

# Nicotinell®

## Patch programme

### Step 1: Nicotinell TTS 30, 21mg/24hour Transdermal Patch

### Step 2: Nicotinell TTS 20, 14mg/24hour Transdermal Patch

### Step 3: Nicotinell TTS 10, 7 mg/24 hours Transdermal Patch

## Nicotine

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

This medicine is available without prescription. However, you still need to use Nicotinell Patches carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What Nicotinell Patches are and what they are used for
2. Before you use Nicotinell Patches
3. How to use Nicotinell Patches
4. Possible side effects
5. How to store Nicotinell Patches
6. Further information

## 1. WHAT NICOTINELL PATCHES ARE AND WHAT THEY ARE USED FOR

Nicotinell Patch is a nicotine replacement therapy (NRT) which reduces:

- some of the unpleasant withdrawal effects that frequently occur when giving up smoking such as feeling ill or irritable.
- your desire to smoke by providing some of the nicotine previously inhaled from cigarettes and therefore helps your willpower to resist cigarettes.

If you need advice before starting to use nicotine patches, talk to your doctor, nurse, pharmacist or a trained counsellor. A support programme will increase your chances of quitting smoking.

Nicotinell Patches are for application to the skin. When applied to the skin, nicotine passes from the patch, through the skin and into your body.

Nicotinell Patches can be used to help you:

- stop smoking completely
- cut down the amount you smoke – perhaps before you go on to stop completely.

In addition, they may be used when you:

- do not wish to smoke. For example in confined spaces (in the car: in the house) or where others (such as children) could be harmed by tobacco smoke
- are unable to smoke
- develop cravings once you have stopped smoking.

Reducing the number of cigarettes smoked can increase the chances that you will move on to quit completely.

Nicotinell Patches can be used during pregnancy and breast-feeding (see Pregnancy and breast-feeding Section 2).

#### There are 3 steps:

1. Nicotinell TTS 30 (Step 1) patches contain 52.5mg of nicotine and deliver on average 21mg of nicotine over 24 hours.
2. Nicotinell TTS 20 (Step 2) patches contain 35mg of nicotine and deliver on average 14mg of nicotine over 24 hours.
3. Nicotinell TTS 10 (Step 3) patches contain 17.5mg of nicotine and deliver on average 7mg of nicotine over 24 hours.

## 2. BEFORE YOU USE NICOTINELL PATCHES

**DO NOT use the patches** if you:

- are allergic to nicotine or to any of the other ingredients in the patches (see Section 6)
- are a non-smoker or occasional smoker
- have a skin disease that might be aggravated by the patches
- are under 12 years of age, except on the advice of a doctor.

#### Take special care with Nicotinell Patches

Before using the patches, tell your doctor, nurse or pharmacist if you:

- have heart disease (including heart attack, worsening chest pain, disorders of heart rate and/or rhythm), uncontrolled high blood pressure or stroke for which you are in hospital. Using nicotine replacement therapy is better than continuing to smoke
- have serious liver or kidney problems
- have ever had a stomach ulcer
- are diabetic (see "Taking other medicines")
- have an overactive thyroid gland
- have a tumour of the adrenal gland (phaeochromocytoma)
- are taking any other medicines (see next section)
- are pregnant or breast-feeding (see Pregnancy/Breast-feeding sections).

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of some medicines can be altered when you stop smoking.

- If you are already taking regular medication you should tell your doctor, nurse or pharmacist,
- Diabetics should monitor their blood sugar levels more often than usual when starting to use a patch because insulin/medication requirements may alter.

#### Pregnancy

Smoking during pregnancy is associated with risks such as poor growth of the baby before birth, premature birth or still birth. Stopping smoking is the single most effective way to improve both your health and that of your baby. The earlier smoking stops, the better.

Ideally, stopping smoking during pregnancy should be done without nicotine replacement therapy. However, if you have tried and this is not possible, nicotine replacement therapy may be used because the risk to the developing baby is less than that expected from continued smoking.

The decision to use nicotine replacement therapy should be made as early on in the pregnancy as possible with the aim of discontinuing use after 2–3 months. Patches may be preferred if you have nausea or sickness. If patches are used, they should be removed before going to bed at night.

Ask your doctor for advice before taking any medicine.

#### Breast-feeding

It is better to use nicotine replacement therapy products that can be taken intermittently (not patches). Try to breast-feed at a time just before you take the product to ensure that the baby gets the smallest amount of nicotine possible. If you need to use nicotine replacement therapy to help you give up smoking, the amount of nicotine that the baby may receive is considerably smaller and less harmful than the secondhand smoke they would otherwise be breathing in.

#### Driving and using machines

These patches are unlikely to affect your ability to drive or operate machinery.

#### Nicotinell Patches contain Aluminium

Remove the patch before a medical scan or cardiac procedure to regulate your heart rate as aluminium is present in one of the layers of the patch.

## 3. HOW TO USE NICOTINELL PATCHES

Always use the patches exactly as your doctor, nurse or pharmacist has told you and always read the leaflet. Ask your doctor, nurse or pharmacist if you are not sure.

The Nicotinell patch programme involves up to 3 steps. There are three patch sizes consisting of three different strengths: 7, 14 and 21 mg/24 hours.

**The correct dose for you depends on the number of cigarettes you smoke per day.** The size of your patch may need to change during your treatment. This is because your dependence on nicotine will change, and therefore the dose of nicotine in your patch may be too low or too high for you. Do NOT cut the patches to reduce the dose.

- If you smoke **20 or more cigarettes a day**, start with:  
**Step 1.** Nicotinell TTS 30 (21mg/24 hours) patches for 3–4 weeks, followed by,  
**Step 2.** Nicotinell TTS 20 (14mg/24 hours) for 3–4 weeks, followed by,  
**Step 3.** Nicotinell TTS 10 (7mg/24 hours) for 3–4 weeks.
- If you smoke **less than 20 cigarettes a day**, start with:  
**Step 2.** Nicotinell TTS 20 (14mg/24 hours) for 3–4 weeks, followed by,  
**Step 3.** Nicotinell TTS 10 (7mg/24 hours) for 3–4 weeks... if necessary, use Step 3 again.  
**Step 3.** Nicotinell TTS 10 may be used for up to a further 3–4 weeks.

Do not start the programme at Step 3.

If you have any questions about this ask a doctor, nurse or pharmacist.

**Apply one patch every day.** It is important to keep the patch on day and night especially if you need help to overcome the early morning craving for a cigarette. If you are pregnant, the patches should be removed before going to bed.

The Nicotinell TTS patch programme therapy can provide sufficient nicotine when used as single therapy. However smokers who smoke 10 or more cigarettes per day, or people who experience breakthrough cravings, or those who have failed to stop smoking using single therapy may benefit from using additional nicotine replacement products. Nicotinell 2mg or 4mg medicated gum can be used to relieve your breakthrough cravings to smoke.

When using Nicotinell gums together with Nicotinell patches, do NOT use more than 15 x 2mg gums or 10 x 4mg gums per day. You should try to use as few pieces of gum as possible each day.

You might feel a sudden craving to smoke long after you have given up smoking and stopped using the Nicotinell TTS patch programme. Remember! you can use nicotine replacement therapy again if you feel a sudden craving to smoke again.

#### Applying your patches

1. Allow yourself time to put the patch on.
2. Decide where you will put the patch. It is important to choose a hairless area of skin to make sure that it sticks properly e.g. the front or side of the chest, the back or the upper arm. Avoid skin which is red or irritated.

- If the patch does not stick successfully you may try it on any other body site (such as the outer thighs or top of the buttocks) or clean the area with surgical spirit and let it dry naturally before re-applying the patch. Avoid areas where the skin creases (such as over a joint) or folds when you move.
- Make sure that the skin is completely clean and dry. After a hot bath or shower you may continue to sweat even after towelling. Wait until the skin is completely dry before sticking the patch on. Never powder or oil your skin before putting on a patch as it may not stick properly.

#### During use

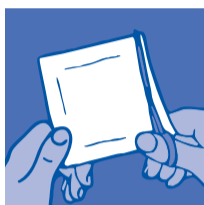
Provided that you have applied the patch correctly, you can bathe, shower or swim with little risk of the patch coming off.

If the patch does fall off, throw it away carefully and apply a new patch to a different area of skin.

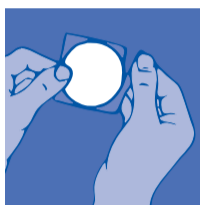
During handling avoid contact with the eyes and nose and wash your hands after application.

#### Changing your patch

- Apply a new patch at roughly the same time each day (preferably in the morning).
- Leave it in place for 24 hours, unless you are pregnant. If you are pregnant you should remove the patch before going to bed.
- When you take off the old patch, fold it in half with the sticky side inwards and throw it away carefully. Even used patches will contain some active medication which could be harmful to children, so make very sure that your patches are always kept well away from children.
- Always place your new patch on a different area of skin.



(a)



(b)

- Cut open the sachet along the dotted line (a) taking care not to damage the patch inside.
- Take out the yellowish patch. Carefully remove the small section of the silver-coloured backing (b).



(c)



(d)

- Remove the larger section of silver-coloured backing (c). Throw away the silver-coloured backing. Avoid touching the sticky surface of the patch with your fingers, as far as possible.
- Place the sticky side of the patch on the chosen site (d).



(e)



(f)

- Press firmly with the palm of your hand for at least 20 seconds (e). It may help to time this with a watch. This is important because the adhesive is pressure sensitive and will not be effective unless pressure is applied for the required time.
- Run your finger around the edge of the patch to make sure that the edge is firmly stuck down (f). Do not fiddle with the patch during the day.
- If you find the patches are not sticking well, it may help to clean the area where you want to apply the patch with a little surgical spirit. Allow this to dry naturally before applying the patch.

#### Duration of use

- The Nicotinell Patch programme usually lasts for 3 months. However, if you have not stopped smoking at the end of the 3 month treatment period, further treatments can be used.

#### Children

Adolescents aged 12–18 years of age should only use Nicotinell Patch for 12 weeks. If longer is required, advice should be sought from a doctor, nurse or pharmacist

#### If you use more Nicotinell Patches than you should

Never use more than one patch at a time. An overdose of nicotine can be dangerous.

**If a child under 12 has used, chewed or swallowed this medicine, contact a doctor or your nearest hospital Accident and Emergency department immediately.** Take this leaflet and the pack with you. Nicotine inhalation or ingestion by a child may result in severe poisoning.

**In the event of an accidental overdose,** remove the patch and wash the skin with water but do NOT use soap. The skin will continue to deliver nicotine into the blood stream for several hours after the patch is removed. Then contact your doctor, pharmacist or nearest hospital casualty department immediately.

#### If you forget to use Nicotinell Patches

If you forget to change your patch at the usual time, change it as soon as you remember. Then go on as before. Do not use 2 patches to make up for a missed dose.

**If you have any further questions on the use of this product, ask your doctor or pharmacist.**

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Nicotinell Patches can cause side effects, although not everybody gets them.

**STOP using the patches and seek medical help immediately** if you have any of the following **allergic reactions:**

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat.
- severe itching of the skin, with a red rash or raised lumps.

**Some side effects are very common** (may affect more than 1 in 10 people)

- application site reactions such as itching, redness, oedema (becoming swollen) and burning sensation where the patch is placed

In the event of a severe skin reaction which will not go away, you should stop treatment and consult your doctor or pharmacist to find another form of nicotine replacement therapy.

These effects are usually caused by not changing the site of application each day. Changing the site each day will allow any irritation to disappear naturally and cause you very little discomfort.

**Some side effects are common** (may affect between 1 and 10 in every 100 people)

- agitation, anxiety, nervousness, difficulty sleeping, abnormal dreams
- headache, dizziness or disorder in muscle condition
- cough
- nausea, abdominal pain or indigestion
- muscle discomfort or arthritis

These effects are often mild and will wear off naturally and rapidly once you have removed the patch

**Some side effects are uncommon** (may affect between 1 and 10 in every 1000 people)

- disturbance in attention, sleepiness, mood changes, irritability, depressed mood or confusional state
- tingling or numbness, changes in taste or blurred vision
- palpitations (feeling of heartbeats)
- high blood pressure or hot flushes
- chest infections
- vomiting, constipation, diarrhoea, flatulence or dry mouth
- excessive sweating
- joint pain, muscle cramp or back pain
- feeling of weakness, pain or discomfort

**Some side effects are rare** (may affect between 1 and 10 in every 10,000 people)

- tremor
- chest pain, shortness of breath or irregular heart beat
- skin discolouration or inflammation of blood vessels often with skin rash

Mouth ulcers may be related to stopping smoking and not to your treatment.

#### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

These patches are NOT suitable for non-smokers or occasional smokers. They may develop signs of nicotine **overdose** including headache, sickness, stomach pains, sweating, increased heart rate, dizziness, disturbed hearing or vision, weakness and diarrhoea. If this happens, remove the patch at once and contact your doctor or nearest hospital casualty department immediately.

## 5. HOW TO STORE NICOTINELL PATCHES

- Keep out of the reach and sight of children.
- Do not use Nicotinell Patches after the expiry date which is stated on the sachet and on the carton. The expiry date refers to the last day of that month.
- Store below 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

## 6. FURTHER INFORMATION

#### What Nicotinell Patches contain

- The active substance is nicotine.
- Nicotinell TTS 30 (Step 1)** patches contain 52.5mg of nicotine and deliver on average 21mg of nicotine over 24 hours.
- Nicotinell TTS 20 (Step 2)** patches contain 35mg of nicotine and deliver on average 14mg of nicotine over 24 hours.
- Nicotinell TTS 10 (Step 3)** patches contain 17.5mg of nicotine and deliver on average 7mg of nicotine over 24 hours.
- The **other** ingredients are: acrylate esters vinylacetate, copolymers, fractionated coconut oil, methacrylic acid esters co-polymers, aluminised and siliconised polyester films.

#### What Nicotinell Patches look like and contents of the pack

Each patch is a transdermal therapeutic system, consisting of a round, flat, yellowish-ochre coloured self-adhesive patch. It is protected by a rectangular metallic release liner backing to be discarded before application.

- Nicotinell TTS 30, 21mg/24hour Patch Transdermal Patch (Step 1) are available in packs of 7, 21 patches. Not all pack sizes may be marketed.
- Nicotinell TTS 20, 14mg/24hour Patch Transdermal Patch (step 3) and Nicotinell TTS 10, 7 mg/ 24 hours Transdermal Patch (step 3) are available in packs of 7 patches

#### Marketing Authorisation Holder

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#### Manufacturer

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