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Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

Nicorette Invisi Patch (nicotine) Product Information

See SmPC for full information

Presentation: Transdermal delivery system available in 3 sizes (22.5, 13.5 and 9cm²) releasing 25mg, 15mg and 10mg of nicotine respectively over 16 hours.

Uses: Nicorette Invisi Patch relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them. Nicorette Invisi Patch is indicated in pregnant and lactating women making a quit attempt. If possible, Nicorette Invisi Patch should be used in conjunction with a behavioural support programme.

Dosage: It is intended that the patch is worn through the waking hours (approximately 16 hours) being applied on waking and removed at bedtime. **Smoking Cessation: Adults (over 18 years of age):** For best results, most smokers are recommended to start on 25 mg / 16 hours patch (Step 1) and use one patch daily for 8 weeks. Gradual weaning from the patch should then be initiated. One 15 mg/16 hours patch (Step 2) should be used daily for 2 weeks followed by one 10 mg/16 hours patch (Step 3) daily for 2 weeks. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) are recommended to start at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg for the final 4 weeks. Those who experience excessive side effects with the 25 mg patch (Step 1), which do not resolve within a few days, should change to a 15 mg patch (Step 2). This should be continued for the remainder of the 8week course, before stepping down to the 10 mg patch (Step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought. **Adolescents (12 to 18 years):** Dose and method of use are as for adults however; recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought. **Smoking Reduction/Pre-Quit:** Smokers are recommended to use the patch to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. Starting dose should follow the smoking cessation instructions above i.e. 25mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day and for lighter smokers are recommended to start at Step 2 (15 mg). Smokers starting on 25mg patch should transfer to 15mg patch as soon as cigarette consumption reduces to less than 10 cigarettes per day. A quit attempt should be made as soon as the smoker feels ready. When making a quit attempt, smokers who have reduced to less than 10 cigarettes per day are

recommended to continue at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg (Step 3) for the final 4 weeks. **Temporary Abstinence:** Use a Nicorette Invisi Patch in those situations when you can't or do not want to smoke for prolonged periods (greater than 16 hours). For shorter periods then an alternative intermittent dose form would be more suitable (e.g. Nicorette inhalator or gum). Smokers of 10 or more cigarettes per day are recommended to use 25mg patch and lighter smokers are recommended to use 15mg patch.

Contraindications: Children under 12 years of age. Known hypersensitivity to nicotine or any component in the patch.

Precautions: Underlying cardiovascular disease, diabetes mellitus, renal or hepatic impairment, seizures, phaeochromocytoma or uncontrolled hyperthyroidism, generalised dermatological disorders, gastrointestinal disease. Angioedema and urticaria have been reported. Erythema may occur. If severe or persistent, discontinue treatment. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response, to adenosine. Keep out of reach and sight of children and dispose of with care. Should be removed prior to undergoing MRI procedures.

Pregnancy and lactation: Smoking cessation during pregnancy should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional.

Side effects:

Very common: pruritus.

Common: headache, dizziness, nausea, rash, urticaria, vomiting.

Uncommon: hypersensitivity, palpitations, paraesthesia, tachycardia, flushing, hypertension, hyperhidrosis, myalgia, application site reactions, asthenia, chest discomfort and pain, malaise, fatigue, dyspnoea.

Rare: Anaphylactic reaction, GI discomfort, angioedema, erythema, pain in extremity. Very rare: reversible atrial fibrillation.

Not known: seizures

RRP (ex-VAT): 25mg packs of 7: £17.01, 25mg packs of 14: £27.93, 15mg packs of 7: £17.00, 10mg packs of 7: £17.01

Legal category: GSL

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