

nicorette®

**invisi patch
nicotine
transdermal patch**

What should you know about

NICORETTE® invisi 25 mg patch Step 1	NICORETTE® invisi 15 mg patch Step 2	NICORETTE® invisi 10 mg patch Step 3
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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, nurse or pharmacist.**

1 What this medicine is for

NICORETTE® invis i patch is a 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 or when cutting down the number of cigarettes you smoke.

Ideally you should always aim to stop smoking. You can use NICORETTE® invis i patch to achieve this by using it to completely replace all your cigarettes.

However, NICORETTE® invis i patch can also be used in other ways,

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

nicorette® invis i 25 mg patch: Each patch releases 25 milligrams of nicotine, the active ingredient, over 16 hours.

nicorette® invis i 15 mg patch: Each patch releases 15 milligrams of nicotine, the active ingredient, over 16 hours.

nicorette® invis i 10 mg patch: Each patch releases 10 milligrams of nicotine, the active ingredient, over 16 hours.

What does nicorette® invis i patch do?

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 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, but will not give you the "buzz" you get from smoking a cigarette.

Benefits you can get from using NRT instead of smoking

For the best effect, ensure that you use NICORETTE® invis i patch correctly – see *"How and when to use this medicine"*

The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT. It is the toxins in cigarette smoke such as **tar, lead, cyanide and ammonia that cause smoking related disease and death, not the nicotine.**

- **You may think that** smoking helps relieve feelings of anxiety and stress, but it does not deal with the cause of the stress and leads to a number of serious diseases. In addition, the feeling of relaxation after smoking is temporary, with withdrawal symptoms and cravings soon returning. NRT can **help relieve nicotine withdrawal symptoms such as irritability, low mood, anxiety, restlessness and cravings** when used in place of cigarettes.

- **NRT may benefit** smokers who want to quit, by helping to **control weight gain** that may be experienced when trying to stop smoking.

Use of NRT is safer than smoking tobacco but as soon as you are ready, you should aim to stop smoking completely.

2 Before using this medicine

❗ Do not use nicorette® invis i patch:

- **if you have an allergy** to nicotine or any of the other ingredients.
- If you are a child under 12 years of age.

⚠ Talk to your doctor, nurse or pharmacist...

- **if you are pregnant or breast-feeding** – you may be able to use nicotine replacement therapy (NRT) to help you give up smoking but you should try to give up without it. See *"If you are pregnant or breast-feeding section"*.

- **if you are in hospital because of heart disease** (including heart attack, disorders of heart rate or rhythm, angina, high blood pressure or stroke). In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.

- if you have **stomach ulcers or oesophagitis** (inflammation of the food pipe).
- if you are to undergo an **MRI procedure.**
- **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® invis i patch 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 are taking any other medicines** such as theophylline, clozapine or ropinirole. Stopping smoking or cutting down may require the dose of these medicines to be adjusted.

- **If any of these apply, talk to your doctor, nurse or pharmacist.**

⚠ If you are pregnant or breast-feeding

If you are pregnant:

- 1) **Firstly, you should try to give up smoking 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, nurse or pharmacist for advice. 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 breast-feeding:

- 1) **Firstly, you should try to give up smoking 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, nurse or pharmacist for advice. Breast-feed just before you use NICORETTE® invis i patch 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. Tobacco smoke produces breathing and other problems in babies and children.

3 How and when to use this medicine

How to use nicorette® invis i patch

- ❶ Follow the instructions below.

Choosing where to apply the patch

- 1 Before applying your NICORETTE® invis i 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.

❶ How to apply the patch

- 1 Wash your hands before applying the patch.

- 2 Each NICORETTE® invis i 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.

❶ Removing and disposing of the patch

- 1 The patch should be removed before you go to bed as NICORETTE® invis i 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.

❶ When to use nicorette® invis i patch

If you are able to stop smoking immediately you should use NICORETTE® invis i patch, when needed, in place of cigarettes by following the dosing instructions detailed under section *"Stopping Immediately"*.

If you are unable to stop smoking or do not feel ready to quit at this time, you should replace as many cigarettes as possible with NICORETTE® invis i patch. There are toxins in cigarettes that can cause harm to your body. NICORETTE® invis i patch provides a safer alternative to smoking, for both you and those around you. Reducing the amount of cigarettes may also help you to become more motivated to stop smoking. As soon as you are ready you should aim to stop smoking completely.

If you are planning to stop smoking or reduce the number of cigarettes you smoke, NICORETTE® invis i patch can be used while you are still smoking. However, during this time, you should aim to replace as many cigarettes as possible with NICORETTE® invis i patch. As soon as you feel ready you should stop smoking completely. Follow the dosing instructions detailed under section *"Stopping Gradually"*.

You can also use NICORETTE® invis i patch on those occasions when you can't or don't want to smoke e.g. long haul flights, social situations, or when at work. However, in smoke 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 and want to stop using NICORETTE® invis i patch but are finding this difficult you should contact your doctor, nurse or pharmacist for advice.

Below is the dosage information for NICORETTE® invis i patch. 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 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 your choice" for more information.
- However all patches are used and applied in the same way.

❶ How to stop smoking - your choice

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

If you find it hard to stop smoking using NICORETTE® invis i patch, you are worried that you will start smoking again without it, or you find it difficult to reduce the number of patches you are using, **talk to your doctor, nurse or pharmacist.**

❶ Children under 12 years

Do not give this product to children under 12 years.

Adults and Children aged 12 years and over

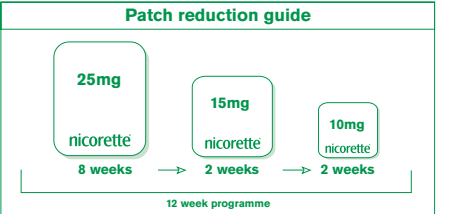
Age	Dose
Adults and children aged 12 years and over	<ul style="list-style-type: none">■ Apply one new patch (of appropriate strength) to the skin when you wake up (usually in the morning).■ Remove 16 hours later which is usually at bed time.
<ul style="list-style-type: none">■ Do not use more than one 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, ensuring they are out of the reach of children and pets.	

Stopping Immediately

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).

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 are recommended to start on 25 mg patch (Step 1) and Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) 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® invis i 25 mg patch the day after you stop smoking completely. Use a new NICORETTE® invis i 25 mg patch each day for eight weeks.

Step 2: If you are successful and avoid smoking 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® invis i 15 mg patch each day for two weeks.**

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

➤ **You might feel a sudden craving to smoke long after you have given up smoking and stopped using NICORETTE® invis i patch. Remember you can use nicotine replacement therapy again if this should happen.**

If you experience excessive side-effects or are a lighter smoker

➤ 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), 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® invis i patch can be used whilst you are still smoking. The idea is to start by gradually replacing some of your cigarettes you smoke whilst using NICORETTE® invis i patch. After achieving this you should aim to give up 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, until you have given up patches completely.

Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) are recommended to start at Step 2 (15 mg). When trying to stop smoking, 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 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) are recommended to use Step 2 (15 mg).

If you have used Nicorette® invis i patch too much

If you have used more than the recommended dosage of NICORETTE® invis i patch, left the patch on for too long or have smoked whilst using NICORETTE® invis i patch, 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.** Take this leaflet and the pack with you.

If a child uses nicorette® invis i patch

➤ **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 inhalation or ingestion by a child may result in severe poisoning.

4 Possible side-effects

Like all medicines, NICORETTE® invis i patch can have side-effects. 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. You may also experience these effects if you under use NICORETTE® invis i patch before you are ready to reduce your nicotine intake.

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
- 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.

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, nurse or pharmacist.

If you notice any of the following; fast heart rate/beat, abnormal beating of the heart, chest palpitations, shortness of breath 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 taking NICORETTE® invis i patch 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.

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.

You can also report side effects directly in Malta via: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5 Storing and disposal

- **Keep NICORETTE® invis i patch 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 NICORETTE® invis i patch above 25°C.
- Do not use NICORETTE® invis i patch after the 'Use before' date shown on the carton or sachet.
- 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.

6 Further information

What's in this medicine?

The active ingredient is: Nicotine.
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, printing inks.

What the medicine looks like

NICORETTE® invis i patch is packed into individual sachets and supplied in packs of 2 (25 mg only), 7 or 14 patches. Not all pack sizes may be marketed.

Who makes nicorette® invis i patch?

The Product Licence holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.
The Manufacturer is
LTS Lohmann Therapie-Systeme AG, Lohmannstrasse 2, D-56626 Andernach, Germany.
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