Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Nicorette QuickMist Cool Berry 1mg/spray mouthspray

(nicotine)

UK Licence No: PL 15513/0395

McNeil Products Limited

LAY SUMMARY
Nicorette QuickMist Cool Berry 1mg/spray mouthspray (nicotine)

This is a summary of the Public Assessment Report (PAR) for Nicorette QuickMist Cool Berry 1mg/spray mouthspray (PL 15513/0395). For ease of reading, this medicinal product will be referred to as Nicorette QuickMist in this Lay Summary.

This summary explains how Nicorette QuickMist was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Nicorette QuickMist.

For practical information about using Nicorette QuickMist, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Nicorette QuickMist and what is it used for?

Nicorette QuickMist is a nicotine replacement therapy (NRT). It is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when people try to stop smoking or when cutting down the number of cigarettes which they smoke. Ideally the person should always aim to stop smoking. People can use Nicorette QuickMist to achieve this by using it to completely replace all of the cigarettes which they smoke. However, Nicorette QuickMist can also be used in other ways,

- if a person feels unable to stop smoking completely, or wishes to replace certain cigarettes, it can therefore help them to cut down the number of cigarettes which they smoke.

- at those times when a person can't and does not want to smoke. For example,

- in places where people don't want to smoke and instead want to avoid harming others e.g. children or family.
- Smoke free areas such as pubs, at work, on public transport for example aeroplanes.

It may also help increase a person's motivation to quit.

When making a quit attempt a behavioural support programme will increase a person's chances of success.

How does Nicorette QuickMist work?

Nicorette QuickMist contains the active ingredient nicotine, which belongs to a group of medicines called nicotine replacement therapy (NRT). It acts to substitute the nicotine that patients normally get from cigarettes and can help them to stop smoking.

How is Nicorette QuickMist used?

Nicorette QuickMist is an oral spray.

People who are able to stop smoking should use the mouthspray, when needed, in place of cigarettes. As soon they can (this could be after a number of weeks or months) they should reduce the number of sprays until they have stopped using cigarettes completely.

People who are unable to stop smoking or do not feel ready to quit at this time, should replace as many cigarettes as possible with the mouthspray. NICORETTE QuickMist provides a safer alternative to tobacco smoking,.

Reducing the number of cigarettes may also help to become more motivated to stop smoking. As soon as the person is ready they should aim to stop smoking completely.

People can also use the mouthspray on those occasions when they can't or don't want to smoke.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. People who have quit smoking and want to stop using the mouthspray but are finding this difficult should contact their doctor, nurse or pharmacist for advice.

Nicorette QuickMist is a general sale list (GSL) medicine.

Please read Section 3 of the PIL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

What benefits of Nicorette QuickMist have been shown in studies?
Nicorette QuickMist is line extension of Nicorette QuickMist 1mg/spray mouthspray. As such the safety and efficacy data provided for Nicorette QuickMist 1mg/spray mouthspray are accepted to be applicable for Nicorette QuickMist.

What are the possible side effects from Nicorette QuickMist?
The most common side effects with Nicorette QuickMist (which may affect more than 1 in 10 people) are hiccups, throat irritation, feeling sick (nausea), headache and cough.

The common side effects with Nicorette QuickMist (which may affect up to 1 in 10 people) are allergic reactions (hypersensitivity), burning sensation in the mouth, dizziness, taste disturbance or loss of taste, tingling or numbness of the hands and feet, toothache, stomach pain or discomfort, excessive gas or wind, vomiting, dry mouth, indigestion, diarrhoea, tiredness (fatigue), sore and inflamed mouth, and increased salivation.

For the full list of all side effects reported with Nicorette QuickMist, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Nicorette QuickMist approved?
The MHRA decided that Nicorette QuickMist's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Nicorette QuickMist?
A risk management plan has been developed to ensure that Nicorette QuickMist is used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPC) and the PIL for Nicorette QuickMist, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Nicorette QuickMist
A Marketing Authorisation for Nicorette QuickMist was granted in the UK on 13 June 2018.

The full PAR for Nicorette QuickMist follows this summary.

This summary was last updated in July 2018.

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I Introduction

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted McNeil Products Limited a Marketing Authorisation for the medicinal product Nicorette QuickMist Cool Berry 1mg/spray mouthspray (PL 15513/0395) on 13 June 2018.

Nicorette QuickMist Cool Berry 1mg/spray mouthspray is a general sales list (GSL) medicine.
The product 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.

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

The application was submitted in accordance with Article 8(3) of Directive 2001/83/EC, as amended, for a known active substance. This is a line extension of Nicorette Quick Mist 1mg/spray mouth spray, granted to McNeil Products Limited (PL 15513/0357) on 30 November 2010. Nicorette QuickMist Cool Berry 1mg/spray mouthspray is similar to the currently marketed Nicorette Quick Mist 1mg/spray mouth spray (PL 15513/0357) with the exception of the flavouring.

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

Abrupt cessation of the use of tobacco-containing products following a prolonged period of daily use results in a characteristic withdrawal syndrome that includes four or more of 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. Nicotine craving is an important element in the withdrawal syndrome after smoking cessation.

No new non-clinical or clinical studies were conducted for the product. However, in support of these applications the applicant has confirmed that the only difference in the composition of QuickMist Cool Berry 1mg/spray mouthspray and Nicorette Quick Mist 1mg/spray mouth spray is the flavouring system.

A summary of the pharmacovigilance system and a detailed Risk Management Plan (RMP) have been provided with the application, and these are satisfactory.

No new or unexpected safety concerns arose during the review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Nicorette QuickMist Cool Berry 1mg/spray mouthspray outweigh the risks and a Marketing Authorisation was granted.

II Quality Aspects

II.1 Introduction

The finished product is an oral nicotine spray (ONS). Each spray contains 1 mg of the active ingredient nicotine. The excipients present are propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, red fruits flavour, cooling flavour, sucralose, acesulfame potassium, hydrochloric acid, and purified water.

All excipients comply with their respective European Pharmacopoeia monographs with the exception of red fruit flavour and the cooling flavour which comply with in-house specifications and the appropriate directive (EC 1334/2008) on the use of flavourings in food stuffs. Satisfactory Certificates of Analysis have been provided for all excipients showing compliance with their proposed specifications.

This product does not contain or consist of genetically modified organisms (GMO).

The finished product is packaged in a polyethylene terephthalate (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 packaged in cardboard cartons containing 1 dispenser or 2 dispensers.

Not all pack sizes may be marketed, however, the marketing authorisation holder has agreed to provide mock-ups of any pack size to the relevant regulatory authorities before marketing.

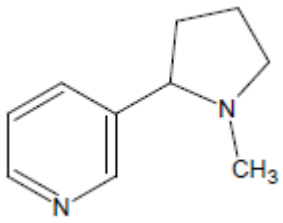
Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2. Drug Substance

Compendial name: Nicotine

Chemical Name: (S)-3-(1-Methyl-2-pyrrolidinyl)pyridine β-Pyridyl-α-N-methyl pyrrolidine 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine

Structure:



Molecular formula:	$C_{10}H_{14}N_2$
Molecular weight:	162.23 g/mol
Appearance:	Colorless to yellow or brownish, oily liquid; very hygroscopic; turns brown or red on exposure to air or light.
Solubility:	Nicotine is freely soluble in water, easily soluble in ethanol, ether and chloroform.

Nicotine is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, nicotine, are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3. Medicinal Product

Pharmaceutical Development

The aim of the pharmaceutical development programme was to produce a flavoured oral nicotine spray that will meet the needs of more smokers during quit attempts. The formulation strategy for Nicorette QuickMist Cool Berry 1mg/spray mouthspray was to utilise the experience and results from the development work of Nicorette Quick Mist 1mg/spray mouth spray. The applicant has provided a satisfactory discussion of the pharmaceutical development of the finished product, including the delivery device system.

Manufacture of the product

A Satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. A validation report for commercial scale batches has been provided. The process validation data provided is satisfactory.

Finished Product Specifications

The proposed finished product specifications are acceptable. The test methods have been described and have been adequately validated. Batch data have been provided that comply with the release specification. Certificates of Analysis have been provided for all working standards used.

Stability of the Products

Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 18 months with the storage condition "Do not store above 25ºC".

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

There are no objections to the approval of the application from a pharmaceutical viewpoint.

III Non-Clinical Aspects

III.1 Introduction

The application is a line extensions of an already approved product. Therefore, the non-clinical assessment was limited to a discussion of the safety of the degradants of nicotine in the drug product and the impurities in nicotine as well as excipients in Nicorette QuickMist Cool Berry 1mg/spray mouthspray.

As the pharmacodynamic, pharmacokinetic and toxicological properties of nicotine are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

The Applicant's non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.3 Pharmacokinetics

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.4 Toxicology

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.5 Ecotoxicity/environmental risk assessment (ERA)

Nicorette QuickMist Cool Berry 1mg/spray mouthspray is the same as a mint flavoured product, already widely marketed in Europe, with the only difference of fruit flavouring; hence the expectation is that environmental exposure to nicotine will not increase due to the approval of the fruit flavoured product, as it is targeting the same patient population that is already being served with use of the mint flavoured product.

The sole active pharmaceutical ingredient (API) is nicotine, some of which, after it is administered, can enter into wastewater. Nicotine is expected to remain predominantly in the aqueous phase after emission into the sewage system, after which it is expected to undergo complete biodegradation to elements found in nature. Chronic toxicity tests have been conducted with aquatic organisms from three trophic levels and respiration inhibition has been tested for activated sludge microorganisms.

The results of the Phase II assessment indicated a predicted effect concentration (PEC)/predicted no-effect concentration (PNEC) value less than the threshold of concern identified in the Guideline. The outcome of the Phase II Tier A ERA rules out the possibility for environmental effects due to the use of nicotine in Nicotine Oromucosal Spray for all environmental media.

No precautionary or safety measures are proposed for Nicotine Oromucosal Spray, as environmental risks are estimated to be below the threshold of concern according to the assessment methods recommended in the ERA Guideline.

III.6 Discussion on the non-clinical aspects

The pharmacological, pharmacokinetic and toxicological properties of nicotine are well characterised. No new non-clinical studies are required and the applicant has not conducted any, the literature review is, therefore, appropriate. The Applicant's non-clinical overview only discusses excipient levels and impurity specifications and does not discuss the pharmacological, pharmacokinetic or toxicological properties of nicotine. As the pharmacological, pharmacokinetic and toxicological properties of nicotine are so well understood this can be accepted.

There are no objections to the approval of the application from a non-clinical viewpoint.

IV Clinical Aspects

IV.1 Introduction

The applicant is introducing a product which is identical to the currently marketed Nicorette Quick Mist 1mg/spray mouth spray with only important difference in excipients pertinent to change in flavour.

The clinical pharmacology of nicotine is well-known. No new pharmacodynamics or pharmacokinetic data are provided or are required for these applications. No new efficacy or safety studies have been performed and none are required for this type of application.

A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of nicotine.

IV.2 Pharmacokinetics

In support of the application, the applicant has provided comparison of the compositions of Nicorette QuickMist 1mg/spray mouthspray and Nicorette QuickMist Cool Berry 1mg/spray mouthspray.

The minor difference in excipients is unlikely to result in any change in pharmacokinetics (PK) of the products. Since the application is also a line extension a bioequivalence study is not deemed necessary.

The parameters that have an impact on the bioavailability of the product are: administered dose of nicotine, buffering capacity and pH of the formulation. All of these parameters are the same for the currently authorised Nicorette QuickMist 1mg/spray mouthspray and Nicorette QuickMist Cool Berry 1mg/spray mouthspray. Therefore, a study to demonstrate bioequivalence is not required.

IV.3 Pharmacodynamics

No new pharmacodynamic data has been submitted with the line extension application and no new pharmacodynamics related claims have been made.

IV.4 Clinical efficacy

No new efficacy data have been submitted with the line extension application and no new claims regarding efficacy have been made.

IV.5 Clinical safety

No new safety data have been submitted with the line extension application and no claims regarding safety have been made.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance system

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended.

There are no differences from the referred product in terms of proposed uses, maximum pack size / strength or pharmaceutical form / formulation that would have any implications for safety.
In line with the referred product, the applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns (labelling in the SmPC and the PIL). This is agreed.
The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

IV.7 Discussion on the clinical aspects

The grant of a Marketing Authorisation is recommended for the application, from a clinical point of view.

V User consultation

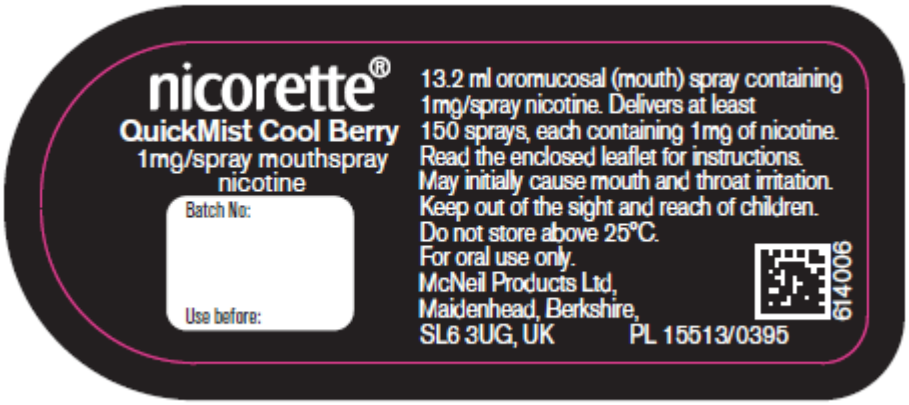
User testing of the package leaflet has been accepted, based on bridging reports provided by the applicant making reference to the user-testing of the PIL for Nicorette Inhalator (PL 15513/0179) and a number of other products in order to standardise the in-house style. A critical analysis demonstrated that the key messages for safe and effective use for both leaflets were similar. The justification on the rationale for bridging is accepted.

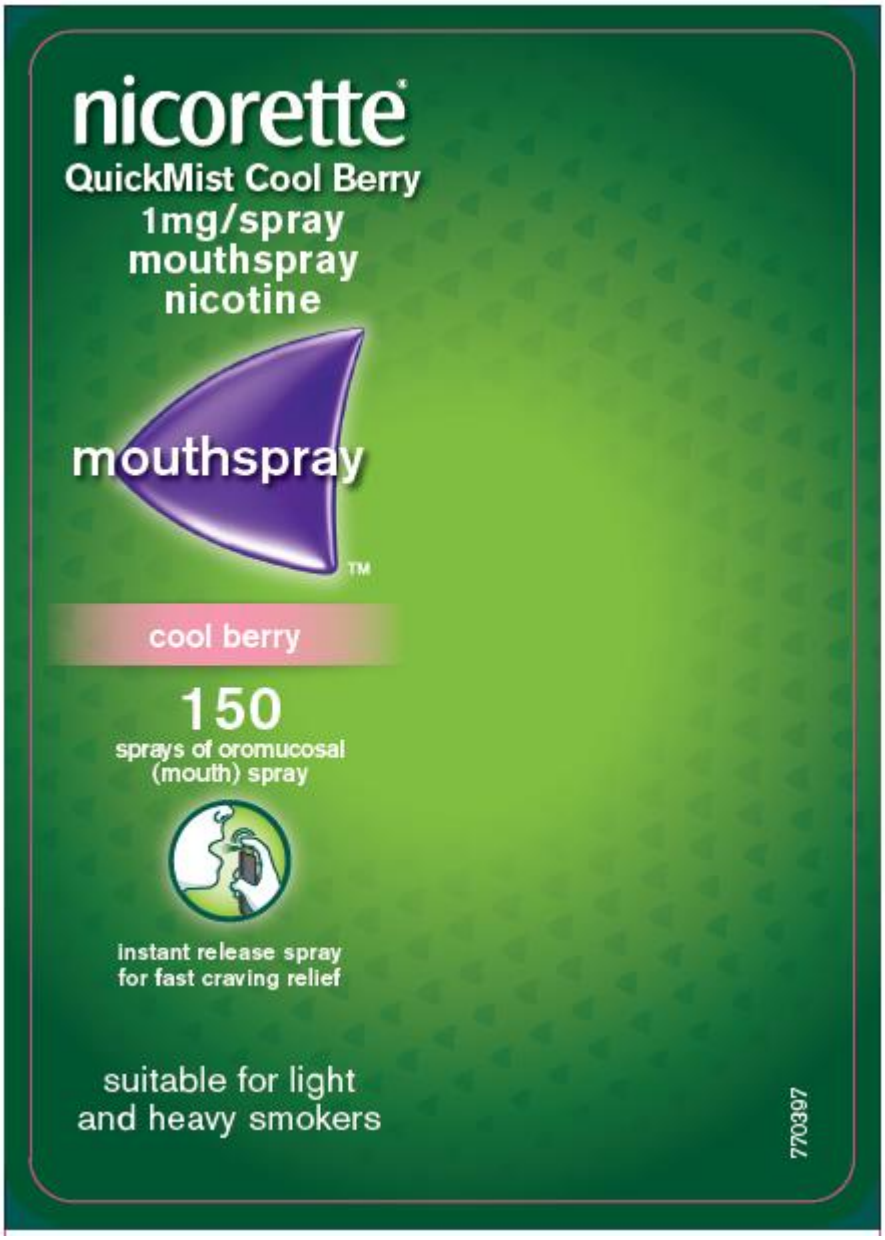
VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the product is acceptable, and no new non-clinical or clinical concerns have been identified. Existing clinical experience with nicotine is considered to have demonstrated the therapeutic value of the active substance as a nicotine replacement therapy. The product is a line extension of the existing authorised product, Nicorette QuickMist 1mg/spray mouthspray. The benefit/risk is, therefore, considered to be positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Nicorette QuickMist Cool Berry 1mg/spray mouthspray is presented below:




nicorette
QuickMist Cool Berry
1mg/spray
mouthspray
nicotine
mouthspray
cool berry
150
sprays of oromucosal (mouth) spray
instant release spray for fast craving relief
suitable for light and heavy smokers
770397

nicorette®

770397

770397

BRAILLE

N406

nicorette® QuickMist Cool Berry · 1 mg/spray mouthspray · nicotine

Use: NICORETTE® QuickMist Cool Berry is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking or when cutting down the number of cigarettes you smoke. It provides a safer alternative to smoking for both the individual and those around them. Ideally you should aim to stop smoking. However it can be used in a number of different ways, either to completely replace all your cigarettes, or if you do not feel ready to stop smoking completely, to replace certain cigarettes and therefore help you to cut down the number of cigarettes you smoke. It may also help increase your motivation to quit.

Directions: For adults and children 12 years and over. It is important to use enough nicotine spray to control cravings, and using 1 or 2 sprays corresponds to the nicotine from a cigarette. Use one spray first and if your cravings do not disappear within a few minutes use a second spray. If 2 sprays are required to control cravings, future doses may be delivered as 2 consecutive sprays. For many smokers this means about 1-2 sprays every 30 minutes to 1 hour. Do not use more than 2 sprays per dose or 4 sprays per hour or 64 sprays per day. Before use, please read the information leaflet carefully.

Warning: Do not take more medicine than the label tells you to.

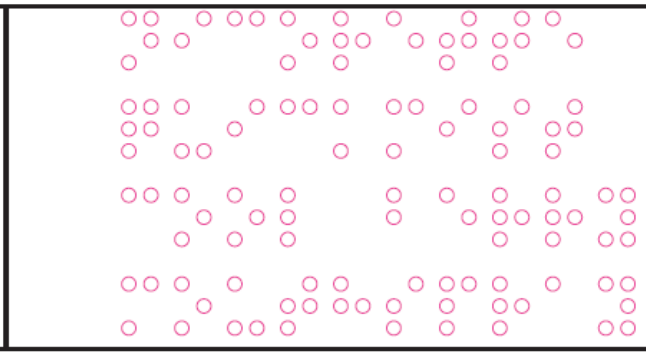
If you are pregnant, talk to your doctor, pharmacist or nurse for advice before using this product. If you need any advice before starting to use this product, talk to your doctor, pharmacist or nurse. May initially cause mouth and throat irritation. Do not use if you are allergic to any of the ingredients listed below. Contains ethanol.

You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor or a support programme.

Contents: This pack contains 1 dispenser, containing 13.2 ml of solution which provides at least 150 oromucosal sprays, each spray containing 1mg nicotine. Other ingredients are: propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, Red fruits flavour, cooling flavour, sucralose, acesulfame potassium, hydrochloric acid, purified water.

Storage: Keep out of the sight and reach of children. Do not store above 25°C. Dispose of sensibly. Please read the enclosed leaflet for instructions.

nicorette
quickmist
cool berry
mouthspray



How to open the QuickMist mouthspray | To UNLOCK NOZZLE

1. Use your thumb to slide down the button (a) until it can be pushed lightly inwards (b). Do not push too hard.
2. While pushing in, slide upwards (c) to unlock the top of the dispenser. Then release the button.

How to prime QuickMist mouthspray

When you use the mouthspray for the first time you must first load the spray pump. Point the spray nozzle safely away from you, any other adults, children or pets near you. Press the top of the QuickMist with your index finger. Press 3 times until a fine spray appears. If you do not use the spray for 2 days, this loading procedure will need to be repeated.

How to use the QuickMist mouthspray

3. Point the spray nozzle towards your open mouth and hold it as close to your mouth as possible.
4. Press the top of the QuickMist to release one spray into your mouth. To avoid getting spray down your throat do not inhale while spraying. For best results, do not swallow for a few seconds after spraying.

How to close the QuickMist mouthspray | To LOCK NOZZLE

5. Slide the button down (d) until it can be pushed inwards (e).
6. While pushing in, slide the top of the dispenser downwards (f). Release the button. The QuickMist mouthspray is now closed.
   To take another dose repeat the steps above.

770398

Close the QuickMist mouthspray every time after use to prevent use of the spray by children and accidental spraying.
If you get spray in your eye, rinse thoroughly with water.

nicorette® QuickMist Cool Berry · 1mg/spray mouthspray · nicotine

Use: NICORETTE® QuickMist Cool Berry is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking or when cutting down the number of cigarettes you smoke. It provides a safer alternative to smoking for both the individual and those around them. Ideally you should aim to stop smoking. However it can be used in a number of different ways, either to completely replace all your cigarettes, or if you do not feel ready to stop smoking completely, to replace certain cigarettes and therefore help you to cut down the number of cigarettes you smoke. It may also help increase your motivation to quit.

Directions: For adults and children 12 years and over. It is important to use enough nicotine spray to control cravings, and using 1 or 2 sprays corresponds to the nicotine from a cigarette. Use one spray first and if your cravings do not disappear within a few minutes use a second spray. If 2 sprays are required to control cravings, future doses may be delivered as 2 consecutive sprays.For many smokers this means about 1-2 sprays every 30 minutes to 1 hour.Do not use more than 2 sprays per dose or 4 sprays per hour or 64 sprays per day. Before use, please read the information leaflet carefully.

Warning: Do not take more medicine than the label tells you to.

If you are pregnant, talk to your doctor, pharmacist or nurse for advice before using this product. If you need any advice before starting to use this product, talk to your doctor, pharmacist or nurse. May initially cause mouth and throat irritation. Do not use if you are allergic to any of the ingredients listed below. Contains ethanol.

You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor or a support programme.

Contents: This pack contains 1 dispenser, containing 13.2 ml of solution which provides at least 150 oromucosal sprays, each spray containing 1mg nicotine. Other ingredients are: propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, Red fruits flavour, cooling flavour, sucralose, acesulfame potassium, hydrochloric acid, purified water.

Storage: Keep out of the sight and reach of children. Do not store above 25°C. Dispose of sensibly. Please read the enclosed leaflet for instructions.

McNeil Products Ltd,
Maidenhead, Berkshire,
SL6 3UG, UK.

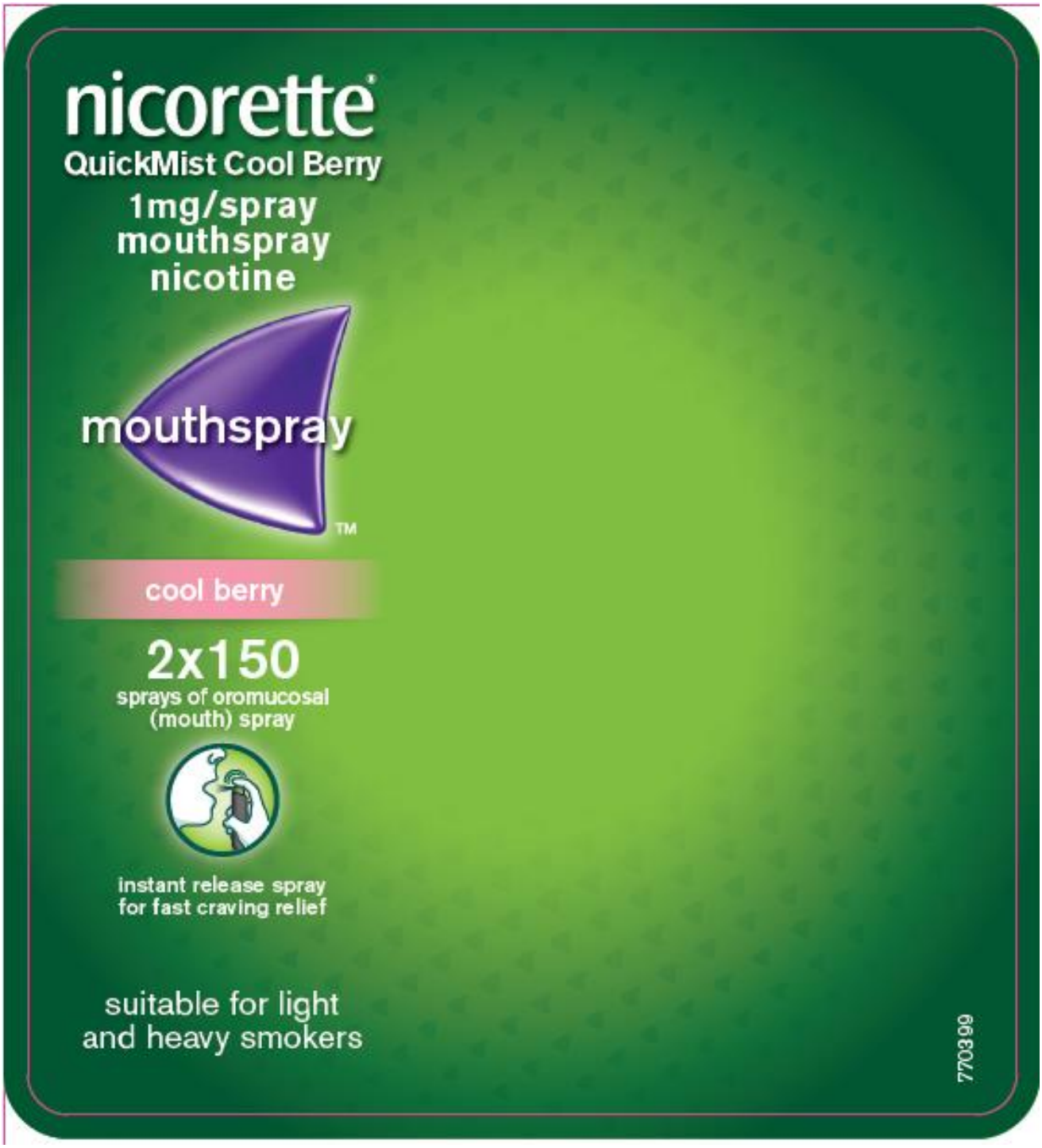
PL 15513/0395

Batch No: 770398

Use before:

3 574661 343563

770398


nicorette
QuickMist Cool Berry
1mg/spray
mouthspray
nicotine
mouthspray
™
cool berry
2x150
sprays of oromucosal
(mouth) spray
instant release spray
for fast craving relief
suitable for light
and heavy smokers
770300

nicorette®

770399

770399

BRAILLE

N406

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You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor or a support programme.

Contents: This pack contains 2 dispensers, each containing 13.2 ml of solution which provides at least 150 oromucosal sprays, each spray containing 1mg nicotine. Other ingredients are: propylene glycol, anhydrous ethanol, trometamol, poloxamer 407, glycerol, sodium hydrogen carbonate, levomenthol, Red fruits flavour, cooling flavour, sucralose, acesulfame potassium, hydrochloric acid, purified water.

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Dispose of sensibly. Please read the enclosed leaflet for instructions.

nicorette
quickmist
cool berry
mouthspray

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McNeil Products Ltd,
Maidenhead, Berkshire,
SL6 3UG, UK.

PL 15513/0395

Batch No: 770400

[redacted]

Use before:

3 574661 343013

770400

How to open the QuickMist mouthspray | To UNLOCK NOZZLE

1. Use your thumb to slide down the button (a) until it can be pushed lightly inwards (b). Do not push too hard.
2. While pushing in, slide upwards (c) to unlock the top of the dispenser. Then release the button.

How to prime QuickMist mouthspray

When you use the mouthspray for the first time you must first load the spray pump. Point the spray nozzle safely away from you, any other adults, children or pets near you. Press the top of the QuickMist with your index finger. Press 3 times until a fine spray appears. If you do not use the spray for 2 days, this loading procedure will need to be repeated.

How to use the QuickMist mouthspray

3. Point the spray nozzle towards your open mouth and hold it as close to your mouth as possible.
4. Press the top of the QuickMist to release one spray into your mouth. To avoid getting spray down your throat do not inhale while spraying. For best results, do not swallow for a few seconds after spraying.

How to close the QuickMist mouthspray | To LOCK NOZZLE

5. Slide the button down (d) until it can be pushed inwards (e).
6. While pushing in, slide the top of the dispenser downwards (f). Release the button. The QuickMist mouthspray is now closed.
   To take another dose repeat the steps above.

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Close the QuickMist mouthspray every time after use to prevent use of the spray by children and accidental spraying.
If you get spray in your eye, rinse thoroughly with water.

Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Date submitted	Application type	Scope	Outcome