

Nicorette[®] invis i 25 mg patch (nicotine)

Patient Information Leaflet

What should you know about Nicorette[®] invis i 25 mg patch Step 3.

Please read this leaflet carefully before you start using this medicine. It provides useful information on how to use it safely. Keep the leaflet, you might need it again.

If you think you are having side-effects, have any questions or are not sure about anything please **ask your doctor, pharmacist or nurse**.

The name of your medicine is Nicorette invis i 25 mg patch and it will be referred to as Nicorette invis i patch throughout the rest of this leaflet. Please note that the leaflet also contains information about other strengths of the medicine, Nicorette invis i 10 mg patch and Nicorette invis i 15 mg patch.

What is in this leaflet

- What Nicorette invis i patch is and what it is used for
- What you need to know before you use Nicorette invis i patch
- How and when to use Nicorette invis i patch
- Possible side-effects
- How to store Nicorette invis i patch
- Contents of the pack and other information

1 What Nicorette invis i patch is and what it is used for

Nicorette invis i patch contains nicotine which belongs to a group of medicines called nicotine replacement therapy (NRT). It is used to relieve and /or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking tobacco or vaping, or when cutting down the number of cigarettes/e-cigarettes you smoke/vape.

Ideally you should always aim to stop smoking and vaping. You can use Nicorette invis i patch to achieve this by using it to completely replace all your cigarettes/e-cigarettes. However, Nicorette invis i patch can also be used in other ways,

- if you feel unable to stop smoking/vaping completely, or wish to increase the time to your next cigarette/e-cigarette with the intention of cutting down the number of cigarettes/e-cigarettes you smoke/vape,
- at those times when you can’t or do not want to smoke/vape. For example,
 - where you don’t want to smoke/vape and want to avoid harm to others e.g. children or family
 - for prolonged periods (greater than 16 hours) where smoking cigarettes/vaping e-cigarettes is not allowed e.g. aeroplanes, work, social occasions

It may also help increase your motivation to quit.

When making a quit attempt a behavioural support programme will increase your chances of success.

What does Nicorette invis i patch do?

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

When you apply a Nicorette invis i 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. It will also help to stop your craving to smoke/vape but will not give you the “buzz” you get from smoking a cigarette or vaping an e-cigarette.

Reporting of side-effects

If you experience 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects, you can help provide more information on the safety of this medicine.

5 How to store Nicorette invis i patch

- Keep this medicine out of the sight and reach of children and animals.** Nicotine in high doses can be very dangerous and sometimes fatal if taken by children.
- Do not store 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 invis i 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 invis i patches sensibly, away from the reach of children and animals.
- If your medicine shows any signs of deterioration or discolouration, consult a pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Nicorette invis i patch contains

The active substance is nicotine. Each 22.5 cm² transdermal patch contains nicotine 1.75 mg/cm², releasing a nominal 25 mg nicotine over 16 hours.

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

What Nicorette invis i patch looks like and contents of the pack
Nicorette invis i patch are beige, semi-transparent patches.

Each Nicorette invis i patch is packed in to individual sachets and supplied in packs of 7 or 14.

Manufacturer and Licence Holder

Manufactured by LTS Lohmann Therapie-Systeme AG, Lohmannstrasse 2, 56626 Andernach, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

<p>PL 15184/2573</p>	<p>Nicorette invis i 25 mg patch</p>
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Blind or partially sighted? Is this leaflet hard to see or read? Phone Lexon (UK) Limited,Tel: 01527 505414 to obtain the leaflet in a format suitable for you

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, light-headedness, blurry vision, nausea
- cough
- constipation
- bleeding gums
- mouth ulcers
- swelling of the nasal passages and back of the throat

Effects of too much nicotine

You may also get these effects if you are not used to inhaling tobacco smoke or e-cigarettes.

These effects include:

- feeling faint
- feeling sick (nausea)
- headache

Side-effects of Nicorette invis i patch

When you use the Nicorette invis i 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, pharmacist or nurse.

If you notice any of the following: fast heart rate/beat, abnormal beating of the heart, chest palpitations, shortness of breath, seizures (fits), or allergic reactions (swelling of the mouth, lips, throat and tongue, itching of the skin, swelling of the skin, ulceration and inflammation of the lining of the mouth) stop using Nicorette invis i patches, do not smoke/vape and contact a doctor immediately.

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

Uncommon side-effects:

(may affect up to 1 in 100 people)

- tingling or numbness of the hands and feet
- allergic reaction
- flushing, high blood pressure
- excessive sweating
- aching muscles, muscle tenderness or weakness not caused by exercise
- chest discomfort and pain
- feeling unwell or tired

Rare side-effects:

(may affect up to 1 in 1,000 people)

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

When you stop smoking you may develop mouth ulcers.

The reason why this happens is unknown.

If you are pregnant or breastfeeding

If you are pregnant:

- 1) **Firstly, you should try to give up smoking/vaping without NRT. Stopping completely is by far the best option. The earlier and quicker you do this the better it is for you and your baby.**
- 2) **Secondly, if you can't manage this, you can use NRT as a safer alternative** to smoking as the risks to your baby are far less than smoking, however you should talk to your doctor, pharmacist or nurse for advice. The effects of vaping on babies and children are not established. Products that are used intermittently may be preferable to nicotine patches. However, patches may be more suitable if you have nausea or sickness. If you do use patches take them off before going to bed at night.

If you are breastfeeding:

- 1) **Firstly, you should try to give up smoking/vaping without NRT.**
- 2) **Secondly, if you can't manage this you are best to use NRT products** that are taken intermittently (not patches), however you should talk to your doctor, pharmacist or nurse for advice.

If you do use the patches, breastfeed just before you use Nicorette invisipatch to ensure that the baby gets the smallest amount of nicotine possible. If you do need to use NRT to help you quit, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the second-hand smoke they would inhale if you smoked. The effects of vaping on your body during pregnancy and breastfeeding are not established. Tobacco smoke produces breathing and other problems in babies and children. The effects of vaping on babies and children are not established.

Nicotine products and children: Nicotine can be very dangerous to children. The amount of nicotine tolerated by adults and adolescents can make children very ill, and can sometimes be fatal. Do not leave your patches where children may get hold of them.

3 How and when to use Nicorette invisipatch

How to use Nicorette invisipatch

Follow the instructions below.

Choosing where to apply the patch

1. Before applying your Nicorette invisipatch, 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 invisipatch 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 invisipatch 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 the sight and reach of children and animals.

When to use Nicorette invisipatch

If you are able to stop smoking/vaping immediately you should use Nicorette invisipatch, when needed, in place of cigarettes/e-cigarettes by following the dosing instructions detailed under section "Stopping Immediately".

If you are unable to stop smoking/vaping or do not feel ready to quit at this time, you should replace as many cigarettes/e-cigarettes as possible with Nicorette invisipatch. There are toxins in cigarettes that can cause harm to your body. The effects of vaping on your body are not established. Nicorette invisipatch provides a safer alternative to smoking tobacco, for both you and those around you. Reducing the amount of cigarettes/e-cigarettes may also help you to become more motivated to stop smoking/vaping. As soon as you are ready you should aim to stop smoking/vaping completely.

If you are planning to stop smoking/vaping or reduce the number of cigarettes/e-cigarettes you smoke/vape, Nicorette invisipatch can be used while you are still smoking/vaping. However, during this time, you should aim to replace as many cigarettes/e-cigarettes as possible with Nicorette invisipatch. As soon as you feel ready you should stop smoking/vaping completely. Follow the dosing instructions detailed under section "Stopping Gradually".

You can also use Nicorette invisipatch on those occasions when you can't or don't want to smoke/vape e.g. long haul flights, social situations, or when at work. However, in smoke/vape free areas such as pub, work breaks, public transport, car journeys etc., an alternative flexible Nicorette product (e.g. gum, inhalator) would be more suitable. Follow the dosing instructions detailed under section "Temporary Abstinence".

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. If you have quit smoking/vaping and want to stop using Nicorette invisipatch but are finding this difficult you should contact your doctor, pharmacist or nurse for advice.

Below is the dosage information for Nicorette invisipatch. This shows the number of patches you should be using, when you should use them and where applicable the maximum amount of time you should be using Nicotine Replacement Therapy (NRT) for.

Please read this information carefully and then go to the "How to stop smoking/vaping your choice" section which shows you how to give up.

- Depending on where you are in your treatment programme, the strength of the patch that you are using may differ. See the "How to stop smoking/vaping your choice" for more information.
- However all patches are used and applied in the same way.

How to stop smoking/vaping - your choice

Because smoking/vaping is an addiction you may find it difficult to give up. From time to time you may still have strong urges to smoke/vape but if you follow these recommendations, you have a good chance of quitting.

If you find it hard to stop smoking/vaping using Nicorette invisipatch, you are worried that you will start smoking/vaping again without it, or you find it difficult to reduce the number of patches you are using, **talk to your doctor, pharmacist or nurse.**

Children under 12 years

Do not give this product to children under 12 years.

Adults and Children aged 12 years and over

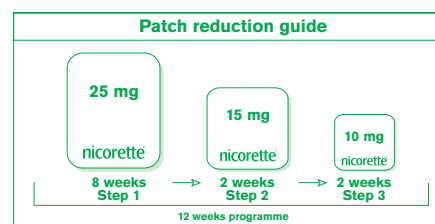
Age	Dose
Adults and children aged 12 years and over	<ul style="list-style-type: none">* Apply one new patch (of appropriate strength) to the skin when you wake up (usually in the morning).* Remove 16 hours later which is usually at bedtime.
<ul style="list-style-type: none">• Do not use more than one patch at a time.• If you lose a patch whilst swimming, bathing or showering you can replace it with another patch.	

Stopping Immediately

The idea is to stop smoking/vaping immediately and use the patch to relieve the cravings to smoke/vape. 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).

Adults and Children aged 12 years and over

The following diagram shows the basic step by step process. Make sure that you read the instructions for each step in the information which follows.



For best results, most smokers/vapers are recommended to start on 25 mg patch (Step 1). Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg for the final 4 weeks.

Step 1: Begin treatment with the highest strength Nicorette invisipatch 25 mg patch the day after you stop smoking completely. Use a new Nicorette invisipatch 25 mg patch each day for eight weeks.

Step 2: If you are successful and avoid smoking/vaping during this eight week period, you should then begin to reduce the amount of nicotine you are getting by switching to a lower strength patch.

- **Now use the Nicorette invisipatch 15 mg patch each day for two weeks.**

Step 3: If you are successful and avoid smoking/vaping over this two week period, then switch from the Nicorette invisipatch 15 mg patch to the Nicorette invisipatch 10 mg patch each day for a further two weeks.

- ▶ **You might feel a sudden craving to smoke/vape long after you have given up smoking/vaping and stopped using Nicorette invisipatch. Remember you can use nicotine replacement therapy again if this should happen.**

If you experience excessive side-effects or are a lighter smoker/vaper When using the highest strength 25 mg patch, if you experience excessive side-effects which do not disappear after a few days of use, you should move to the medium strength 15 mg patch and use it for the remainder of the 8 weeks. You should then reduce to the low strength 10 mg patch and use it for the remaining 4 weeks of the treatment programme.

- If you are a lighter smoker (less than 10 cigarettes per day) or a light to moderate vaper (e.g. vape infrequently or use low strength e-liquid), you should start on the medium strength 15 mg patch and use it for 8 weeks and then step down to the lower strength 10 mg patch for the last 4 weeks of treatment.

Stopping Gradually

Nicorette invisipatch can be used whilst you are still smoking/vaping. The idea is to start by gradually replacing some of your cigarettes/e-cigarettes you smoke/vape whilst using Nicorette invisipatch. After achieving this you should aim to give up cigarettes/e-cigarettes completely whilst using the patch. Finally, you should stop using the patch completely.

For best results, you should ideally start on 25 mg patch (Step 1). Slowly reduce the amount of nicotine that you are getting by switching to 15 mg (Step 2) as soon as the number of cigarettes you smoke is less than 10 cigarettes per day or you are vaping infrequently or using low strength e-liquid, until you have given up patches completely.

Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg). When trying to stop smoking/vaping, you are recommended to continue on 15 mg (Step 2) for 8 weeks and then step down to the lower strength 10 mg (Step 3) for the last 4 weeks of treatment.

Temporary Abstinence

A patch should be applied in those situations when you are unable to smoke/vape e.g. long haul flights, social situations or when at work.

For best results, you should use 25 mg patch (Step 1). However, lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to use Step 2 (15 mg).

If you have used too many Nicorette invisipatch

If you have used more than the recommended dosage of Nicorette invisipatch, left the patch on for too long or have smoked/vaped whilst using Nicorette invisipatch, you may experience nausea (feeling sick), vomiting, increased salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbance 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. Do not smoke or vape.** Take this leaflet and the pack with you.

If a child uses Nicorette invisipatch

▶ **Contact a doctor or your nearest hospital Accident and Emergency department immediately** if a child under 12 years uses, chews, sucks or swallows this medicine. Take this leaflet and the pack with you.

Nicotine ingestion by a child may result in severe poisoning.

4 Possible side-effects

Like all medicines, Nicorette invisipatch can have side-effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking/vaping.

Effects related to stopping smoking/vaping (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking/vaping you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use Nicorette invisipatch before you are ready to reduce your nicotine intake.