Nicotinell TTS

Transdermal therapeutic system (TTS)
Aid to smoking cessation (on a scientific basis)

Composition
Active substance: nicotine, Transdermal therapeutic system (TTS) with a contact surface of 10cm^2, 20cm^2 or 30cm^2.

1 Nicotinell TTS 10 contains 17.5mg nicotine. The average rate of active substance released onto the skin is 7 mg/24 hours.
1 Nicotinell TTS 20 contains 35mg nicotine. The average rate of active substance released onto the skin is 14 mg/24 hours.
1 Nicotinell TTS 30 contains 52.5mg nicotine. The average rate of active substance released onto the skin is 21 mg/24 hours

Indications/Methods of use
To aid smoking cessation; to reduce addictive behavior and the various withdrawal symptoms in nicotine-dependent smokers. Treatment should not exceed 3 months. Data currently available show that application of Nicotinell TTS compared with placebo is effective in the short term.
The long-term success of treatment after smoking cessation does not depend on Nicotinell TTS, but is essentially determined by the patient's willpower and any further psychological support he or she may be receiving.

Dosage/Directions for use
The patient should be told to stop smoking completely as soon as treatment with Nicotinell TTS is started.
Nicotinell TTS is intended for use in adults over the age of 18 years. If you are under 18 years old, ask a healthcare professional before use. One Nicotinell TTS should be applied daily and left on the skin for 24 hours. Since the amount of nicotine released from Nicotinell TTS per cm^2 is constant, the dose administered is determined solely by the contact area of the system. To avoid local irritation of the skin, a new site of application should be chosen each day. Nicotinell TTS is available in three dosage strengths: Nicotinell TTS 30, Nicotinell TTS 20 and Nicotinell TTS 10.
The dosage cannot be adjusted by cutting the TTS transdermic system.
Nicotinell TTS 30 is generally intended for smokers with a consumption of more than 20 cigarettes a day. Nicotinell TTS 20 is sufficient for smokers with a consumption of up to 20 cigarettes daily. Nicotinell TTS 10 is designed to reduce nicotine replacement towards the end of therapy.

Treatment should be initiated with one of the larger systems (Nicotinell TTS 30 or 20) and reduced in stages. The dosage can be adapted to the patient's response after a few days.
Heavy smokers should be given Nicotinell TTS 30 followed by Nicotinell TTS 20 and finally Nicotinell TTS 10 for about 4 weeks in each case. Moderate smokers should use Nicotinell TTS 20 for about 8 weeks and Nicotinell TTS 10 for about 4 weeks.
Smoking cessation therapy should not expose the user to more nicotine than smoking.
After removing the protective foil, the nicotine patch should be applied to a clean, dry, hair-free and unbroken area of skin (free from lotion, alcohol, or traces of ointment) on your chest, back, upper arm or hip. With your hand held over the entire surface of the patch, press it against the skin for 10-20 seconds. Make sure that the patch adheres properly at the edges. To minimize the risk of skin irritation, do not apply the Nicotinell transdermal patches at the same spot twice in a row. You should instead allow a week to pass before using the same spot again. This prevents the skin from becoming irritated (red) or damaged. Wash your hands after applying the transdermal patch to avoid irritating your eyes and nose from nicotine from your fingers.
If the patient has not stopped smoking with the aid of Nicotinell TTS at the end of the treatment period, treatment should be discontinued. Another withdrawal attempt can be made with Nicotinell TTS at a later point.

Note
Nicotinell TTS can be used to supplement smoking cessation programmes, self-motivation techniques, behavioural therapy, or psychotherapy.

Restrictions on use
Contraindications
Hypersensitivity of the skin to nicotine or one of the components of TTS, systemic skin disease, unstable or worsening angina pectoris, acute myocardial infarction, severe cardiac arrhythmias, recent cerebrovascular accident, pregnancy and lactation.

Precautions
The patient should be urged to stop smoking completely when using Nicotinell TTS. Patients should be informed that if they continue to smoke while using Nicotinell TTS, they may experience increased adverse effects due to the hazards of smoking, including cardiovascular effects.
The Nicotinell patch contains aluminium. The patch should therefore be removed prior to undergoing any MRI (Magnetic Resonance Imaging) procedures.
Given the pharmacological effects of nicotine, the use of Nicotinell TTS calls for careful weighing of the risks and benefits before it can be considered in patients with the following diseases:

- If you have diabetes you should monitor your blood sugar levels more often than usual when you start using the nicotine patch. Your insulin or medicine requirements may change.
- If you had a recent heart attack, stroke or suffer from severe heart rhythm problems you should try to quit smoking without using the patch unless your healthcare professional tells you to use them. Consult your healthcare professional if you experience an increase in heart problems.
- If you suffer from kidney or liver disease.
- If you have ever experienced seizures.
- If you have stomach or duodenal ulcers or an inflamed oesophagus or gullet (the passage between the mouth and stomach) because nicotine replacement therapy can make your symptoms worse.
- If you have an overactive thyroid gland
- If you have high blood pressure, heart failure, angina or circulatory problems

Allergic reactions: in clinical studies, contact sensitivity occurred in a few patients when using transdermal nicotine. In such cases, it should be noted that contact sensitivity may recur when other nicotine-containing products, including tobacco are used.
Intermittent use: There is no sufficient data on the intermittent use of Nicotinell TTS. However, in cases of chronic insomnia, the patch can be removed after 16 hours.

Pregnancy, breast feeding
No controlled studies in pregnant women are available. Nicotinell TTS should not be used during pregnancy and breast feeding. Nicotine passes into the breast milk. Nicotine in any form may cause harm to your unborn baby. However, if you have tried and failed to quit smoking without using nicotine replacement therapy, nicotine replacement therapy should only be used upon advice by a healthcare professional to help you stop smoking.

Undesirable side effects
In principle, Nicotinell TTS can cause nicotine side effects similar to those associated with smoking. However, smoking carries additional risks because of the known harmful effects of carbon monoxide, irritant gases, and tar. Since the plasma nicotine concentrations produced by Nicotinell TTS are substantially lower than those produced by smoking, the nicotine side effects during treatment with Nicotinell TTS can be expected to be less marked. However, if the patient continues to smoke while using Nicotinell TTS, the side effects of nicotine may be more frequent and more pronounced. Like all medicines, Nicotinell can cause side effects, although not everybody gets them.

Skin
Owing to the properties of the active substance, nicotine, Nicotinell TTS may cause mild erythema and pruritus in up to 35% of patients. The incidence of severe erythema, which can be reversed by removing the system, increases from the third week of treatment (up to 8% of cases). Allergy, herpes, and rash have been observed in rare cases.
Nicotinell TTS is left on the skin for one day, producing an occlusive effect.
This effect can cause skin irritation in the form of dermatitis. As with normal adhesive plasters, reactions may occur as a result of intolerance to the adhesive. Erythema usually disappears within a few hours of removing the system. To reduce local irritation a different site of application should be chosen each day. Patients with a known history of allergy to adhesive plasters should be carefully monitored for skin reactions during the first few days of treatment.
Stop using the product and consult a healthcare professional:

- if you experience severe allergic reaction symptoms of which include sudden wheeziness or tightness of chest, rash and feeling faint
- if you experience fast or irregular heart beat
- When using this product, you may experience: Redness, itching, burning or a tingling sensation at the site of application. This usually disappears quickly after removal of the patch
- Rashes or other skin reactions at the site of application
- Feeling your heartbeat (palpitations)
- Shortness of breath
- Stomach pain
- Diarrhoea
- Constipation
- Joint and muscle pain
- Sleep disturbances including lack of sleep (insomnia) and abnormal dreams
- Headache, dizziness, feeling sick (nausea), vomiting.
- Indigestion
- Nervousness
- Cough
- Sore or swollen throat
- Dry mouth
- Tiredness or weakness
- Trembling
- Sensitivity of the skin to sunlight
- Arthritis, disorder in muscle coordination
- Disturbance in attention, sleepiness, dramatic mood swings, irritability, depressed mood, confusional state, disturbed taste, blurred vision, high blood pressure, hot flushes, upper respiratory tract infections, excessive sweating.
- Chest pain, skin discolouration, inflamed blood vessels on the skin, migraine, increased appetite, dysphagia.

Interactions
The enzyme induction observed in smokers is not attributable to nicotine, but to the tar compounds contained in tobacco smoke. This means that when tobacco consumption ceases, even if nicotine is replaced with Nicotinell TTS, there may be a change (normalisation) in the metabolism and the pharmacological effects of concomitant medication. Smoking can lower serum concentrations of some drugs, such as phenazone, estrogens, nordazepam, lidocaine, oxazepam, warfarin, phenacetin, caffeine, theophylline, imipramine, and pentazocine. Other reported effects of smoking include reduced analgesic efficacy of propoxyphene, reduced diuretic response to furosemide, and altered pharmacological response to propranolol, as well as altered rates of ulcer healing with H2-antagonists.
Both smoking and nicotine can increase levels of circulating cortisol and catecholamines. Dosages of nifedipine, adrenergic agonists, or adrenergic blocking agents may need to be adjusted.
Smoking cessation, even under (partial) nicotine substitution with Nicotinell TTS, may eliminate the above-mentioned phenomena. Therefore, in patients who are being treated with the above-mentioned drugs while undergoing smoking cessation, it may be necessary to adapt the dosage of the co – medication. Owing to the various pharmacological effects of nicotine on the sympathetic and parasympathetic nervous systems, the action of betablockers may be influenced in various ways.

Overdosage
Toxic effects
The toxicity of nicotine cannot be directly compared to that of smoking, because tobacco smoke contains additional toxic substances (eg. carbon monoxide, irritant gases, and tar)

Chronic smokers can endure doses of nicotine that would be more toxic in a non-smoker, owing to the development of tolerance.
Application of several Nicotinell TTS patches could result in serious overdosage.
Slower absorption after cutaneous exposure to nicotine favour the development of tolerance to toxic effects.
Rapid systemic delivery of nicotine from Nicotinell TTS would not be expected on chewing and swallowing, owing to the slow release of nicotine from the patch and first-pass metabolism.

Acute effects
The acute fatal dose of nicotine in adults is 40-60mg nicotine orally. This is equal to the amount of nicotine in 4-6 cigarettes or in a cigar. In children, the following symptoms have been described after ingestion of tobacco products: vomiting, nausea, diarrhoea, pallor, weakness, absence of reactions, and twitching of the extremities.

Acute toxic effects
Signs and symptoms of overdosage would be the same as those of acute nicotine poisoning. In non- smokers, these include pallor, sweating, nausea, salivation, vomiting, abdominal cramps, diarrhea, headache, dizziness, hearing and vision disturbances, tremor, mental confusion, muscle weakness, convulsions, prostration, absence of neurological reactions, and respiratory failure. Lethal doses may produce exhaustion, seizures, low blood pressure leading to circulatory collapse or respiratory failure may occur.

Chronic effects
The development of tachyphylaxis is a feature of chronic smoking, which means that chronic smokers can tolerate acute, highly toxic doses of nicotine.
Chronic overdosage may produce symptoms similar to those characteristic of acute nicotine poisoning.

Management
If the patient shows signs of overdosage, Nicotinell TTS should be removed immediately. The skin surface may be washed with water and dried (no soap should be used). The skin will continue to deliver nicotine into the blood stream for several hours after removal of the system, possibly because of a depot of nicotine in the skin. Other treatment measures for acute nicotine poisoning include artificial respiration in the case of respiratory paralysis, maintaining normal body temperature, and treatment for hypotension and cardiovascular collapse.

Further remarks
Incompatibilities
Local tolerability of Nicotinell TTS: In transdermal drug administration a distinction should be made between skin tolerability of the active substance (in this case nicotine) and that of the system itself.

Safety note concerning children
Nicotine is a highly toxic substance. Even small quantities of nicotine are dangerous and possibly life-threatening in children. In other words, application of Nicotinell TTS in play can be fatal for children if not noticed on time. Nicotinell TTS must therefore be kept out of reach of children at all times. If poisoning is suspected in a child, consult a healthcare professional immediately.
To protect children, Nicotinell TTS is sealed in a child-resistant sachet. This sachet should be opened immediately before use with a pair of scissors, taking care that the patch inside is not damaged. The patches still contain nicotine after removal and should be disposed of carefully and kept out the sight and reach of children.

Use and Handling
When you take off a patch, fold it in half with a sticky side inwards and place it in the sachet from which you have just taken your new patch.
Dispose the sachet containing the used patch carefully, making sure it is out of the reach of children or pets.

Storage
Store below 30°C
The product may be used up to the date <EXP> shown on the pack

Packaging
Nicotinell TTS 10: 7 and 28 systems
Nicotinell TTS 20: 7 and 28 systems
Nicotinell TTS 30: 7 and 28 systems
For further pack sizes, see country-specific information

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