SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette invisi 15 mg patch

NicAssist Translucent 15 mg Patch.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each patch is 13.5 sq.cm, containing nicotine 1.75 mg/sq.cm, releasing a nominal 15 mg of nicotine per 16 hours.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch.

Semi-transparent, beige, imprinted 13.5 cm^2 rectangular TTS with rounded corners. Centrally located on a rectangular, aluminized and siliconised release liner.

4.1 Therapeutic indications

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 (see section 4.6).

4.2 Posology and method of administration

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate.

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.

	Dose	Duration
Step 1	Nicorette Invisi 25 mg Patch	First 8 weeks
Step 2	Nicorette Invisi 15 mg Patch	Next 2 weeks
Step 3	Nicorette Invisi 10 mg Patch	Last 2 weeks

Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. 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 / 16 hours patch (Step 1), which do not resolve within a few days, should change to a 15 mg / 16 hours patch (Step 2). This should be continued for the remainder of the 8 week course, before stepping down to the 10 mg / 16 hours patch (Step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought.

Adolescents (12 to 18 years)

The dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

Smoking/Vaping 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.

The starting dose should follow the smoking/vaping cessation instructions above i.e. 25 mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day or heavy vapers (e.g. vape frequently or use high strength e-liquid Lighter smokers (i.e. those who smoke less than 10 cigarettes per day)

and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to start at Step 2 (15 mg).

Smokers/vapers starting on 25 mg patch (Step 1) should transfer to 15 mg patch (Step 2) as soon as cigarette consumption reduces to less than 10 cigarettes per day or vaping dependency decreases.

A quit attempt should be made as soon as the smoker/vaper feels ready. When making a quit attempt patients 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/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 (e.g. vape frequently or use high strength e-liquid) are recommended to use 25 mg patch. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) and light to moderate vapers (e.g. vape infrequently or use low strength e-liquid) are recommended to use 15 mg patch.

How to apply the patches
Nicorette Invisi Patch should be applied to clean, dry intact areas of hairless skin, for example on the hip, upper arm, or chest. These areas should be varied each day, and the same site should not be used on consecutive days.

1. Wash your hands before applying the patch.
2. Cut open the pouch with scissors along the side, as indicated. Select a clean, dry, hairless intact area of skin, such as the hip, upper arm or chest.
3. Peel one part of the silvery aluminium backing away. Avoid touching the sticky surface of the patch with your fingers.
4. Apply the sticky part of the patch carefully onto the skin and peel off the remaining half of the silvery aluminium backing.
5. Press the patch firmly onto the skin with your palm or fingertips.
6. Rub your fingers firmly round the edge to ensure that the patch sticks firmly.

Use of skin oils or talc can prevent proper adhesion of the patch.

After removal, used patches should be disposed of carefully.

4.3 Contraindications

Nicorette Invisi Patches should not be administered to patients with known hypersensitivity to nicotine or any component of the patch.

4.4 Special warnings and precautions for use

Any risks that may be associated with NRT 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: In stable cardiovascular disease this product presents a lesser hazard than continuing to smoke. However dependent smokers currently hospitalised as a result of myocardial infarction, unstable or worsening angina including Prinzmetal angina, severe dysrhythmia or CVA and who are considered to be haemodynamically unstable and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, this product may be considered, but as data on safety in this patient group are limited, initiation should only be under medical supervision. The risks of continued vaping are not yet established.

Diabetes mellitus: Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when quitting and NRT is initiated as reductions in nicotine induced catecholamine release can affect carbohydrate metabolism.

Renal or hepatic impairment: This product should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects.

Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy as cases of convulsions have been reported in association with nicotine.

Danger in children: Doses of nicotine tolerated by adult and adolescent smokers or vapers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children. After removal, the patch should be folded in half, adhesive side innermost, and placed inside the opened sachet, or in a piece of aluminium foil. The used patch should then be disposed of carefully, away from the reach of children or animals.

Phaeochromocytoma and uncontrolled hyperthyroidism: As nicotine causes release of catecholamines, this product should be used with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma.

Transferred dependence: Transferred dependence is rare and is both less harmful and easier to break than smoking dependence.

Stopping smoking: Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole.

Gastrointestinal Disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions.

Generalised dermatological disorders: Patients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use this product.

Angioedema and urticaria have been reported.
Erythema may occur. If it is severe or persistent, treatment should be discontinued.

Minor skin reactions are seen at the patch application site in a proportion of patients when commencing treatment (see also section 4.8). If skin reactions become more severe or more generalized, patients should be advised to discontinue use of patches and seek further medical help regarding nicotine replacement therapy.

This product should be removed prior to undergoing any Magnetic Resonance Imaging (MRI) procedures to prevent the risk of burns.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

4.6 Fertility, pregnancy and lactation

Pregnancy
Stopping smoking is the single most effective intervention for improving the health of both the pregnant smoker and her baby, and the earlier abstinence is achieved the better. Ideally smoking cessation during pregnancy should be

achieved without NRT. Nicotine passes to the foetus and affects its breathing movements and circulation. The effect on the circulation is dose-dependent. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used as the risk to the foetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable Nicorette Invisi Patch may be used in pregnancy as a safer alternative to smoking. Because of the potential for nicotine-free periods, intermittent dose forms are preferable, but patches may be considered as an alternative if there is significant nausea and/or vomiting. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

There is no or limited data regarding the effect of vaping in pregnancy.

Use of NRT by the pregnant smoker/vaper should only be initiated after advice from a health care professional.

Lactation
Nicotine should be avoided during breast-feeding. 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 lactating women.

Use of NRT by breast feeding smokers/vapers should only be initiated after advice from a health care professional.

Fertility
In females tobacco smoking delays time to conception, decreases in-vitro fertilization success rates, and significantly increases the risk of infertility.

In males tobacco smoking reduces sperm production, increases oxidative stress, and DNA damage. Spermatozoa from smokers have reduced fertilizing capacity.

The specific contribution of nicotine to these effects in humans is unknown.

There is no or limited data regarding the effect of vaping on fertility.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Effect of Smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include irritability/aggression, dysphoria/depressed mood, anxiety, restlessness, poor concentration, increased appetite/weight gain, urges to smoke (cravings), night-time awakenings/sleep disturbance, decreased heart rate, dizziness, presyncopal symptoms, cough, constipation, gingival bleeding or nasopharyngitis. Increased frequency of aphthous ulcer may occur after abstinence from smoking. The causality is unclear.

Effects of Vaping Cessation
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.

Adverse Drug Reactions (ADRs)
This product may cause adverse reactions similar to those associated with nicotine given by other means, including smoking and vaping, and these are mainly dose-dependent. At recommended doses this product has not been found to cause any serious adverse effects. Excessive use of this product by those who have not been in the habit of inhaling tobacco smoke or vaping could possibly lead to nausea, faintness or headaches.

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent.

About 20% of Nicorette Invisi Patch users experience mild local skin reactions, during the first weeks of treatment. In some patients the skin reactions may become more severe e.g. skin blistering or burning sensation or may be more generalized (see section 4.4).

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of this product.

Adverse events observed in patients treated with nicotine patch formulations during clinical trials and post-marketing surveillance are listed below by system organ class (SOC).

*Frequencies are defined in accordance with current guidance, as: *very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1 000, <1/100); rare (≥1/10 000, <1/1 000); very rare (<1/10 000), not known - cannot be estimated from the available data. ** Frequency category estimated using the "Rule of 3"

Body System	**Reported adverse event (Preferred Term)**	**Incidence***

Body System	**Reported adverse event (Preferred Term)**	**Incidence***
Immune system disorders	Hypersensitivity[a#]	Uncommon
	Anaphylactic reaction[a]	Rare**
Nervous system disorders	Dizziness Headache[a§]	Common
	Paraesthesia[a#]	Uncommon
	Seizures	Not known
Cardiac disorders	Palpitations[a] Tachycardia[a]	Uncommon
	Reversible atrial fibrillation	Very rare
Vascular disorders	Flushing[a] Hypertension[a]	Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Dyspnoea[a]	Uncommon
Gastrointestinal disorders	Nausea[a§] Vomiting[a]	Common
	Gastrointestinal discomfort[a]	Rare**
Skin and subcutaneous tissue disorders	Pruritus	Very common
	Rash[a] Urticaria[a]	Common
	Hyperhidrosis[a]	Uncommon
	Angioedema[a] Erythema[a]	Rare**
Musculoskeletal and Connective Tissue Disorders	Myalgia[b]	Uncommon
	Pain in extremity	Rare**

Body System	Reported adverse event (Preferred Term)	Incidence*
General disorders and administration site conditions	Application site reactions Asthenia[a] Chest discomfort and pain[a] Malaise[a] Fatigue[a#§]	Uncommon

[a] Systemic effects; [b] In vicinity/region of patch
[#] Although the frequency is <1% the PT occurred at a frequency ≥1% in another formulation in which the PT was identified as a systemic ADR.
[§] Although the frequency in the active group is less than that of the placebo group, the frequency in the specific formulation in which the PT was identified as a systemic ADR was greater in the active group than the placebo group.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: Symptoms of overdose with nicotine from this product may occur in smokers/vapers who have previously had a low nicotine intake from cigarettes/e-cigarettes or if other sources of nicotine are used concomitantly with this product.

Acute or chronic toxicity of nicotine in man is highly dependent on mode and route of administration. Adaptation to nicotine (e.g. in smokers/vapers) is known to significantly increase tolerability compared with non-smokers/vapers.

The minimum lethal dose of nicotine in a non-tolerant man has been estimated to be 40 to 60 mg. Symptoms of acute nicotine poisoning include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In extreme cases, these symptoms may be followed by hypotension, rapid or weak or irregular pulse,

breathing difficulties, prostration, circulatory collapse and terminal convulsions.

Management of an overdose: All nicotine intake should stop immediately and the patient should be treated symptomatically. Remove the patch and rinse the application site with water. Artificial respiration should be instituted if necessary. Activated charcoal reduces the gastro-intestinal absorption of nicotine.

Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in children and may prove fatal. Suspected nicotine poisoning in a child should be considered a medical emergency and treated immediately.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.
ATC code: N07B A01

Nicotine has no therapeutic uses except as replacement therapy for the relief of abstinence symptoms in nicotine-dependent smokers/vapers.

Owing to its many actions, the overall effects of nicotine are complex. A wide variety of stimulant and depressant effects are observed that involve the central and peripheral nervous, cardiovascular, endocrine, gastro-intestinal and skeletal motor systems. Nicotine acts on specific binding sites or receptors throughout the nervous system.

Increased appetite is a recognised symptom of nicotine withdrawal and post-cessation weight gain is common. Clinical trials have demonstrated that Nicotine Replacement Therapy can help control weight following a quit attempt.

5.2 Pharmacokinetic properties

The patches are labelled by the average amount of nicotine released over 16 hours.

A linear relationship exists between released amount of nicotine (dose) and plasma levels of nicotine over the therapeutic dose range, 10-25 mg/16 hours The mean peak plasma levels of nicotine (C_{max}) achieved are calculated to:

Dose nicotine (mg/16 hours)	C_{max} (ng/ml)
10	10
15	15.5
25	26.5

The calculated peak plasma levels are in the same range as true measured peak

plasma concentrations: 11 ng/mL for the 10 mg patch and 25 ng/mL for the 25 mg patch. Interpolation yields a peak plasma concentration of 16 ng/m for the 15 mg patch.

The maximum level of plasma concentration after administration is reached after approximately 9 hours (t_{max}). The plasma peak is in the afternoon/ evening when the risk of relapse is highest.

The volume of distribution of nicotine is about 2 to 3 L/kg and the half-life approximately 3 hours. The major eliminating organ is the liver, and average plasma clearance is about 70 L/hour. The kidney and lung also metabolise nicotine. More than 20 metabolites of nicotine have been identified, all of which are believed to be less active than the parent compound.

Plasma protein binding of nicotine is less than 5%. Therefore, changes in nicotine binding from use of concomitant drugs or alterations of plasma proteins by disease states would not be expected to have significant effects on nicotine kinetics.

The primary metabolite of nicotine in plasma, cotinine, has a half-life of 15 to 20 hours and concentrations that exceed nicotine by 10-fold.
The primary urinary metabolites are cotinine (12% of the dose) and trans-3-hydroxy-cotinine (37% of the dose). About 10% of nicotine is excreted unchanged in the urine.

Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Raised nicotine levels have been seen in smoking patients undergoing haemodialysis.

The pharmacokinetics of nicotine is unaffected in cirrhotic patients with mild liver impairment (Child score 5) and nicotine clearance is decreased in cirrhotic patients with moderate liver impairment (Child score 7).

A minor reduction in total clearance of nicotine has been demonstrated in healthy elderly patients, however, not justifying adjustment of dosage.

Plasma nicotine concentrations show dose proportionality for the three patch doses.

5.3 Preclinical safety data

Preclinical data indicate that nicotine is neither mutagenic nor genotoxic.

There are no other findings derived from preclinical testing of relevance to the prescriber in determining the safety of the product which have not been considered in other relevant sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium-chain
basic butylated methacrylate copolymer
Polyethylenterephthalate film (PET)

Acrylate Matrix

Acrylic adhesive solution
Potassium hydroxide
Croscarmellose sodium
Aluminium acetylacetonate

Release Liner

Polyethylenterephthalate (PET) film single side aluminised, both sides siliconised

Printing Ink Solution

Blending varnish
Printing ink brown

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and contents of container

Package sizes: 15 mg/16 h 7 and 14 patches
All pack sizes may not be marketed.
Each patch is packed in a heat-sealed laminate pouch consisting of paper, PET film, aluminium acrylnitrilcopolymer or cyclo olefine copolymer coextrudate.

6.6 Special precautions for disposal

Nicotine residues in the used patches may present a hazard to children and pets, thus used patches should be folded, sticky sides together, put back in an empty pouch and placed in household rubbish.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
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Station Hill
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8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0160

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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