

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nicotinell TTS 30, 21 mg/24 hours Patches

Nicotinell TTS 20, 14 mg/24 hours Patches

Nicotinell TTS 10, 7 mg/24 hours Patches

Nicotine

Patch Programme

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 it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to your doctor if you do not feel better or if you feel worse.
- If any of the side effects gets serious, or if you notice any side effects 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
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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:

1. Nicotinell TTS 30 (Step 1) patches contain 52.5 mg of nicotine and deliver on average 21 mg of nicotine over 24 hours.
2. Nicotinell TTS 20 (Step 2) patches contain 35 mg of nicotine and deliver on average 14 mg 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 any heart problems, including angina or a recent heart attack or severe heart beat irregularities
- 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.

Take special care with Nicotinell Patches

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

- have any heart disease (including heart attack and worsening chest pain, uncontrolled high blood pressure, disorders of heart rate and/or rhythm) 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 high blood pressure
- have an overactive thyroid gland
- lack of blood supply mainly to limbs, hands and feet
- have phaeochromocytoma (tumour of the adrenal glands)
- are taking any other medicines (see next section)
- are pregnant or breast-feeding (see Pregnancy/Breast-feeding sections).

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. If you develop a skin reaction to nicotine, a severe reaction from smoking or other nicotine products may occur.

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 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, frusemide, propranolol, antipyrine, caffeine, desmethyldiazepam, imipramine, lignocaine, pentazocine, ropinirole, clozapine and olanzapine, phenacetin, theophylline, dextropropoxyphene, nifedipine, adrenergic agonist (adrenaline-type drug) or adrenergic blocking agents (a class of drugs also called beta blocker that block the effect of adrenaline, used to prevent abnormally fast heart rates or irregular heart rhythms or lower blood pressure).
- Diabetics should monitor their blood sugar levels more often than usual when starting to use a patch because insulin/medication requirements may alter.
- Smoking may reduce ulcer healing if taking H₂-antagonists such as cimetidine and ranitidine.

Pregnancy and Breast-feeding

It is 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 pregnant and breast-feeding women are advised to give up smoking without the use of nicotine products. 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.

Important information about some of the ingredients of Nicotinell

Because Nicotinell Patches contains aluminium: You should not wear your Nicotinell Patches during MRI (Magnetic Resonance Imaging) procedures.

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 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.

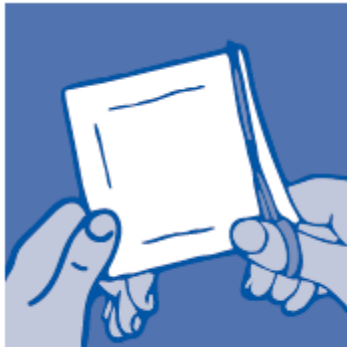
If you have any questions about this ask a doctor, nurse or pharmacist.

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.

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.
3. 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.

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.



(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.

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 eyes and nose. Wash your hands after applying the patch.

Changing your patch

1. Apply a new patch at roughly at the same time each day (preferably in the morning). Leave it in place for 24 hours.
2. 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.
3. Always place your new patch on a different 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.

Children

Nicotinell TTS should not be given to children under 18 years of age without recommendation from a doctor.

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.

Symptoms are: paleness of the skin, sweating, nausea, salivation, vomiting, abdominal cramps, diarrhoea, headache, dizziness, hearing and vision disturbances, shakes, mental confusion, muscle weakness, convulsions, extreme exhaustion, absence of neurological reaction, and respiratory failure.

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 can cause side effects, although not everybody gets them.

STOP using Nicotinell Patches and seek medical help if you have any of the following

- Difficult breathing or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with red rash or raised bumps

The frequency of some side effects is unknown: allergic reactions such as urticaria, rash and pruritis; angioedema and anaphylactoid reaction.

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

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 common (*may affect between 1 and 10 in every 100 people*)

- agitation, anxiety, nervousness, sleepiness, difficulty sleeping, abnormal dreams
- headache, dizziness or disorder in muscle condition, chest pain
- cough, cold and flu like symptoms
- nausea, abdominal pain, menstrual pain in females or indigestion
- muscle discomfort or poor co-ordination or arthritis

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

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.

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 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.
- Do not store above 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 contains:

- The active substance is nicotine.
- **Nicotinell TTS 30 (Step 1)** patches contain 52.5 mg of nicotine and deliver on average 21 mg of nicotine over 24 hours.
- **Nicotinell TTS 20 (Step 2)** patches contain 35 mg of nicotine and deliver on average 14 mg of nicotine over 24 hours.

- **Nicotinell TTS 10 (Step 3)** patches contain 17.5 mg of nicotine and deliver on average 7 mg 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 looks 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 (Step2) 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, 21 mg/24 hours Patch Transdermal Patch (Step 1) are available in packs of 2, 3, 7, 14, 21, 28 patches. Not all pack sizes may be marketed.
- Nicotinell TTS 20, 14 mg/24 hours 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

Novartis Consumer Health, Camberley, GU15 3YL, UK

Manufacturer

FAMAR S.A., 48th km National Road Athens-Lamia, 19011, Avlonas, Attiki, Greece

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PA 30/21/2

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