

Information for the user



NicAssist Translucent Patch (Nicotine)

NicAssist Translucent 25 mg Patch (Step 1)

NicAssist Translucent 15 mg Patch (Step 2)

NicAssist Translucent 10 mg Patch (Step 3)

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to help relieve and/or prevent unpleasant withdrawal symptoms and cravings for nicotine when you are trying to give up smoking or for when you can't or don't want to smoke cigarettes. However, you need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

This medicine contains nicotine which belongs to a group of medicines called nicotine replacement therapy (NRT). It acts to substitute the nicotine that you normally get from cigarettes and can be used to relieve and/or prevent unpleasant withdrawal symptoms and cravings for nicotine when you are stopping smoking, cutting down or for when you can't or don't want to smoke cigarettes.

Ideally you should always aim to stop smoking completely. You can use Boots NicAssist Translucent Patches to achieve this by using them to completely replace all of your cigarettes.

However, you can also use the patches in other ways:

- If you feel unable to stop smoking completely, or wish to increase the time between cigarettes, with the intention of cutting down the number of cigarettes you smoke, or
- If you feel unable to stop smoking but you can't or don't want to smoke. For example:
 - When you don't want to smoke or you want to avoid causing harm to others, such as when you are with friends or family
 - When you can't smoke for long periods of time (greater than 16 hours), such as where smoking is not allowed. For example on a plane, at work, social occasions etc.

Using the patches in this way may also help increase your motivation to stop smoking.

To help you cut down or stop smoking completely you should also try to use a behavioural support programme to increase your chances of successfully stopping smoking.

When you stop smoking, cut down, or you can't or don't want to smoke, your body misses the nicotine that you have been getting from the smoke. You may experience unpleasant feelings and a strong desire to smoke ("craving").

This shows that you are dependent on nicotine. When you use the patch, nicotine is released and passes into your body through your skin. The nicotine is sufficient to relieve and/or prevent the unpleasant withdrawal symptoms. It will also help to relieve and/or prevent your craving to smoke but will not give you the "buzz" you get from a cigarette.

Benefits you can get from using NRT instead of smoking

For the best effect, ensure that you use Boots NicAssist Translucent Patches correctly – see “How to use the patches”.

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

Nicotine replacement therapy **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.

Before you use this medicine

This medicine can be used by adults and children of 12 years and over. However, some people should not use this medicine or should seek the advice of their pharmacist or doctor first.

X Do not use:

- **If you are allergic** to any of the ingredients in this medicine (see “**What is in this medicine**”)
- **If you are a child under 12 years of age**

! Talk to your pharmacist, nurse or doctor:

- If you are in hospital because of heart disease (e.g. heart attack, problems with your heart rate or rhythm, stroke, angina or high blood pressure) – try to give up smoking first without using NRT. However, once you are out of hospital, if you still need help to stop smoking, you can use this medicine. For other heart conditions that do not require you to be in hospital, using NRT is better than continuing to smoke
- If you have diabetes – monitor your blood sugar levels more often when you start using this medicine. You may find that you need to adjust the amount of insulin that you use, or the amount of tablets that you take (ask your doctor or diabetes nurse about this)
- If you have an ulcer in your stomach or upper intestine or problems such as pain or swelling of the stomach or oesophagus (the passage between your mouth and stomach)
- If your liver or kidneys do not work properly
- If you have an overactive thyroid gland
- If you have high blood pressure due to a tumour near your kidney (your doctor may have told you that you have a condition called phaeochromocytoma)
- If you have skin problems such as psoriasis, eczema, or raised red itchy skin covering large areas of your body – you should not use the patches (ask your pharmacist about other NRT products that may be more suitable for you)
- If you are taking other medicines regularly prescribed by your doctor (see “**If you take other medicines**”)
 - If you have ever experienced seizures (fits)
- If you are pregnant or breastfeeding (see “**Other important information**”)

Other important information

If you are pregnant: You should try to stop smoking without using NRT.

However, if you still need help to stop smoking, you can use this product as the risk to your

baby is far less than if you continue to smoke. You should talk to your pharmacist, nurse or doctor for more advice.

NRT products that are used intermittently may be preferable to nicotine patches. However, if you feel sick or are sick (morning sickness) the patches may be better for you. If you do use nicotine patches they should be taken off before bedtime.

If you are breastfeeding: You should try to stop smoking without using NRT.

However, if you still need help to stop smoking, it is recommended that you use NRT products that are used intermittently, not patches. You should talk to your pharmacist, nurse or doctor for more advice.

If you do use the patches, breastfeeding your baby just before you apply the patches makes sure that your baby gets the smallest amount of nicotine possible.

The amount of nicotine that your baby may receive when you are using the patches or other NRT products is much smaller and less harmful than the second-hand smoke they would inhale if you smoked. Tobacco smoke causes breathing and other health problems in babies and children. If your husband, partner or other family members smoke too, try to get them to give up with you.

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.

NicAssist patches and medical scans:

Remove the patch before a medical scan to prevent the risk of burns.

If you take other medicines

Before you use this medicine, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Theophylline, clozapine, ropinirole – your doctor may want to monitor the amount of medicine that you take

When you stop smoking or reduce the amount of cigarettes you smoke, your metabolism slows down. This can mean that some medicines may stay in your body longer than usual.

If you take any medicine on a regular basis, tell your doctor that you intend to stop smoking or reduce the amount of cigarettes you smoke, and follow his or her advice about these other medicines.

✓ How and when to use this medicine

Check the foil pouch is not broken before use. If it is, do not use that patch.

How to use the patches

See the following directions, which tell you where to apply the patch, how to apply and how to remove the patch.

Choosing where to apply the patch

1. Before you apply the patch, choose a completely clean, dry area of hairless skin on the front or side of the chest, upper arm or hip.
2. Do not place 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 apply the patches to the same area of skin on two consecutive days. This will help prevent irritation.

How to apply the patch

1. Wash your hands before applying the patch.
2. Each 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 backing foil away. Do not touch 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 other half of the silvery backing foil.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Run your fingers around the edge of the patch to ensure that it sticks properly.

Removing and disposing of the patch

1. The patch should be removed before you go to bed, as it is not designed to be worn when you go to sleep at night or for more than 16 hours per 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 the patch

Read all of the following information carefully before starting to use the patches:

- Follow the instructions in the table on the back of the leaflet, which shows how many patches you should be using and when you should be using them
- **If you are ready to stop smoking completely**, you should use the patches, when needed, to replace all of your cigarettes by following the instructions under “Stopping Immediately”
- **If you are not ready to stop smoking completely**, you should replace as many cigarettes as possible with the patches. Boots NicAssist Translucent Patches provide a safer alternative to smoking for you and those around you, as it is the toxins in cigarette smoke that cause harm, not the nicotine. Reducing the amount of cigarettes you smoke may also help you to become more motivated to stop smoking.

If you are planning to stop smoking or reduce the number of cigarettes you smoke, Boots NicAssist Translucent Patches can be used while you are still smoking. However, during this time, you should aim to replace as many cigarettes as possible with the patch. As soon as you feel ready you should stop smoking completely. Follow the instructions under “Stopping Gradually”.

- **You can also use the patches when you can't or don't want to smoke**, such as long haul flights, social occasions, or when at work. However, in smoke free areas such as the pub, work breaks, on a train or bus, car journeys etc., an alternative flexible Boots NicAssist product (Gum, Inhalator) maybe more suitable. Follow the instructions under “Temporary Abstinence”

When making an attempt to stop smoking completely behavioural therapy advice and support will normally improve the success rate.

Depending on where you are in your treatment programme, the strength of patch that you should be using may differ.

- See the “How to stop smoking - your choice” instructions to see what strength of patch you should be using and, where applicable, for how long
- Use the “How to use the patch” instructions to make sure that you apply the patches correctly to ensure that nicotine is released and passes into your body through the skin

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 stopping smoking completely or reducing the number of cigarettes you smoke.

If you find it hard to stop smoking when using nicotine patches, you are worried that you will start smoking again without them, or you find it difficult to reduce the number or strength of patches you are using, talk to your pharmacist, nurse or doctor.

Children under 12 years

Do not give this medicine to children under 12 years.

! Stopping immediately

Adults and children of 12 years and over

Age	How many and how often to use them
Adults and children of 12 years and over	Apply one new patch (of appropriate strength) to the skin when you wake up (usually in the morning). Remove the patch 16 hours later, which is usually at bedtime.
<p>Don't use more than one patch at a time.</p> <p>If you lose a patch whilst swimming, bathing or showering you can replace it with another patch for the remainder of the 16 hours.</p> <p>Dispose of used patches carefully out of the sight and reach of children and animals.</p>	

The idea is to stop smoking immediately and use the patches 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).

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.

Patch reduction guide		
25 mg	15 mg	10 mg
8 weeks	2 weeks	2 weeks
12 week programme		

For best results, most smokers are recommended to start on the 25 mg patch (step 1) and follow the instructions below.

However, if you are a lighter smoker (those who typically smoke less than 10 cigarettes per day) or you notice excessive side effects when using the 25 mg patch see "If you notice excessive side effects or you are a lighter smoker" and follow those instructions.

Step 1: Begin treatment with the highest strength 25 mg patch the day after you stop smoking completely. Use a new 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 15 mg patch (step 2) each day for two weeks.

Step 3: If you are successful and avoid smoking over this two week period, then switch from the 15 mg patch to the 10 mg patch (step 3) 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 Boots NicAssist Translucent Patches. Remember you can use nicotine

replacement therapy again if this should happen.

If you notice excessive side effects or you are a lighter smoker

When using the highest strength 25 mg patch, if you notice excessive side effects, which do not disappear after a few days of use, you should use the 15 mg patch (step 2) for the remainder of the 8 weeks. You should then switch to the 10 mg patch (step 3) and use for the remaining 4 weeks.

Lighter smokers (those who typically smoke less than 10 cigarettes per day) are recommended to start on the 15 mg patch (step 2) for 8 weeks then use the 10 mg patch (step 3) for the final 4 weeks.

! Stopping gradually

Boots NicAssist Translucent Patch can be used whilst you are still smoking. **The idea is to start by gradually replacing some of the cigarettes you smoke** whilst using the patch. After achieving this, you should aim to stop smoking completely whilst using the patch. Finally, you should stop using the patch completely.

For best results, you should ideally start on the 25 mg patch (step 1). Slowly reduce the amount of nicotine you are getting by switching to the 15 mg patch (step 2) as soon as you have reduced the number of cigarettes you smoke to less than 10 cigarettes per day, until you have given up patches completely.

Lighter smokers (those who typically smoke less than 10 cigarettes per day) are recommended to start on the 15 mg patch (step 2). When trying to stop smoking it is recommended to continue on the 15 mg patch (step 2) for 8 weeks and then switch to the 10 mg patch (step 3) for the last 4 weeks.

! Temporary abstinence

A patch should be used in those situations when you can't or don't want to smoke such as long haul flights, social occasions or when at work.

For best results, you should use a 25 mg patch (step 1). However, lighter smokers (those who typically smoke less than 10 cigarettes per day) are recommended to use the 15 mg patch (step 2).

- ! If you have used too many patches:** If you have used more than the recommended number of patches, left the patch on for too long or have smoked whilst using the patch, you may get the following symptoms – nausea (feeling sick), vomiting, increased salivation, pain in your stomach, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness. **If this happens remove the patch immediately and rinse the application site with water. Do not smoke. Contact a doctor or hospital casualty department straight away.** Take the medicine and this leaflet with you.

If a child under 12 accidentally uses, sucks or chews a patch take them to casualty immediately. Take the medicine and this leaflet with you. Nicotine absorption or ingestion by a child may result in severe poisoning.

Possible side effects

Most people can use this medicine without any problems but sometimes you may notice some side effects. Many of these effects are due to nicotine, they may also happen when you smoke.

If you notice any of the following serious side effects, stop using the medicine, do not smoke and see your doctor as soon as possible:

- You develop a fast, slow or irregular heart beat
- You have an allergic reaction to the patch such as rash, difficulty breathing or swallowing, itching or swelling of the tongue, mouth or throat (go straight to casualty if severe)
- You experience seizures (fits)

Effects related to stopping smoking (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking or using the patch when you are unable to smoke you have reduced the amount of nicotine you are getting. You may also experience these effects if you reduce the strength of your patch that you use before you are ready to reduce your nicotine intake.

These effects include:

- Irritability or aggression, feeling low, anxiety, restlessness
- Poor concentration, urges to smoke (craving), night time awakening or sleep disturbance
- Increased appetite or weight gain
- 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 as you smoke. You may be able to relieve these effects by reducing the strength of the patch you are using.

These effects include:

- Feeling faint, feeling sick (nausea), headache

Side effects of the patch

When you use Boots NicAssist Translucent Patch for the first time they may cause a mild skin reaction. This is usually redness or itching of the skin where the patch has been applied. This will usually disappear after a few days.

Rarely, this reaction may continue for longer, or the reaction may be more severe. If this happens, stop using the patches and talk to your pharmacist, nurse or doctor.

Very common side effects:

(more than 1 in every 10 people are affected)

- Itching

Common side effects:

(less than 1 in every 10 people are affected)

- Dizziness, headache
- Feeling sick, being sick
- Skin rash, hives

Uncommon side effects:

(less than 1 in every 100 people are affected)

- Allergic reactions
- Pins and needles
- Changes in heart rhythm (you may notice a fast heart rate or beat)
- Flushing, high blood pressure
- Excess sweating, shortness of breath
- Muscle pain where the patch is applied
- Application site reactions such as itching, redness, swelling or burning sensation where the patch is placed
- Generally feeling unwell or weak, feeling tired, chest pains

Rare side effects:

(less than 1,000 people are affected)

- Severe allergic reaction, swelling or redness of the skin

- Stomach discomfort
 - Pain in the arms and legs
- Very rare side effects:
(less than 1 in 10,000 people are affected)
- Abnormal beating of the heart

! When you stop smoking you may also develop mouth ulcers. The reason why this happens is unknown.

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 on 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.

How to store and dispose of this medicine

Do not store above 25°C.

Keep this medicine in a safe place out of the sight and reach of children and animals, preferably in a locked cupboard. Nicotine in high amounts can be very dangerous and sometimes fatal if used or swallowed by children.

Use by the date on the patch sachet foil or the end flap of the carton. After this date return any unused medicine to your nearest pharmacy for safe disposal.

Dispose of the 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 patches sensibly, out of the sight and reach of children and animals.

What is in this medicine

This pack contains 7 patches packed into individual sachets.

Each transdermal patch contains nicotine, which is the active ingredient.

Boots NicAssist Translucent 25 mg Patch releases 25 milligrams of nicotine, the active ingredient, over 16 hours.

Boots NicAssist Translucent 15 mg Patch releases 15 milligrams of nicotine, the active ingredient, over 16 hours.

Boots NicAssist Translucent 10 mg Patch releases 10 milligrams of nicotine, the active ingredient, over 16 hours.

As well as the active ingredient, the patches also contain 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.

Who makes this medicine

The product is manufactured for The Boots Company PLC Nottingham NG2 3AA by LTS Lohmann Therapie-Systeme AG Lohmannstrasse 2 D-56626 Andernach Germany.

The Marketing Authorisation holder is McNeil Products Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Leaflet prepared January 2021.

If you would like any further information about this product, please contact The Boots Company PLC Nottingham NG2 3AA.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference Number
---------------------	-------------------------

Boots NicAssist Translucent 25 mg Patch	15513/0161
---	------------

Boots NicAssist Translucent 15 mg Patch	15513/0160
---	------------

Boots NicAssist Translucent 10 mg Patch	15513/0159
---	------------

This is a service provided by the Royal National Institute of Blind People.

Reference 6516704 OIV b