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**Adverse events should also be reported to
McNeil Products Limited on 0808 238 9999.**

Nicorette Invisi Patch (Nicotine) Prescribing Information

See SmPC for full information

Presentation:

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

Uses:

Nicorette Invisi Patch relieves and/or prevents craving and nicotine withdrawal symptoms in nicotine dependence, such as those arising from the use of tobacco or electronic cigarettes. It is indicated to aid quitting or reduction prior to quitting, to assist those who are unwilling or unable to use such products, and as a safer alternative to smoking tobacco for smokers and those around them. Nicorette Invisi Patch is indicated in pregnant and lactating women making a quit attempt.

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/Vaping Cessation: *Adults (over 18 years of age):* For best results, most smokers/vapers 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 who smoke less than 10 cigarettes per day and light to moderate vapers who vape infrequently or use low strength e-liquid 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 8-week 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/vapers are recommended to use the patch to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible. Starting dose should follow the smoking/vaping cessation instructions above i.e. wherein 25 mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day or heavy vapers who vape frequently or use high strength e-liquid, and, while 15 mg (Step 2) is suitable for lighter smokers or light to moderate vapers are recommended to start at Step 2 (15 mg). Smokers/vapers starting on 25

mg patch should transfer to 15 mg patch as soon as cigarette consumption reduces to less than 10 cigarettes per day or as vaping dependency decreases. A quit attempt should be made as soon as the smoker/vaper 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. When vapers have reduced their dependency sufficiently (e.g. vape infrequently or use low strength e-liquid), they should continue at Step 2 (15 mg) for 8 weeks and then step down 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 or vape 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 or heavy vapers are recommended to use 25 mg patch and lighter smokers or light to moderate vapers are recommended to use 15 mg patch.

Contraindications:

Nicorette Invisi Patch is contraindicated in children under 12 years of age and in individuals with known hypersensitivity to nicotine or any component in the patch.

Precautions:

Any risks that may be associated with NRT use are substantially outweighed by the well-established dangers of continued smoking. The risks of continued vaping are not yet established. A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions: 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. This product may enhance the haemodynamic effects of, and pain response, to adenosine. Doses of nicotine tolerated by adult and adolescent smokers/vapers can produce severe toxicity in children that may be fatal. Keep out of reach and sight of children and dispose of with care. Nicorette Invisi Patch should be removed prior to undergoing MRI procedures.

Pregnancy and Lactation:

During pregnancy, nicotine passes to the foetus and affects its breathing movements and circulation. The effect on circulation is dose dependent. Smoking/vaping 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 as the risk to the foetus with NRT is lower than that expected with smoking tobacco. If patches are used as they should, if possible, these should be removed at night when the foetus would not normally be exposed to nicotine. Nicotine should be avoided during breastfeeding; however, the relatively small amounts of nicotine found in breast milk during NRT use are less hazardous to the infant than second-hand smoke. Intermittent dose forms would minimize the amount of nicotine in breast milk and permit feeding when levels were at their lowest. There is no or limited data regarding the effect of vaping in pregnant and lactating women.

Side effects:

Very common: pruritus.

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

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

Rare: anaphylactic reaction, gastrointestinal discomfort, angioedema, erythema, pain in extremity.

Very rare: reversible atrial fibrillation.

Not known: seizures

The nicotine withdrawal effects of vaping cessation have not been established; however, it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation.

NHS cost: 25 mg packs of 7: £111.61, 25 mg packs of 14: £22.07, 15 mg packs of 7: £111.61, 10 mg packs of 7: £111.61

Legal category: GSL

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG

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