

Package leaflet: Information for the user

Nicotinell TTS 30, 21 mg/24 hours Transdermal Patch Nicotinell TTS 20, 14 mg/24 hours Transdermal Patch Nicotinell TTS 10, 7 mg/24 hours Transdermal Patch nicotine

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.

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 for application to the skin. When applied to the skin, nicotine passes from the patch, through the skin and into your body. Nicotinell patches help you stop smoking as part of an overall treatment programme.

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.

There are 3 steps:

Step 1: Nicotinell TTS 30 patches	Each patch contains 52.5mg of nicotine and releases 21mg of nicotine over 24 hours.
Step 2: Nicotinell TTS 20 patches	Each patch contains 35mg of nicotine and delivers 14mg of nicotine over 24 hours.
Step 3: 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)
- have had a recent heart attack
- have had a stroke recently
- have a skin disease that might be aggravated by the patches
- are under 18 years of age, except on the advice of a doctor
- continue to smoke



Warnings and precautions

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

- are in hospital for heart disease (including heart attack, worsening chest pain, disorders of heart rate and/or rhythm) or stroke, suffer from liver or kidney problems
- have ever had a stomach ulcer or oesophagitis
- are diabetic (see “Taking other medicines”)
- have an overactive thyroid gland
- have a lack of blood supply mainly to limbs, hands and feet
- have tumour of the adrenal glands (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 health care professional

- If you develop a skin reaction (contact sensitisation) to nicotine patches, a severe reaction from smoking or using other nicotine products may occur. 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. Nicotine patches should not be used in children under 12.

Take care when handling the patch, and do not leave lying around as doses of nicotine that are tolerated by adult smokers during treatment can produce severe symptoms of poisoning in small children and may prove fatal. Keep out of the sight and reach of children.

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, for example, oestrogens, oxazepam, warfarin, antipyrine, caffeine, desmethyldiazepam, imipramine, lignocaine, pentazocine, ropinirole, clozapine, olanzapine, phenacetin and theophylline.
- 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

It was very important to stop smoking during pregnancy because it can result in poor growth of your baby. It can also lead to premature births and even stillbirths.

Ideally, if you are pregnant or breast-feeding you should give up smoking without the use of nicotine replacement therapy products. 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 to help you stop smoking.

Do not use if you are pregnant or breast-feeding except on the advice of your doctor.

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

You should not wear your patch during MRI (Magnetic Resonance Imaging) procedures or a 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 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 dose 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.

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.



Before applying the patches

1. Users should stop smoking completely during treatment with nicotine 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.



Changing your patch

1. Apply a new patch at roughly at 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 eyes and nose. Wash your hands after applying the patch.

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. 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

1. 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 and pets, so make sure that the used patches are disposed and are kept away from children and pets.
2. 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, consult your doctor before starting further treatment that may be recommended by your doctor after consultation. If you are still using the patch after 12 months, talk to a healthcare professional for advice.

Use in Children and adolescents

Adolescents aged between 12-17 years of age should seek medical advice before using Nicotinell TTS and should not use beyond 10 weeks.

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 paleness of the skin, sweating, salivation, vomiting, shortness of breath, abdominal cramps, diarrhoea, headache, dizziness, hearing and vision disturbances, shakes, mental confusion, cardiac arrhythmia, muscle weakness, convulsions, extreme exhaustion, absence of neurological reaction, circulatory collapse and respiratory failure (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 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 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 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.

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
- sleep disorders including insomnia and abnormal dreams
- headache or dizziness

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 up to 1 in 10)

- agitation, anxiety or nervousness
- disorder in muscle condition or tremor
- palpitations
- cough
- abdominal pain, indigestion, diarrhoea, dry mouth or constipation
- muscle discomfort
- 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.

Some side effects are 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
- flatulence
- excessive sweating
- joint pain
- discomfort, flu-like symptoms, feeling of weakness, pain or discomfort

Some side effects are rare (may affect up to 1 in 1,000 people)

- shortness of breath or irregular heart beat

Some side effects are very rare (may affect up to 1 in 10,000 people)

- anaphylactic reactions
- dermatitis allergic*, dermatitis contact*, photosensitivity

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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. The expiry date refers to the last day of that month.
- Store below 25°C.
- Used patches must be disposed carefully by folding them in half with the adhesive sides inwards and ensuring they are out of the sight and reach of children and pets.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. 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.
- 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 printed 'CG EME' (Step 1), CG FEF (Step 2) or CG CWC (Step 3) on the patch surface. It is protected by a rectangular metallic release liner backing to be discarded before application.

- Nicotinell TTS 30, (21mg/24hour) (Step 1) is available in packs of 2, 3, 7, 14, 21, 28 patches.
- Nicotinell TTS 20, 14mg/24hour Patch Transdermal Patch (Step 2) and Nicotinell TTS 10, 7mg/24 hours Transdermal Patch (Step 3) are available in packs of 7, 14, 21, 28 patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Dr. Reddy's Netherlands B.V.
Claude Debussylaan 10
1082 MD Amsterdam
Netherlands

Manufacturer

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

For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie.

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