

K kenvue **SGK**
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Project Name / Design | E Nicorette Invisipatch 10/15mg_7_PIL_Diamond (CRD 12098 12096)

New Component / Item Code | 6518743 | ArtWorks ID | EMEA_2023_00010082_002

Old Component / Item Code | 6515545 | Languages | English

Product / Eurocode / Mat. ID Code | 8409607 8409707 | Job / Version No. | 403470004_r0 | Date | 11-10-2023

Black

REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

MANUFACTURING SITE

Reference | Leaflet once prefolded Nicorette | Technical Code | 5891

Substrate | WHITE | PC-Spec | PC-0006331

Braille Nr | N/A | Colour Target Ref | N/A

TECHNICAL DETAILS

Component | Leaflet | Plant | LTS

Dimensions | 130 x 700 mm | Master Dieline | JJEXT_00287_V3 | Date | 10-06-2022

Profile | Text Limit | Bleed | Fold/Technical | Perforation | Stamping Area

Coding (Silent Zone) | Print & Varnish Free | Print Free | Varnish Free | Seal Area | Tamper Evident Label Area

Braille Grid

FONTS USED

| | |
|----------------------------|---------------------------|
| AkzidenzGroteskPro-Bold | SMALLEST TEXT SIZE |
| AkzidenzGroteskPro-It | 4,88 pt |
| AkzidenzGroteskPro-Mid | AVE. TEXT SIZE |
| AkzidenzGroteskPro-Regular | 9 pt |
| FrutigerLTPro-Bold | LARGEST TEXT SIZE |
| MetaPlusBlack-Roman | 9,75 pt |
| Orette-Bold | |
| ZapfDingbatsTC | |

Package leaflet: Information for the user

nicorette®

**Nicorette Invisi
10mg/16 hours
15mg/16 hours
Transdermal Patch**

Nicotine

A guide for users

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nicorette Invisi Patch is and what it is used for
2. What you need to know before you use Nicorette Invisi Patch
3. How to use Nicorette Invisi Patch
4. Possible side effects
5. How to store Nicorette Invisi Patch
6. Contents of the pack and other information

1. What Nicorette Invisi Patch is and what it is used for
Nicorette Invisi Patch is a nicotine replacement therapy (NRT). It is

used to relieve withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking.

Nicorette Invisi 10mg and 15mg Patch can sometimes be used in combination with either Nicorette 2mg Gum or Nicorette 15mg Inhaler for the treatment of tobacco dependence as part of a stop smoking programme.

Nicorette® Invisi 15mg Patch: Each patch releases 15 milligrams of nicotine, over 16 hours.

Nicorette® Invisi 10mg Patch: Each patch releases 10 milligrams of nicotine, over 16 hours.

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

When you apply a Nicorette Invisi Patch to the skin, nicotine is released and passes into your body through the skin. The nicotine released is sufficient to relieve the unpleasant nicotine withdrawal symptoms and your cravings to smoke.

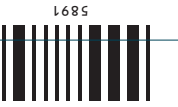
2. What you need to know before you use Nicorette Invisi Patch

Do not use Nicorette Invisi Patch:

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you are a non-smoker or are under 18 years of age.
- if you are pregnant or breast-feeding.

Warnings and Precautions

- Talk to your doctor or pharmacist before using Nicorette Invisi Patch
- **if you have heart disease** (including heart attack, disorders of heart rate or rhythm, or stroke)



- **if you have liver or kidney disease.**
 - **if you have an overactive thyroid gland** or have a phaeochromocytoma (a tumour of the adrenal gland that can affect blood pressure) – your doctor will have told you this.
 - **if you have diabetes** – monitor your blood sugar levels more often when starting to use Nicorette Invisi Patches as you may find your insulin or medication requirements alter.
 - **if you have a skin disorder** such as psoriasis, eczema or hives (urticaria) covering a large area of your skin.
 - **if you have high blood pressure.**
 - **if you have bad circulation.**
 - **if you have had a stomach ulcer or oesophagitis** (inflammation of the food pipe).
 - **if you have a history of epilepsy or seizure.**
 - **if you have persistent indigestion or pains in the chest.**
- **If any of these applies, talk to your doctor or pharmacist.**
- **Transferred dependence:** Nicotine in any dose form can result in a dependence syndrome after continued use. Transferred dependence can occur with this medicine, but is unusual and is both less harmful and easier to break than smoking dependence.

Nicorette Invisi Patch should be removed before you have an MRI scan.

Other medicines and Nicorette Invisi Patch

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including the following medicines as stopping smoking may require the doses of these medicines to be adjusted:

- theophylline to treat asthma
- tacrine for Alzheimer's disease,
- clozapine or olanzapine for schizophrenia
- imipramine, clomipramine, fluvoxamine to treat depression

- ropinirole for Parkinson's disease
- pentazocine to treat pain
- flecainide or adenosine to treat irregular or fast heart beats

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant: ideally, you should try to give up smoking without NRT. If you can't manage this, you can use NRT as the risks to your baby are far less than smoking, however you should talk to your doctor or pharmacist for advice.

3. How to use Nicorette Invisi Patch

Always use this medicine exactly as described in this leaflet or as your doctor, nurse or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to use Nicorette Invisi Patch

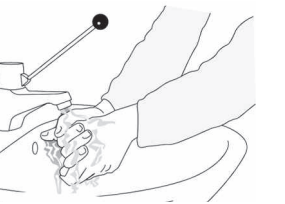
Follow the instructions below.

Choosing where to apply the patch

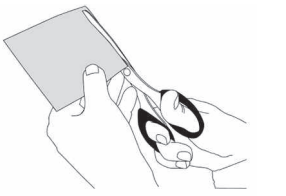
1. Before applying your Nicorette Invisi Patch, choose a completely clean, dry area of hairless skin on the front or side of the chest, upper arm or hip.
2. Avoid placing the patch onto any area of skin that is red, cut or irritated.
3. Do not apply oil or talcum powder to the skin before putting on the patch as this may prevent it from sticking properly.
4. It is important that you **do not use** the same area on two consecutive days to help avoid irritating that site.

How to apply the patch

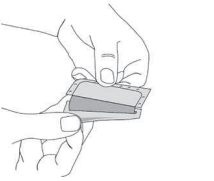
1. Wash your hands before applying the patch.



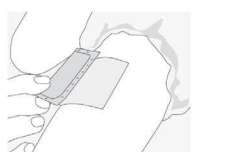
2. Each Nicorette Invisi Patch comes in a child resistant sachet which can be opened by cutting along the edge with a pair of scissors.



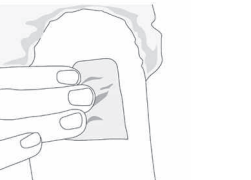
3. Remove the patch from its sachet and then peel one part of the silvery aluminium backing away. Avoid touching the sticky surface of the patch with your fingers.



4. Carefully apply the sticky part of the patch to the chosen area of skin and then peel off the remaining half of the silvery aluminium backing foil.



5. Press the patch firmly onto the skin with your palm or finger tips.



6. Run your fingers around the edge to ensure it sticks firmly.

Removing and disposing of the patch

1. The patch should be removed before you go to bed as Nicorette Invisi Patch is not designed to be worn when you go to sleep at night or for more than 16 hours each day.
2. After removal, the patch should be folded in half, sticky side inwards and placed inside the opened sachet or a piece of aluminium foil.
3. The patch should then be disposed of carefully in the household rubbish, out of reach of children and animals.

Children under 18 years

Do not give this product to children under 18 years.

Adults and Children aged 18 years and over

Stopping Smoking

The idea is to stop smoking immediately and use the patch to relieve the cravings to smoke. After achieving this you then slowly reduce the amount of nicotine that you are getting by switching to lower strength patches. You then stop using the patches. You should aim to do this within 12 weeks (3 months).

| Age | Dose |
|---|---|
| Adults and children aged 18 years and over | <ul style="list-style-type: none"> ▪ Apply one new patch (of appropriate strength) to the skin when you wake up (usually in the morning). ▪ Remove 16 hours later which is usually at bed time. |
| | <ul style="list-style-type: none"> ▪ Do not use more than one patch at a time. ▪ If you lose a patch whilst swimming, bathing or showering you can replace it with another patch. ▪ Dispose of the patches carefully after you have removed them, ensuring they are out of reach of children and pets. ▪ Adults aged 18 years and over should not use the patches for longer than 6 months in total without asking for help and advice from a doctor or pharmacist. |

If you are a lighter smoker (less than 20 cigarettes a day)

If you are a lighter smoker, you should start on the medium strength 15mg patch and use it for 8 weeks and then step down to the lower strength 10mg patch for the last 4 weeks of treatment.

If you are a heavier smoker (more than 20 cigarettes a day)

If you are a heavier smoker, you should start on the extra strength

25mg patch and use it for 8 weeks and then step down to the lower strength 15mg patch for 2 weeks and then the 10mg patch for the last 2 weeks of treatment.

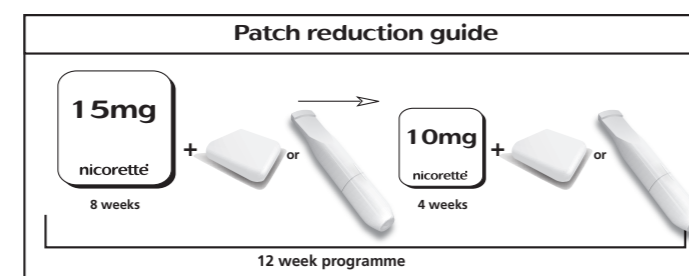
Combination Therapy

Nicotine replacement therapy often provides sufficient nicotine when used as a single therapy. However, heavy smokers (more than 20 cigarettes a day), who experience breakthrough cravings, or those who have failed with single therapy may benefit from using combination therapy with patch and 2mg gum or patch and inhaler.

Combination Therapy Guide

Directions for combination use

| Age | Dosage of Invisi Patch | Dosage of 2mg Gum or 15mg Inhaler |
|---|---|--|
| Adults and children aged 18 years and over | <ul style="list-style-type: none"> Apply one new 15mg Invisi Patch to the skin when you wake. Do this for the first 8 weeks. Apply one new 10mg Invisi Patch to the skin when you wake. Do this for the next 4 weeks | <ul style="list-style-type: none"> One 2mg gum or the Inhaler as required to relieve cravings |
| | <ul style="list-style-type: none"> Use only one Invisi Patch and chew only one piece of gum at a time. Remove the patch 16 hours after application, usually at bedtime. Do not exceed 15 pieces of chewing gum or 6 inhaler cartridges per day. | |



If you use too many Nicorette Invisi Patches

If you have used more than the recommended dosage of Nicorette Invisi Patch, you may experience nausea (feeling sick), increased salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbances or weakness.

➤ If you do get any of these effects contact a doctor or your nearest hospital Accident and Emergency department immediately. Remove the patch and rinse the application site with water. Take this leaflet and the pack with you.

If a child has used or swallowed Nicorette Invisi Patches

➤ Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child under 18 years uses, chews or swallows this medicine. Take this leaflet and the pack with you.

4. Possible side-effects

Like all medicines, this medicine can cause side-effects, although not everyone gets them. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to stopping smoking (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking.

These effects include:

- irritability or aggression
- feeling low
- anxiety
- restlessness
- poor concentration
- increased appetite or weight gain
- urges to smoke (craving)
- night time awakening or sleep disturbance
- lowering of heart rate
- dizziness, lightheadedness, blurry vision, nausea
- coughs and colds
- constipation
- mouth ulcers
- bleeding in the mouth
- swelling of the nasal passages and back of the throat

Side-effects of Nicorette Invisi Patch

When you use the Nicorette Invisi Patch for the first time it may cause a mild skin reaction. This is usually redness or itching of the skin where the patch has been. This will usually disappear after a few days. Rarely the reaction may persist or if there is a more severe skin reaction, you should stop using the patches and consult a doctor or pharmacist.

If you experience any of the following, stop using the patch and seek medical help immediately:

- Swelling of the face, lips, tongue, throat or other parts of the body, wheezing or difficulty breathing or swallowing

- Chest pain, palpitations, an abnormal or fast heart beat
- Pins and needles

Other side-effects include:

Very common side-effects:

(may affect more than 1 in 10 people)

- itching – this usually disappears within a few days

Common side-effects:

(may affect up to 1 in 10 people)

- headache
- feeling sick (nausea)
- sickness (vomiting)
- hives (urticaria) or rash

Uncommon side-effects:

(may affect up to 1 in 100 people)

- allergic reaction
- flushing, high blood pressure
- shortness of breath
- excessive sweating
- aching muscles, muscle tenderness or weakness not caused by exercise
- rash where the patch is applied
- chest discomfort and pain
- feeling unwell or tired

Rare side-effects:

(less than 1 in 1,000 people are affected)

- pain in your hands or feet
- redness of the skin – this usually disappears within a few days
- stomach discomfort and/or pain

Not known: frequency cannot be estimated from the available data

- Seizure

Reporting of side-effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance Website: www.hpra.ie.

You can also report side effects directly in Malta via:

ADR Reporting at:

www.medicinesauthority.gov.mt/adrportal

By reporting side-effects you can help provide more information on the safety of this medicine.

5. How to store Nicorette Invisi Patch

- Keep out of the sight and reach of children.
- Remember that there is still nicotine left in the used patches.
- Do not store Nicorette Invisi Patch above 25°C.
- Do not use this medicine after the expiry date which is stated on the carton and sachet after "EXP". The expiry date refers to the last day of that month.
- Dispose of Nicorette Invisi Patch as directed by folding it in half and placing inside the empty sachet (or wrapping in a piece of aluminium foil) before throwing away. Always dispose of used Nicorette Invisi Patches sensibly, away from the reach of children and animals.

6. Contents of the pack and other information

What Nicorette Invisi Patch contains

The active substance is: nicotine.

The other ingredients are: medium chain triglycerides, basic butylated methacrylate copolymer, polyethyleneterephthalate film (PET), acrylic adhesive solution, potassium hydroxide, croscarmellose sodium, aluminium acetylacetonate, siliconised PET release liner with aluminised single side, printing inks.

What Nicorette Invisi Patch looks like and contents of the pack

Nicorette Invisi Patch is a beige semi-transparent patch consisting of pre coated backing layer, nicotine source layer and a skin contact adhesive layer with "Nicorette" printed on the top face of the product. Nicorette Invisi Patch is packed in individual sachets and supplied in packs of 1,2,3,5,7 and 14. Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

The product authorisation holder is:

JNTL Consumer Health I (Ireland) Ltd.

Block 5, High Street, Tallaght, Dublin 24, Ireland

The manufacturer is:

LTS Lohmann Therapie-Systeme AG, Lohmannstrasse 2, D-56626 Andernach, Germany.

For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie.

This leaflet was last revised in December 2023.