SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nicorette QuickMist Spearmint 1mg/spray mouthspray
Nicorette QuickMist Spearmint SmartTrack 1mg/spray mouthspray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

0.07 ml contains 1 mg nicotine, corresponding to 1 mg nicotine/spr-ay dose.
Excipients with known effect:
Ethanol 7.1mg/spray
Propylene glycol 11.7mg/spray
Butylated hydroxytoluene 368ng/spray

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray.

A clear to weakly opalescent, colourless to light yellow solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product 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.

This product is 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 or vaping completely during treatment with this product.

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

Directions for use

For those using this product for the first time or those who have not used the spray for 2 days, they must first prime the spray pump.
Priming

1. Point the spray safely away from you and any other adults, children or pets that are near you.
2. Press the top of the QuickMist with your index finger 3 times until a fine spray appears.

Note: priming reduces the number of sprays you may get from this product.

After priming, point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into your mouth, avoiding the lips. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.
The patient should not eat or drink when administering the oromucosal spray. Care should be taken not to spray the eyes whilst administering the mouth spray.

Adults and Children over 12 years of age

Use 1 or 2 sprays when you would normally have smoked or vaped or if cravings emerge. If after the first spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays.
Most smokers will require 1-2 sprays every 30 minutes to 1 hour.

You may use up to 4 sprays per hour. Do not exceed 2 sprays per dosing episode and 64 sprays (4 sprays per hour over 16 hours) in any 24-hour period.

Each mouthspray contains at least 150 sprays.

This product should be used whenever the urge to smoke or vape is felt or to prevent cravings in situations where these are likely to occur.

Patients willing or able to stop smoking/vaping immediately should initially replace all their cigarettes/e-cigarettes with this product and as soon as they are able, reduce the number of sprays used until they have stopped completely.

Patients aiming to reduce cigarettes/e-cigarettes should use the Mouthspray, between smoking/vaping episodes, as needed, to prolong smoke/vape-free intervals and to reduce their use as much as possible.

As soon as they are ready patients should aim to quit smoking/vaping completely.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking/vaping but are having difficulty discontinuing their Mouthspray are recommended to contact their pharmacist or doctor for advice.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients of the mouthspray listed in section 6.1.

This product is contraindicated in children under 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's angina, severe dysrhythmia or cerebrovascular accident 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 released by nicotine 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.

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.

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.

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. See Section 4.9 Overdose.

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.

Excipients: The mouthspray contains about 7 mg of alcohol (ethanol) in each spray which is equivalent to 97 mg/ml. The amount in one spray of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. This medicine contains about 12 mg propylene glycol in each spray which is equivalent to 157 mg/mL. Due to the presence of a small amount of butylated hydroxytoluene (BHT), this medicine may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. This medicine contains less than 1 mmol sodium (23 mg) per spray, i.e. is essentially ‘sodium- free’.
Care should be taken not to spray the eyes whilst administering the spray.

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

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.

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 fetus is lower than that expected with smoking tobacco. Stopping completely is by far the best option but if this is not achievable this product 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 fetus would not normally be exposed to nicotine.

Use of nicotine by the pregnant smoker should only be initiated after advice from a health care professional.
There is no or limited data regarding the effect of vaping in pregnancy.

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.
Use of the nicotine by breast feeding smokers should only be initiated after advice from a health care professional. Women should take the product as soon as possible after breastfeeding.

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

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

Effects of smoking Cessation
Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include the following: dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, restlessness or impatience; decreased heart rate; and increased appetite or weight gain. These have been observed in those using the mouthspray.

Increased frequency of aphthous ulcer, cough and nasopharyngitis may occur after abstinence from smoking. The causality is unclear.

In addition to this, other cessation-associated symptoms were seen in those using the mouth spray: dizziness, presyncopal symptoms, constipation, and gingival bleeding.

Nicotine craving, which is recognised as a clinically relevant symptom, is an important element in nicotine withdrawal after smoking cessation.

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
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.

Most adverse events reported with this product occur during the early phase of treatment and are similar to those seen with other orally delivered forms. During the first few days of treatment irritation to the mouth and throat may be experienced and hiccups are particularly common. Tolerance is normal with continued use.

Daily collection of data from trial subjects demonstrated that very commonly occurring adverse events were reported with onset in the first 2-3 weeks of use of the spray, and declined thereafter.

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

The adverse reactions observed in patients treated with oral nicotine 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).

Body System	**Incidence**	**Reported Adverse Event (Preferred Term)**
Immune System Disorders	Common	Hypersensitivity[a]
	Not known	Anaphylactic reaction[a]
Psychiatric disorders	Uncommon	Abnormal dreams[*]
Nervous System Disorders	Very common	Headache[a#]
	Common	Burning sensation[c]
	Common	Dizziness
	Common	Dysgeusia
	Common	Paraesthesia[a]
	Not known	Seizures
Eye Disorders	Not known	Blurred Vision
	Not known	Lacrimation increased
Cardiac Disorders	Uncommon	Palpitations[a]
	Uncommon	Tachycardia[a]
	Not known	Atrial fibrillation
Vascular Disorders	Uncommon	Flushing[a]
	Uncommon	Hypertension[a]
Respiratory, Thoracic and Mediastinal Disorders	Common	Cough**
	Very common	Hiccups****
	Very common	Throat irritation **
	Uncommon	Bronchospasm
	Uncommon	Dysphonia
	Uncommon	Dyspnoea[a]
	Uncommon	Nasal congestion
	Uncommon	Oropharyngeal pain
	Uncommon	Rhinorrhoea
	Uncommon	Sneezing
	Uncommon	Throat tightness
Gastrointestinal Disorders	Very common	Nausea[a]
	Common	Abdominal pain
	Common	Diarrhoea***
	Common	Dry mouth
	Common	Dyspepsia
	Common	Flatulence
	Common	Salivary hypersecretion
	Common	Stomatitis
	Common	Toothache
	Common	Vomiting[a]
	Uncommon	Eructation

	Uncommon Uncommon Uncommon Uncommon Rare Rare Rare Not known Not known Not known	Gingivitis Glossitis Oral mucosal blistering and exfoliation Paraesthesia oral*** Dysphagia Hypoaesthesia oral*** Retching Dry throat Gastrointestinal discomfort[a] Lip pain
Musculoskeletal and connective tissue disorders	Uncommon Uncommon Not known	Pain in jaw[b] Musculoskeletal pain Muscle tightness[b]
Skin and Subcutaneous Tissue Disorders	Uncommon Uncommon Uncommon Uncommon Uncommon Not known Not known	Dry skin Hyperhidrosis[a] Pruritus[a] Rash[a] Urticaria** Angioedema[a] Erythema[a]
General disorders and administration site conditions:	Common Uncommon Uncommon Uncommon	Fatigue[a] Asthenia[a] Chest discomfort and pain[a] Malaise

[a] Systemic effects; [b] Tightness of jaw and pain in jaw with nicotine gum formulation
[c] At the application site
[*]Identified only for formulations applied during the night
[**]Higher frequency observed in clinical studies with inhaler formulation.
***Reported the same or less frequently than placebo
**** Higher frequency observed in clinical studies with mouth spray 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

When used as directed, symptoms of overdose with nicotine may occur in patients with low pre-treatment nicotine intake or if other sources of nicotine are used concomitantly.

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 60mg. Symptoms of overdose are those of acute nicotine poisoning and include nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. At high doses, these symptoms may be followed by hypotension, rapid or weak or irregular pulse, breathing difficulties, prostration, circulatory collapse and general convulsions.

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.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drug used in nicotine dependence.

ATC code: N07B A01

Nicotine is an agonist at nicotine receptors in the peripheral and central nervous system and has pronounced CNS and cardiovascular effects.

Clinical studies have shown that nicotine replacement products can help smokers abstain from use by relieving these withdrawal symptoms.

A parallel, double-blind, placebo-controlled, randomised pharmacodynamic study conducted in solus, regular vapers has shown that the mouth spray is effective in relieving momentary urges to vape (cravings) following ad lib use of the spray over 11 hours. A significantly higher proportion of subjects ($p<0.001$) in the mouth spray group (82.6%) had a maximum reduction of at least 50% vs. baseline in momentary urges-to-vape scores during the two hours follow-up compared to the placebo group (55.1%).

Compared to nicotine gum or nicotine lozenge, the absorption of nicotine from the mouth spray is more rapid (section 5.2) and based on prior experience with

nicotine replacement therapy, this will result in a faster onset of relief of cravings and other symptoms.
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 pharmacokinetics of nicotine has been extensively studied, and variations in delivery format have been found to have significant effects on rate and extent of absorption.

The pharmacokinetics of the mouth spray has been studied in 4 studies. The studies included 141 subjects.

Absorption
The oral spray form means that the nicotine dose is administered instantaneously, and as a result the absorption of nicotine from the mouth spray is rapid: In trials, nicotine uptake from the oral nicotine spray was detected at 2 minutes, the first timepoint tested.

A maximum concentration of 5.3 ng/mL is reached within 13 minutes after administration of a 2 mg dose. The nicotine AUCs over the first 10 minutes after administration of the mouth spray at a dose of 1 and 2 mg exceeds those of nicotine gum as well as nicotine lozenge at doses of 4 mg (0.48 and 0.64 h*ng/mL vs. 0.33 and 0.33 h*ng/mL).

AUC∞ estimates show the bioavailability of nicotine administered by mouth spray is somewhat higher than that of nicotine gum or lozenge. The AUC∞ of the mouth spray 2 mg measured 18.9 h*ng/mL as compared with 16.2 h*ng/mL for nicotine gum 2 mg. Allowing for differences in administered dose, bioavailability was also higher in a second study. The nicotine AUC∞ of the mouth spray 2 mg measured 14.0 h*ng/mL in comparison with 23.0 h*ng/mL and 26.7 h*ng/mL for and nicotine gum 4 mg and nicotine lozenge 4 mg, respectively.

Steady-state average nicotine plasma concentrations achieved after administration of the maximum dose (i.e. 2 sprays of the mouth spray 1 mg every 30 minutes) are approximately 28.8 ng/mL as compared with 23.3 ng/mL for nicotine gum 4 mg (1 gum, hourly) and 25.5 ng/mL for nicotine lozenge 4 mg (1 lozenge, hourly).

Given the rapid absorption and the similar, high relative bioavailability, the majority of the nicotine released from the mouth spray is apparently absorbed through the buccal mucosa.

Distribution
The volume of distribution following intravenous administration of nicotine is about 2 to 3 l/kg.

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 any significant effects on the nicotine pharmacokinetics.

Biotransformation
Nicotine metabolism and elimination are independent of the choice of nicotine formulation, and thus results from studies with intravenous administration of nicotine are used to describe biotransformation and elimination.

The major nicotine-eliminating organ is the liver, although 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.

Elimination
The average plasma clearance of nicotine is 70 l/hour and the half-life is 2-3 hours.
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. As much as 30% of nicotine may be excreted unchanged in the urine with high flow rates and acidification of the urine below pH 5.

Linearity/non-linearity
There is only a small deviation from dose-linearity of AUC_{∞} and Cmax as shown when single doses of 1, 2, 3 and 4 sprays of the 1 mg mouth spray are given.

Characteristics in specific groups of subjects:

Renal Impairment
Progressive severity of renal impairment is associated with decreased total clearance of nicotine. Nicotine clearance was on average decreased by 50%, in subjects with severe renal impairment. Raised nicotine levels have been seen in smokers undergoing hemodialysis.

Hepatic Impairment
In smokers with liver cirrhosis but only mild liver impairment (Child-Pugh score 5) the pharmacokinetics of nicotine is unaffected. However, in smokers with moderately impaired liver (Child-Pugh score 7) total clearance has been reported to be reduced by 40-50%. There is no information available in subjects with a Child-Pugh score > 7.

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

5.3 Preclinical safety data

Nicotine was positive in some *in vitro* genotoxicity tests but there are also negative results with the same test systems. Nicotine was negative in *in vivo* tests.

Animal experiments have shown that nicotine exposure results in decreased birth-weight, decreased litter size and decreased survival of offspring.
The results of carcinogenicity assays did not provide any clear evidence of a tumorigenic effect of nicotine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol (E1520)
Anhydrous ethanol
Trometamol
Poloxamer 407 (containing butylated hydroxytoluene (E321))
Glycerol (E422)
Sodium hydrogen carbonate
Levomenthol
Spearmint flavour
Sucralose
Acesulfame potassium
Hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

PET bottle containing 13.2 ml of solution. One bottle contains at least 150 sprays. The bottle is placed in a dispenser with a mechanical spray pump. Nicorette QuickMist Spearmint SmartTrack 1mg/spray mouthspray: Includes an inactive NFC chip on the outer of the dispenser to allow smartphone connectivity.
Pack Sizes: 1 dispenser, 2 dispensers
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

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UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0416

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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