 7 patches

Route of administration: Apply on dry intact area of skin

Store below 30°C
Dispose sensibly
Do not use if you are pregnant or breastfeeding
Not for sale to or use by persons under age 18
Keep out of the reach of children
Jauhi ubat daripada kanak-kanak

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 February 2024 (CCDS V3.0 19 Apr 2022)