

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Nicotinell® TTS20

## 14mg / 24 Hour Patch

(nicotine)

MPT1576L1

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.
- The name of your medicine is Nicotinell TTS20 14mg / 24 Hour Patch but it will be referred to as Nicotinell Patches throughout the remainder of this leaflet.
- This medicine is also available in other strengths.

### What is in this leaflet:

1. What Nicotinell Patches are and what they are used for
2. What you need to know before you use Nicotinell Patches
3. How to use Nicotinell Patches
4. Possible side effects
5. How to store Nicotinell Patches
6. Contents of the pack and other information

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

Nicotinell Patches are a nicotine replacement therapy (NRT). They are 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. They are for application to the skin. When applied to the skin, nicotine passes from the patch, through the skin and into your body.

Ideally you should always aim to stop smoking completely, but Nicotinell Patches can be used in a number of ways to help you:

- cut down the amount you smoke – perhaps before you go on to stop completely.
- to reduce the number of cigarettes you smoke – which can increase the chances that you will move on to quit completely.

In addition, they may be used when you:

- do not wish to smoke. For example, in confined spaces (in the car or house) or where others could be harmed by tobacco smoke e.g. children
- are unable to smoke
- develop cravings once you have stopped smoking
- experience withdrawal effects that frequently occur when giving up smoking such as feeling ill or irritable
- have a 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 can be used during pregnancy and breast-feeding (see Section 2).

### There are 3 steps:

<b>Step 1:</b> Nicotinell TTS 30 Patches	Each patch contains 52.5mg of nicotine and releases 21mg of nicotine over 24 hours.
<b>Step 2:</b> Nicotinell TTS 20 Patches	Each patch contains 35mg of nicotine and delivers 14mg of nicotine over 24 hours.
<b>Step 3:</b> Nicotinell TTS 10 Patches	Each patch contains 17.5mg of nicotine and releases 7mg of nicotine over 24 hours.

## 2. WHAT YOU NEED TO KNOW 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 (listed in Section 6)
- are a non-smoker or occasional smoker
- have a skin disease that might be aggravated by the patches

### ! Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Nicotinell Patches if you:

- have any heart problems such as recently had a heart attack, suffer from heart rhythm problems, heart failure or chest pain (angina, including Prinzmetal's angina), uncontrolled high blood pressure
- had a "stroke" (cerebrovascular accident)
- suffer from liver or kidney problems
- have ever had a stomach ulcer or oesophagitis
- are diabetic (see "Other medicines and Nicotinell Patches")
- have an overactive thyroid gland
- have a tumour of the adrenal gland (phaeochromocytoma)
- have ever experienced seizures
- are taking any other medicines (see next section)
- are pregnant or breast-feeding (see Pregnancy/Breast-feeding sections).

### ! Stop using the patch and consult a healthcare professional

- If you get skin redness, swelling or rash. You are more likely to get these reactions if you have a history of skin disorders such as eczema or hives.

### ! Children and adolescents

If you are under 18 years old, ask a healthcare professional before use. Nicotinell Patches should not be used in children under 12.

### ! Other medicines and Nicotinell Patches

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

The effect of some medicines can be altered when you stop smoking and may require adjustment of the dose. 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, breast-feeding and fertility

#### 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 has not worked, nicotine replacement therapy should only be used upon advice from a healthcare professional to help you stop smoking, as nicotine replacement therapy may be used when the risk to the developing baby is less than that expected from continued smoking.

Patches may be preferred if you have nausea or sickness. If patches are used, they should be removed before going to bed at night.

#### Breast-feeding

If you are breast-feeding, you should first stop smoking without using nicotine replacement therapy. Stopping completely is by far the best option. However, if you have tried and this has not worked, nicotine replacement therapy should only be used upon advice by a healthcare professional because nicotine can pass into breast milk. 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 second-hand smoke they would otherwise be breathing in.

#### Fertility

Smoking increases the risk of infertility in women and men. The effects of nicotine on fertility is unknown.

### ! Driving and using machines

These patches are unlikely to affect your ability to drive or operate machinery. However, smoking cessation can cause behavioural changes.

### ! 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 described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse 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 strength for you depends on the number of cigarettes you smoke per day.** The strength 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.

### Adults over 18 years

#### For smokers of more than 20 cigarettes a day:

	Dose	Duration
Step 1	Nicotinell TTS 30 (21mg/24h)	First 3-4 weeks
Step 2	Nicotinell TTS 20 (14mg/24h)	Next 3-4 weeks
Step 3	Nicotinell TTS 10 (7mg/24h)	Last 3-4 weeks

#### For smokers of less than 20 cigarettes a day:

	Dose	Duration
Step 2	Nicotinell TTS 20 (14mg/24h)	Next 3-4 weeks
Step 3	Nicotinell TTS 10 (7mg/24h)	Last 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.

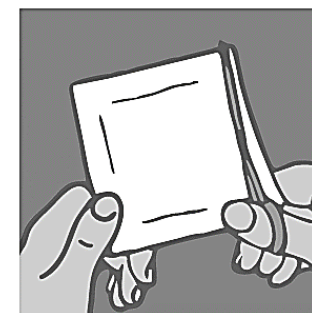
You might feel a sudden craving to smoke long after you have given up smoking and stopped using the Nicotinell TTS Patch programme. Remember you can use nicotine replacement therapy again if you feel a sudden craving to smoke again.

### ✓ Before applying the patches

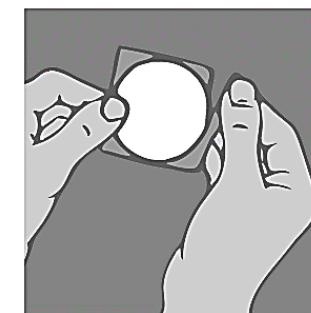
1. Users should stop smoking completely during treatment with Nicotinell Patches.
2. Decide where you will put the patch. It is important to choose a hairless area of skin to make sure that it sticks properly e.g. shoulder blade, hip, the front or side of the chest, the back or the upper arm. Avoid skin which is red, broken or irritated.
3. If the patch does not stick successfully you may try it on another 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.
4. 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.
5. A different site of application should be chosen each day and 7 days should be allowed to elapse before a new patch is applied to the same area of skin.

### ✓ How to apply the patch

1. Apply a new patch at roughly the same time each day (preferably in the morning).
2. Cut open the sachet along the dotted line (a) taking care not to damage the patch inside.
3. Take out the yellowish patch. Carefully remove the small section of the silver-coloured backing (b).

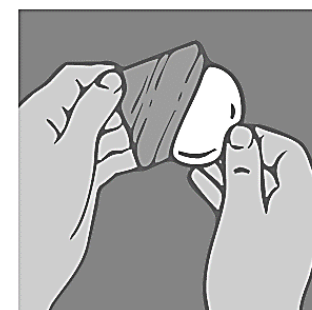


(a)

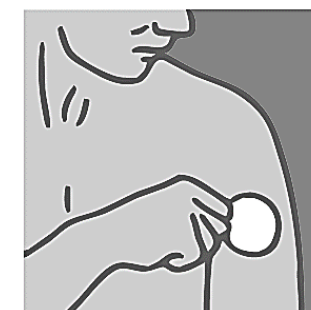


(b)

4. 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.
5. Place the sticky side of the patch on the chosen site (d).



(c)

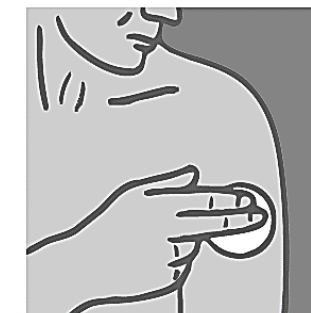


(d)

6. 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.
7. 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. During handling avoid contact with the eyes and nose and wash your hands after application.
8. 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.
9. Leave it in place for 24 hours, unless you are pregnant. If you are pregnant you should remove the patch before going to bed.



(e)



(f)

### 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.

#### Removing and disposing of the patch

- After 24 hours remove the patch. 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 out of the sight and reach of children.
- Always place your new patch on a different area of skin and allow at least 7 days to elapse before a new patch is applied to the same area of skin.

#### 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. If you are still using the patch after 12 months, talk to a healthcare professional for advice.

#### Use in Children and Adolescents

Adolescents aged 12–17 years of age should seek medical advice before using Nicotinell Patches and should not use beyond 10 weeks. If longer is required, advice should be sought from a doctor, nurse or pharmacist.

Nicotinell Patches are not recommended for use in children under 12 years.

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

If you have used more than the recommended dosage of Nicotinell Patches or left the patch on for too long, you may experience sweating, shaking, nausea, shortness of breath, irregular heart beat, palpitations, vomiting, salivation, pain in your abdomen, diarrhoea, headache, dizziness, hearing disturbance or weakness (all common symptoms of nicotine poisoning). Never use more than one patch at a time.

**In the event of an accidental overdose**, remove the patch **immediately**, 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 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.

#### ! 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, pharmacist or nurse.

## 4. POSSIBLE SIDE EFFECTS

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

Symptoms related to nicotine withdrawal:

- depression, irritability, nervousness, restlessness, mood lability, anxiety, drowsiness, impaired concentration, insomnia and sleep disturbances.
- asthenia, headache, dizziness, coughing or influenza-like illness.

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.

**Other side effects that may occur:**

#### **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
- sleep disorders including insomnia and abnormal dreams
- headache or dizziness
- nausea or vomiting

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.

#### **Common** (*may affect up to 1 in 10 people*)

- agitation, anxiety or nervousness
- disorder in muscle condition or tremor
- palpitations
- cough or shortness of breath
- abdominal pain, indigestion, diarrhoea, dry mouth or constipation
- muscle discomfort or arthritis
- increased sweating
- application site pain, weakness or fatigue

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

#### **Uncommon** (*may affect up to 1 in 100 people*)

- hypersensitivity
- disturbance in attention, sleepiness, mood changes, irritability, depressed mood or confusional state
- tingling or numbness, changes in taste or blurred vision
- tachycardia
- high blood pressure or hot flushes
- chest infections
- flatulence
- joint pain, muscle cramp or back pain
- discomfort, flu-like symptoms, feeling of weakness, pain or discomfort

#### **Rare** (*may affect up to 1 in 1,000 people*)

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

#### **Very rare** (*may affect up to 1 in 10,000 people*)

- anaphylactic reactions
- allergic dermatitis, contact dermatitis, photosensitivity

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

If you are a non-smoker or occasional smoker you may develop signs of nicotine overdose including headache, sickness, stomach pains, sweating, increased heart rate, dizziness, disturbed hearing or vision, weakness or diarrhoea. If this happens, remove the patch at once and contact your doctor or nearest hospital casualty department immediately.

#### **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) 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 NICOTINELL PATCHES

- **Keep out of the sight and reach of children.**
- Do not use Nicotinell Patches after the expiry date which is stated on the sachet and on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Do not throw away any medicines 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 Nicotinell Patches contain**

- The **active substance** is nicotine. Each patch contains 35mg nicotine releasing 14mg over 24 hours.

- The **other ingredients** are: methacrylic acid esters copolymers (Eudragit E100), polyester films, Durotak 387-2516, Miglyol 812, paper 26g/m<sup>2</sup>, 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 patch with 'CG FEF' printed on the patch surface. It is protected by a rectangular metallic release liner backing to be discarded before application.

Nicotinell Patches are available in sachets in packs containing 7 patches.

Manufactured by  
LTS Lohmann Therapie-Systeme AG, Lohmannstrasse 2,  
56626 Andernach, Germany.

Procured from within the EU. Repackaged by the Product Licence Holder:  
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PL: 33532/1576

Leaflet dated 11<sup>th</sup> August 2025

Leaflet coded MPT1576L1

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