

nicorette®

invisi patch

nicotine

transdermal patch

with



ActiveStop

Supporting you, body & mind

A guide for users

What you should know about

**nicorette®
invisi 25mg
patch
Step 1**

**nicorette®
invisi 15mg
patch
Step 2**

**nicorette®
invisi 10mg
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, nurse or pharmacist.

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1 What this medicine is for

Nicorette invisipatch 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.

To help quit smoking you should also try to use a behavioural support programme to increase your chances of success. Details of Nicorette ActiveStop are shown in Section 8 of this booklet.

Nicorette® invisipatch 25mg patch: Each patch releases 25 milligrams of nicotine, the active ingredient, over 16 hours.

Nicorette® invisipatch 15mg patch: Each patch releases 15 milligrams of nicotine, the active ingredient, over 16 hours.

Nicorette® invisipatch 10mg patch: Each patch releases 10 milligrams of nicotine, the active ingredient, over 16 hours.

What does Nicorette Invisi Patch do?

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 invisipatch 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.

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.

2 Before using this medicine

Do not use Nicorette Invisi Patch:

- if you have an allergy to nicotine or any of the other ingredients.

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 page 7 *If you are pregnant or breast-feeding.*
- if you are in hospital because of heart disease (including heart attack, disorders of heart rate or rhythm, or stroke).
In other heart conditions not requiring you to be in hospital, using NRT is better than continuing to smoke.
- 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 invisipatches 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 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 applies, talk to your doctor, nurse or pharmacist.

If you are pregnant or breast-feeding

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, 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: ideally, you should try to give up smoking without NRT. 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 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. Tobacco smoke produces breathing and other problems in babies and children.

3 How and when to use this medicine

i How to use Nicorette Invisi Patch

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 nicotine 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.

i Removing and disposing of the patch

- 1 The patch should be removed before you go to bed as nicotine 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 reach of children and animals.



i When to use Nicorette Invisi Patch

Below is the dosage information for the nicorette invisipatch. This shows the number of patches you should be using, when you should use them and 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" 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" section on page 14 for more information.
- However all patches are used and applied in the same way.

i Children under 12 years

Do not give this product to children under 12 years.

i 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.• Children aged 12 years up to 18 years should not use for longer than 12 weeks in total without asking for help and advice from a doctor, nurse or pharmacist.• Adults aged 18 years and over should not use for longer than 9 months in total without asking for help and advice from a doctor, nurse or pharmacist.	

i How to stop smoking

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.

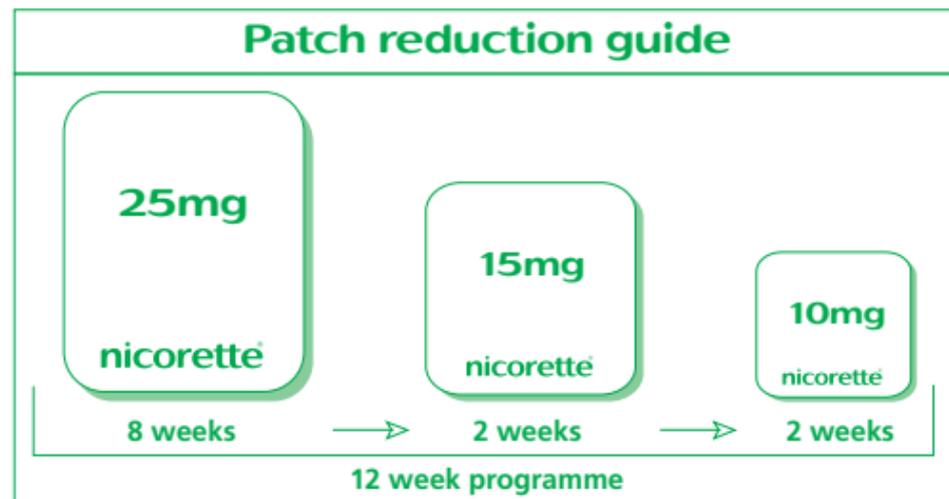
If you find it hard to stop smoking using nicorette invisipatch, you are worried that you will start smoking again without it, or you find it difficult to reduce the number of patches you are using, **talk to your doctor, nurse or pharmacist**. Remember nicorette invisipatches are not intended as a substitute for smoking, they are an aid to give up.

i 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).

i Adults aged 18 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.



Step 1: Begin treatment with the highest strength nicotine invis 25mg patch the day after you stop smoking completely. Use a new nicotine invis 25mg 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 nicotine invis 15mg patch each day for two weeks.

Step 3: If you are successful and avoid smoking over this two week period, then switch from the nicotine invis 15mg patch to the nicotine invis 10mg 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 nicotine invis patch. Remember you can use nicotine replacement therapy again if this should happen.

- Do not use for more than 9 months in total without asking for help and advice from a doctor, nurse or pharmacist.

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

When using the highest strength 25mg patch, if you experience excessive side-effects which do not disappear after a few days of use, you should move to the medium strength 15mg patch and use it for the remainder of the 8 weeks. You should then reduce to the low strength 10mg 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 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.

i Children aged 12 years and over

Children can follow the same method as adults,

however they should not use NRT for longer than 12 weeks without asking for help and advice from a doctor, nurse or pharmacist.

If you use too many Nicorette Invisi Patches

If you have used more than the recommended dosage of Nicorette invisipatch, left the patch on for too long or have smoked whilst using nicorette invisipatch, you may experience nausea, 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.** 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 12 years uses, chews 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.

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 invisipatch 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

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 Invisi Patch

When you use the nicorette invisipatch 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.

Very common side-effects

(more than 1 in every 10 people are affected)

- itching – this usually disappears within a few days

Common side-effects:

(less than 1 in every 10 people are affected)

- headache
- dizziness
- stomach discomfort
- feeling sick (nausea)

- sickness (vomiting)
- redness of the skin – this usually disappears within a few days

Uncommon side-effects:

(less than 1 in every 100 people are affected)

- hives (urticaria)
- chest palpitations

Very rare side-effects:

(less than 1 in 10,000 people are affected)

- abnormal beating of the heart

- **If you notice these or any other unwanted effects not listed in this leaflet tell your doctor, nurse or pharmacist.**
- When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

5 Storing and disposal

- **Keep nicorette invisipatch out of the reach and sight of children and animals.** Nicotine in high doses can be very dangerous and sometimes fatal if taken by small children.
- Do not store nicorette invisipatch above 25°C.
- Do not use a nicorette invisipatch after the 'Use before' date shown on the carton or sachet.
- Dispose of nicorette invisipatch 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 used nicorette invisipatches 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 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 Invisi 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.

This leaflet was prepared in November 2008. ©

7 Helpful tips on giving up

You may have tried to stop smoking before and you know from bitter experience that it's not easy to give up cigarettes.

However, you have now taken the first constructive step towards becoming a non-smoker. In overcoming your tobacco dependence you will have to tackle two problems:

- 1 Your smoking habit.
- 2 Your addiction to nicotine.

Willpower

The overriding success factor in quitting is how determined you are. The first few weeks of quitting

will probably be the most difficult because your smoking ritual is still fresh in your mind.

However, you will find that as time goes by, your willpower becomes stronger. Telling friends, family and work colleagues that you have quit smoking and that you envisage a tough time ahead will encourage them to support you.

1 Pick the right day

There is never a perfect time to give up smoking, but you should plan ahead by choosing a date in the not too distant future on which you are going to give up cigarettes completely. This is your Quit Day. Try to pick a day when you will not be too stressed.

2 Break your routine

For a number of years you will have become accustomed to smoking at certain times, with particular people or in certain situations. Think about the times you will miss smoking the most and plan

how you will cope on these occasions. Changing your routine will help you break the habit of smoking.

3 Quit with a friend

Quitting with a fellow smoker is a good idea. It will strengthen your resolve and build on your determination.

Encourage a friend or family member to quit with you. It will give your morale a boost since there will be another person knowing exactly what you're feeling and with whom you can share your resolve to quit smoking.

4 Remove any temptation

To help yourself succeed be sure to remove all cigarettes, matches, lighters etc. from your home, car and work. Ask your friends and colleagues not to offer you cigarettes or smoke close by you but be careful not to offend them. Explain that you have given up. This type of support from friends is of greatest benefit for

the first couple of weeks of quitting, as this is your most vulnerable time. The last thing you want is a cigarette close at hand in a moment of weakness.

5 Take one day at a time

When you reach your Quit Day, don't allow yourself to think that you're quitting for good. That will make it seem like a superhuman task. Just promise yourself "I won't have a cigarette today" and take it one day at a time. You'll be surprised how much that little thought helps.

6 Distract yourself

Whenever you feel the urge to smoke coming on, distract yourself by keeping active. Don't feel sorry for yourself. Get up and **do** something. Do that job around the house or garden that you've been putting off or take up a hobby.

Remember that the craving only lasts a few minutes.

7 Learn to relax

Once you have stopped smoking, taking exercise regularly will not only help you get fitter but will encourage you to relax. Exercise has the ability to relieve stress and tension. Taken regularly it will benefit you physically and psychologically.

If you haven't exercised for some time, take it slowly to begin with and increase the amount of time spent exercising over the course of a few weeks. Not only will exercising help you relax but it also helps to keep your weight under control, which some people find a problem when quitting.

8 Think cash not ash

One of the really noticeable benefits of 'stopping' is the extra cash that's suddenly available. To emphasise the point put the money into a pot marked 'cash not ash' and watch it accumulate. But be sure to use the money to treat yourself. You deserve a **reward** for **not** smoking.

9 Dealing with relapses

You might find that in times of stress, reaching for a cigarette is the only thing that will help you through. There may also be certain situations – particularly social situations such as a party or in the pub – where temptation just gets the better of you, so you smoke one or two cigarettes. You might feel that your only option is to go back to smoking. Don't think of it as having failed, just think through the reasons why you wanted to quit in the first place and don't let those couple of cigarettes get the better of you. Refer back to your plan and start again. You can beat it!

10 If you don't succeed

Giving up is more difficult for some people than others.

If you fail to stop first time, don't be disheartened. Try again at a later date – you **can** do it!

Remember the most successful long term ex-

smokers have usually had to try several times to stop smoking – **if you don't succeed – quit quit again.**

For further information

Read about Nicorette ActiveStop on the next few pages. This is a personalised support programme which works with nicorette to support you, with the aim of helping you give up smoking. All you need is internet access and a mobile telephone.

8 Nicorette ActiveStop



Personalised support programme

**Enrol on the internet or call
now on 0800 244 838.**

How can ActiveStop help me?

- Nicorette ActiveStop is an advanced, interactive online programme with mobile phone support. It has been devised by experts and is based on proven scientific principles, to help you give up smoking for good.
- It has been specially designed to be used alongside nicorette and is on hand 24 hours a day through the internet and your mobile phone.
- Nicorette works with your body to help you deal with the physical craving for nicotine, whilst ActiveStop gives you practical daily support coaching you all the way until you've stopped smoking.

Call now on 0800 244 838.



What will I get?

On your personalised ActiveStop web pages you'll have access to:

Diary

Through a series of daily tasks, we'll guide you through managing your thoughts, feelings and behaviour and how you can plan each day so that you are ready to face whatever arises.

Progress Monitor

The Progress Monitor brings together all of the headway you are making in one easy-to-view place. From how much money you're saving, to health facts and fitness levels, it will keep you motivated throughout the programme.

Today's Articles

Daily articles cover a range of topics from the changes your body is undergoing to tips to cope with the inevitable cravings.

And the Craving Help-Line

If ever you feel the urge to smoke you can call anytime day or night and by selecting the kind of problem you are experiencing, you'll be able to listen to relevant, on-the-spot advice.

Enrol on the internet or call now on 0800 244 838.

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ActiveStop

Supporting you, body & mind

Personalised support programme

**Enrol on the internet or call
now on 0800 244 838.**