SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette Nasal Spray
Boots NicAssist 10 mg/ml Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotine 10 mg/ml. Each spray of 50 µl delivers 0.5 mg nicotine.

Excipient(s) with known effect
Methyl parahyroxybenzoate
Propyl parahydroxybenzoate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal Spray, solution.

4.1 Therapeutic indications

Nicorette Nasal Spray 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.

It is also indicated in pregnant and lactating women making a quit attempt.

4.2 Posology and method of administration

The patient should make every effort to stop smoking/vaping completely during treatment with Nicorette Nasal Spray.

Behavioural therapy, advice and support will normally improve the success rate.

This product must only be used with other NRT products under the advice of a healthcare professional.

This product is sprayed into the nostril when the unit is activated. If the eyes are sprayed, rinse thoroughly with water.

Directions for use

1) Remove the protective cap.
2) Prime Nicorette Nasal Spray by placing the nozzle between first and second finger with the thumb on the bottom of the bottle. Press several times firmly and quickly until a fine spray appears (up to 7-8 strokes). **Important**: Point the spray safely away when priming it. Do not prime it near children or pets.
3) Insert the spray tip into one nostril, pointing the top towards the back of the nose. Press firmly and quickly. Give a spray into the other nostril.
4) Put on the protective cap

Smoking/Vaping Cessation

Adults (over 18 years of age)

1. The frequency of use depends on the previous smoking/vaping habit of the individual and the level of their nicotine dependence.
2. On commencing treatment the patient uses the spray to treat craving as required, subject to a limit of one spray to each nostril twice an hour.
3. A 50 µl dose of solution is sprayed into the nostril when the unit is activated. This is described as a "spray" and dosage is described using this term. Each spray delivers 0.5 mg of nicotine, about half of which is absorbed.
4. The daily limit of use is 32 mg of nicotine (64 sprays) which is the equivalent of two sprays to each nostril every hour for 16 hours.
5. The method of use of the spray should be according to the instructions.
6. The 3 month course should take the following pattern:
    a. For 8 weeks the patient uses the spray as required, subject to the maxima described above, to relieve craving.
    b. After this period the patient reduces usage until after 4 more weeks treatment has ended. It is suggested that after 2 weeks into this period usage will have been reduced by a half and usage be zero by the last day. Spraying into a single nostril during this period may be helpful in achieving this.
    c. Treatment should be limited to three months. The patient should understand the aim of decreasing the use of the spray to make a final break with nicotine at the end of the course, and also accept that for the first few days of the course nasal irritation may be unpleasant.

Adults who use NRT beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

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

Adults (over 18 years of age)
Use this product between smoking/vaping episodes to manage the urge to smoke/vape, to prolong smoke/vape-free intervals and with the intention to reduce smoking/vaping as much as possible. If a reduction in number of cigarettes/e-cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the patient feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking/vaping cessation instructions above can be followed.

Adolescents (12 to 18 years)
Where adolescents are motivated to stop smoking/vaping abruptly, smoking/vaping cessation should be recommended. However, smoking/vaping reduction can be considered where adolescents are not ready or able to stop smoking/vaping abruptly. As data are limited in this age group, and the recommended duration of NRT is 12 weeks, adolescents should consult a healthcare professional before starting the "smoking/vaping reduction prior to stopping" regimen.

Use this product between smoking/vaping episodes, as needed to manage the urge to smoke/vape, to prolong smoke/vape-free intervals and to reduce their use as much as possible. If a reduction in number of cigarettes/e-cigarettes per day has not been achieved after 6 weeks, professional advice should be sought.

A quit attempt should be made as soon as the patient feels ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

When making a quit attempt the smoking/vaping cessation instructions for adolescents (12 to 18 years) given above can be followed.

4.3. Contraindications

Hypersensitivity to any component of the nasal spray.
Nicorette Nasal Spray is contraindicated in children under the age of 12 years.

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 catecholamines release can affect carbohydrate metabolism.

GI disease: Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and NRT preparations should be used with caution in these conditions. Ulcerative stomatitis has been reported.

Renal or hepatic impairment: Nicorette Nasal Spray 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.

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.

Bronchial asthma: A few cases of exacerbation of bronchospasm in patients with bronchial asthma have been reported. Use of the spray in patients with hyperreactive airways is not recommended.

Excipients: This product contains methyl- and propyl- hydroxybenzoates (E217 and E218); which may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm.

A clinical study confirms the safe use of this product, by smokers with chronic rhinitis and sinusitis.

Care should be taken not to spray the eyes whilst administering the spray.

4.5 Interaction with other medicinal products and other forms of interactions

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

NRT is not contraindicated in pregnancy. The decision to use NRT should be made on a risk-benefit assessment as early on in the pregnancy as possible with the aim of discontinuing use as soon as possible.

Smoking during pregnancy is associated with risks such as intra-uterine growth retardation, premature birth or stillbirth. Stopping smoking is the single most effective intervention for improving the health of both pregnant smoker and her baby. 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 for women unable to quit on their own, NRT may be recommended to assist a quit attempt.

However the risk of using NRT to the foetus is lower than that expected with tobacco smoking, due to lower maximal plasma nicotine concentration and no additional exposure to polycyclic hydrocarbons and carbon monoxide.

Because of the potential for nicotine-free periods, intermittent dose forms are preferable as these usually provide a lower daily dose of nicotine than patches. However, patches may be considered if the woman is suffering from nausea during pregnancy. If patches are used they should be removed before going to bed.

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. However, NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk. However the amount of nicotine the infant is exposed to is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to.

Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be more easily prolonged.

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. Women should use the product as soon as possible after breastfeeding.

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

The nasal spray should not be used whilst the user is driving or operating machinery as sneezing and watering eyes could contribute to accidents.

4.8 Undesirable effects

Effects 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 with tobacco smoking cessation.

Adverse Drug Reactions

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.

During the first 2 days of treatment, nasal irritation as sneezing, running nose, watering eyes, cough was reported by nearly all (94%) of the patients. Both the frequency and severity declined with continued use.

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

The adverse reactions observed in patients treated with nicotine nasal spray formulations during clinical trials and post-marketing experience 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).

System Organ Class	**Reported Adverse Event**	**Incidence**
Immune System Disorders	Hypersensitivity[ac#] Anaphylactic reaction[b]	Uncommon Not known
Psychiatric Disorders	Abnormal dreams[*]	Uncommon
Nervous System Disorders	Headache[a] Dizziness Paraesthesia[a] Seizures	Common Common Common Not known
Eye Disorders	Lacrimation increased	Not known
Cardiac Disorders	Palpitations[a] Atrial fibrillation Tachycardia[a]	Common Very rare Not known
Vascular Disorders	Flushing[a] Hypertension[a]	Uncommon Uncommon
Respiratory, Thoracic and Mediastinal Disorders	Rhinorrhoea Cough[**] Throat irritation** Dyspnoea[a] Epistaxis Nasal discomfort Oropharyngeal discomfort and pain Sneezing	Very common Common Common Common Common Not known Not known Not known
Gastrointestinal Disorders	Nausea[a] Vomiting[a] Gastrointestinal discomfort[a]	Common Common Not known
Skin and Subcutaneous Tissue Disorders	Hyperhidrosis[a] Pruritus[a] Rash[a] Angioedema[a] Erythema[a]	Common Common Common Not known Not known

	Urticaria[a]	Not known
General Disorders and Administration Site Conditions	Chest discomfort and pain[a] Fatigue[ac] Malaise[a] Asthenia[a]	Common Uncommon Uncommon Not known

[a] Systemic effects; [b] Reported the same or less frequently than placebo.
[c] 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
[*]Identified only for formulations applied during the night
**Higher frequency observed in clinical studies with inhaler formulation.
[#] 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. 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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.

ATC code: N07B A01

Through rapid uptake of nicotine through the nasal membranes Nicorette Nasal Spray provides early relief of nicotine withdrawal symptoms. Clinical studies have shown that the nicotine containing products can help people give up smoking.

5.2 Pharmacokinetic properties

Following administration of one dose Nicorette Nasal Spray approximately 56% of the nicotine enters the systemic circulation.

The volume of distribution following i.v. administration of nicotine is approximately (2 to) 3 l/kg and the half-life ranges from 1 to 2 hours. The major eliminating organ is the liver, and average plasma clearance is about 1.2 l/min; 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. 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.

Plasma protein binding of nicotine is <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 a significant effect on the nicotine kinetics.

The primary urinary metabolites are cotinine (15% of dose) and trans-3-hydroxycotinine (45% of the dose). Usually about 10% of nicotine is excreted unchanged in the urine. As much as 30% may be excreted in the urine with high urine flow rates and acidification below pH5.

Plasma levels of nicotine obtained with Nicorette Nasal Spray rise rapidly, reaching a maximum level – mean – after approximately 10-15 minutes. The mean peak plasma level of nicotine – after steady –state is achieved – given 1 dose/hour, 2 doses/hour and 3 doses/hour approximately 10, 19 and 28 ng/ml respectively.

After repeated administration of the Nicorette Nasal Spray the AUC was significantly higher during the last dosing interval as compared to the first giving an accumulation ratio of 3.1. No dose-dependency has been shown for the doses 0.5 mg and 1 mg nicotine.

The therapeutic blood concentrations of nicotine, (i.e. the blood levels which relieve craving) are individually based on the patient's nicotine dependence.

5.3 Preclinical safety data

No further information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate

Sodium dihydrogen phosphate dihydrate

Anhydrous citric acid

Sodium chloride

Polysorbate 80

NNS aroma DZ-03226 (B-ionine)

Methyl parahydroxybenzoate

Propyl parahydroxybenzoate

Disodium edetate

Purified water

6.2 Incompatibilities

None relevant.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

No special temperature conditions. Should be stored protected from light.

6.5 Nature and contents of container

The solution is filled in a Type III Amber glass container equipped with a spray pump consisting of a polypropylene nosepiece, a polyoxymethylene nozzle and a polypropylene protective cap.
Pack size: 10ml. Each bottle provides approximately -175 metered sprays / 100 doses.

6.6. Special precautions for disposal and handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
1 Station Hill Square
Station Hill
Reading
RG1 1LN
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0180

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 February 2008

10 DATE OF REVISION OF THE TEXT

02/04/2026