

Prescribing information for Nicorette (nicotine) Products: Nicorette Invisi Patch, Nicorette Quickmist, Nicorette Inhalator, Nicorette Gum, Nicorette Lozenge, Nicorette Microtab, Nicorette Nasal Spray

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

Nicorette Invisi Patch Prescribing Information:

Presentation: Transdermal delivery system available in 3 sizes (22.5, 13.5 and 9cm²) releasing 25mg, 15mg and 10mg of nicotine respectively over 16 hours. **Uses:** Nicorette Invisi Patch 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. Nicorette Invisi Patch is indicated in pregnant and lactating women making a quit attempt. If possible, Nicorette Invisi Patch should be used in conjunction with a behavioural support programme. **Dosage:** It is intended that the patch is worn through the waking hours (approximately 16 hours) being applied on waking and removed at bedtime. **Smoking Cessation: Adults (over 18 years of age):** For best results, most smokers are recommended to start on 25 mg / 16 hours patch (Step 1) and use one patch daily for 8 weeks. Gradual weaning from the patch should then be initiated. One 15 mg/16 hours patch (Step 2) should be used daily for 2 weeks followed by one 10 mg/16 hours patch (Step 3) daily for 2 weeks. Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) are recommended to start at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg for the final 4 weeks. Those who experience excessive side effects with the 25 mg patch (Step 1), which do not resolve within a few days, should change to a 15 mg patch (Step 2). This should be continued for the remainder of the 8 week course, before stepping down to the 10 mg patch (Step 3) for 4 weeks. If symptoms persist the advice of a healthcare professional should be sought. **Adolescents (12 to 18 years):** Dose and method of use are as for adults however, recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought. **Smoking Reduction/Pre-Quit:** Smokers are recommended to use the patch to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. Starting dose should follow the smoking cessation instructions above i.e. 25mg (Step 1) is suitable for those who smoke 10 or more cigarettes per day and for lighter smokers are recommended to start at Step 2 (15 mg). Smokers starting on 25mg patch should transfer to 15mg patch as soon as cigarette consumption reduces to less than 10 cigarettes per day. A quit attempt should be made as soon as the smoker feels ready. When making a quit attempt smokers who have reduced to less than 10 cigarettes per day are recommended to continue at Step 2 (15 mg) for 8 weeks and decrease the dose to 10 mg (Step 3) for the final 4 weeks. **Temporary Abstinence:** Use a Nicorette Invisi Patch in those situations when you can't or do not want to smoke 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 are recommended to use 25mg patch and lighter smokers are recommended to use 15mg patch. **Contraindications:** Hypersensitivity. **Precautions:** Underlying cardiovascular disease, diabetes mellitus, renal or hepatic impairment, phaeochromocytoma or uncontrolled hyperthyroidism, generalised dermatological disorders, gastrointestinal disease. Angioedema and urticaria have been reported. Erythema may occur. If severe or persistent, discontinue treatment. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response, to adenosine. Keep out of reach and sight of children and dispose of with care. Should be removed prior to undergoing MRI procedures. **Pregnancy and lactation:** Smoking cessation during pregnancy should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional. **Side effects:** Very common: pruritus. Common: headache, dizziness, nausea, rash, urticaria, vomiting. Uncommon: hypersensitivity, palpitations, paraesthesia, tachycardia, flushing, hypertension, hyperhidrosis, myalgia, application site reactions, asthenia, chest discomfort and pain, malaise, fatigue, dyspnoea. Rare: Anaphylactic reaction, GI discomfort, angioedema, erythema, pain in extremity. Very rare: reversible atrial fibrillation. **NHS Cost:** 25mg packs of 7: £11.15, 25mg packs of 14: £18.28, 15mg packs of 7: £11.10, 10mg packs of 7: £10.99. **Legal category:** GSL. **PL holder:** McNeil Products L.td, Roxborough Way, Maidenhead, Berkshire, SL6 3UG. **PL numbers:** 15513/0161; 15513/0160; 15513/0159. **Date of preparation:** May 2016

Nicorette QuickMist 1mg/spray mouthspray & Nicorette QuickMist Cool Berry 1mg/spray mouthspray Prescribing Information:

Presentation: Oromucosal spray. Each 0.07 ml contains 1mg nicotine, corresponding to 1mg nicotine/spray dose. **Uses:** 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. It is indicated in pregnant and lactating women making a quit attempt. **Dosage:** Adults and Children over 12 years of age: The patient should make every effort to stop smoking completely during treatment with Nicorette QuickMist. One or two sprays to be used when cigarettes normally would have been smoked 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. Up to 4 sprays per hour may be used; not exceeding 2 sprays per dosing episode and 64 sprays in any 24-hour period. Nicorette QuickMist should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Nicorette QuickMist and as soon as they are able, reduce the number of sprays used until they have stopped completely. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Smokers aiming to reduce cigarettes should use the Mouthspray, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. **Contraindications:** Children under 12 years of age and hypersensitivity to any of the ingredients. **Precautions:** Underlying cardiovascular disease, diabetes mellitus, G.I disease, uncontrolled hyperthyroidism, phaeochromocytoma, hepatic or renal impairment. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and

easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children and dispose of with care. Care should be taken not to spray the eyes whilst administering the spray. **Pregnancy & lactation:** Smoking cessation during pregnancy should be achieved without NRT. However, if the mother cannot (or is considered unlikely to) quit without pharmacological support, NRT may be used after consulting a healthcare professional. **Side effects:** Very common: Headache, cough, throat irritation, nausea, hiccups. Common: Toothache, hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, stomatitis, vomiting, dyspepsia, fatigue. Uncommon: Abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, dry skin, urticaria, angioedema, hyperhidrosis, pruritus, rash, erythema, pain in jaw, asthenia, chest discomfort and pain, malaise, oropharyngeal pain, rhinorrhoea, gingivitis, musculoskeletal pain, hyperhidrosis. Rare: Dysphagia, hypoaesthesia oral, retching. Not known: Atrial fibrillation, anaphylactic reaction, blurred vision, lacrimation increased, dry throat, GI discomfort, lip pain, muscle tightness, angioedema, erythema. **NHS Price:** Nicorette QuickMist 1mg/spray mouthspray: 1 dispenser pack £13.03, 2 dispenser pack £20.58, Nicorette QuickMist Cool Berry 1mg/spray mouthspray: 1 dispenser pack £ 13.03, 2 dispenser pack £20.58. **Legal category:** GSL **PL holder:** McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG **PL number:** Nicorette QuickMist 1mg/spray mouthspray: 15513/0357, Nicorette QuickMist Cool Berry 1mg/spray mouthspray: 15513/0395 **Date of preparation:** June 2018

Nicorette Inhalator (nicotine) Prescribing Information

Presentation: Inhalation cartridge containing 15mg nicotine for oromucosal use via a mouthpiece. **Uses:** Relieves and/or prevents cravings 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. It is indicated in pregnant and lactating women making a quit attempt. **Dosage:** Adults and Children over 12 years of age: Nicorette Inhalator should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the Inhalator and as soon as they are able, reduce the number of cartridges used until they have stopped completely. Smokers aiming to reduce cigarettes should use the Inhalator, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. As soon as they are ready smokers should aim to quit smoking completely. Maximum of 6 cartridges per day should be used. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking, but are having difficulty discontinuing their Inhalator are recommended to contact their pharmacist or doctor for advice. **Contraindications:** Children under 12 years and Hypersensitivity. **Precautions:** Underlying cardiovascular disease, diabetes mellitus, G.I disease, uncontrolled hyperthyroidism, phaeochromocytoma, hepatic or renal impairment, chronic throat disease, obstructive lung disease or bronchospastic disease. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children and dispose of with care. Best used at room temperature. **Pregnancy & lactation:** Smoking cessation during pregnancy should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional. **Side effects:** Very common: headache, cough,

throat irritation, nausea, hiccups, stomatitis. *Common:* hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, vomiting, dyspepsia, fatigue, nasal congestion. *Uncommon:* abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, urticaria, hyperhidrosis, pruritus, rash, pain in jaw, asthenia, chest discomfort and pain, malaise, chest discomfort and pain. *Rare:* dysphagia, hypoaesthesia oral, retching. *Very rare:* reversible atrial fibrillation. *Not known:* anaphylactic reaction, angioedema, blurred vision, lacrimation increased, dry throat, lip pain, muscle tightness, erythema, gastrointestinal discomfort. Please refer to Summary of Product Characteristics for detailed information **NHS cost:** 4-cartridge pack: £4.87, 20-cartridge pack: £17.78, 36-cartridge pack: £28.28 **Legal category:** GSL PL holder: McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG. **PL number:** 15513/0358 **Date of preparation:** 27th June 2016

Nicorette Gum (Nicotine) Prescribing Information

Presentation: Nicorette 2mg gum, Nicorette 4mg gum, and Nicorette 6mg gum contain 2mg, 4mg and 6mg of nicotine respectively, in a chewing gum base. Original, Icy White, Fruitfusion and Freshmint flavours. **Uses:** 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. It is indicated in pregnant and lactating women making a quit attempt. **Dosage:** **Adults and Children over 12 years of age:** The strength of gum to be used will depend on the smoking habits of the individual. In general, if the patient smokes 20 or less cigarettes a day, the 2mg nicotine gum is indicated. If the patient smokes more than 20 cigarettes a day, the 4mg or 6mg nicotine gum will be needed to meet the withdrawal of the high serum nicotine levels from heavy smoking. The 6mg gum can be recommended particularly to those requiring enhanced craving relief compared to 4mg gum. Nicorette gum should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the gum and as soon as they are able, reduce the number of gums used until they have stopped completely. Smokers aiming to reduce cigarettes should use Nicorette Gum, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. As soon as they are ready smokers should aim to quit smoking completely. Maximum daily dose: 15 pieces per day. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking, but are having difficulty discontinuing Nicorette Gum are recommended to contact their pharmacist or doctor for advice. For those using the 4 mg gum, switching to the 2 mg gum may be helpful when stopping treatment or reducing the number of gums used each day. The chewing gums should be used whenever there is an urge to smoke according to the "chew and rest" technique described on the pack. After about 30 minutes of such use, the gum will be exhausted. **Contraindications:** Children under 12 years of age. Hypersensitivity to nicotine or any of the excipients in the gum. **Precautions:** Underlying cardiovascular disease, diabetes mellitus, G.I disease, hepatic or renal impairment, uncontrolled hyperthyroidism, phaeochromocytoma, keep out of reach and sight of children. Smokers who wear dentures may experience difficulty in chewing. The gum may stick to,

and may in rare cases damage dentures. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of adenosine. See SPCs for further details. **Fertility, Pregnancy and Lactation:** Smoking cessation should be achieved without NRT, however if the mother is unable to quit without pharmacological support, NRT may be used. See SPC for further information. **Side effects:**Very common: headache, cough, sore mouth or throat, throat irritation, nausea, hiccups. Common: hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, stomatitis, vomiting, dyspepsia, fatigue. Uncommon: abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, urticaria, hyperhidrosis, pruritus, rash, pain in jaw, asthenia, chest discomfort and pain, malaise. Rare: dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema. Very rare: reversible atrial fibrillation. Not known: anaphylactic reaction, blurred vision, lacrimation increased, dry throat, gastrointestinal discomfort, lip pain, erythema, muscle tightness. **RRP NHS Cost:** Original 2mg gum (105) £10.27, (210) £16.42, 4mg gum (105) £12.56, (210) £20.28; Icy White 2mg gum (25) £3.52, (105) £10.26, 4mg gum (105) £12.55; Fruitfusion 2mg gum, (105) £10.27; 4mg gum, (105) £12.57; 6mg gum £12.97 (105) £20.81 (210) Freshmint 2mg gum (25) £3.52, (105) £10.27, (210) £16.42; 4mg gum (25) £3.53, (105) £12.56, (210) £20.28. **Legal category:** GSL. **PL Holder:** McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG.**PL Number(s):** Original 2mg 15513/0169, 4mg 15513/0170; Icy White 2mg 15513/0152, 4mg 15513/0153; Fruitfusion 2mg 15513/0136, 4mg 15513/0137, 6mg 15513/0381; Freshmint 2mg 15513/0173, 4mg 15513/0174. **Date of prep:** 4th September 2017

Nicorette Cools 2mg Lozenge (Nicotine), Nicorette Cools 4mg Lozenge (Nicotine), Nicorette Fruit 2mg Lozenge (Nicotine) Prescribing Information.

Presentation: Nicorette Cools 2mg Lozenge, Nicorette Fruit 2mg Lozenge, Nicorette Cools 4mg Lozenge contain 2 mg and 4 mg nicotine respectively (as nicotine resinate). **Uses:** 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. It is indicated in pregnant and lactating women making a quit attempt. **Dosage: Adults and Children over 12 years of age:** The strength of lozenge to be used will depend on the smoking habits of the individual. If the patient smokes 20 or fewer cigarettes a day, 2 mg nicotine lozenge is indicated. If more than 20 cigarettes per day are smoked, 4 mg nicotine lozenge should be used. Nicorette Lozenges should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Smokers willing or able to stop smoking immediately should initially replace all their cigarettes with the lozenge and as soon as they are able, reduce the number of lozenges used until they have stopped completely. Smokers aiming to reduce cigarettes should take the lozenge, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. As soon as they are ready smokers should aim to quit smoking completely. Most smokers require 8 to 12 lozenges per day, not to exceed 15 lozenges. When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. Those who have quit smoking, but are having difficulty discontinuing with the lozenge are recommended to contact their pharmacist or doctor for advice. **Contraindications:** Children under 12 years and Hypersensitivity. **Precautions:** Underlying cardiovascular disease, diabetes mellitus, hepatic or renal

impairment, uncontrolled hyperthyroidism, phaeochromocytoma, G.I disease, keep out of reach and sight of children. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and both less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response to, adenosine. Dispose of with care. **Pregnancy & lactation:** Only after consulting a healthcare professional. **Side effects:** Very common: Headache, cough, sore mouth or throat, throat irritation, nausea, hiccups. Common: Hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, abdominal pain, diarrhoea, dry mouth, flatulence, salivary hypersecretion, stomatitis, vomiting, dyspepsia, fatigue. Uncommon: Abnormal dreams, palpitations, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnoea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, urticaria, hyperhidrosis, pruritus, rash, pain in jaw, asthenia, chest discomfort and pain, malaise. Rare: dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema. Very rare: reversible atrial fibrillation. Not known: anaphylactic reaction, blurred vision, lacrimation increased, dry throat, lip pain, muscle tightness, erythema, GI discomfort. **NHS Price:** Nicorette Cools 2mg Lozenge: 20 pack £3.34, 80 (4x20) pack £12.05. Nicorette Fruit 2mg Lozenge: 80 pack £12.05. Nicorette Cools 4mg Lozenge: 80 (4x20) pack £12.17 **Legal category:** GSL **PL holder:** McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG **PL number:** Nicorette Cools 2mg Lozenge:15513/0374, Nicorette Fruit 2mg Lozenge: 15513/0393, Nicorette Cools 4mg Lozenge: 15513/0375 **Date of preparation:** May 2018

Nicorette Microtab 2mg Sublingual Tablet (nicotine B-cyclodextrin) Prescribing Information

Presentation: Microtab for sublingual use consisting of nicotine B-cyclodextrin complex 17.4 mg, equivalent to 2 mg nicotine. Uses: Relief of nicotine withdrawal symptoms as an aid to smoking cessation. It is used to help smokers ready to stop smoking immediately and also smokers who need to cut down their cigarette use before stopping. It is also indicated in pregnant and lactating women.

Dosage: Adults (over 18 years): The tablet is used sublingually with a recommended dose of one tablet per hour or, for heavy smokers (more than 20 cigarettes per day), two tablets per hour. Most smokers require 8-12 or 16-24 tablets per day, not to exceed 40 tablets. Smoking cessation: Patients should stop smoking during treatment. Duration of treatment is individual but up to 3 months of treatment is recommended. The nicotine dose should then be gradually reduced by decreasing the total number of tablets used per day. Treatment should be stopped when daily consumption is down to one or two tablets. Those who use NRT beyond 9 months should consult a healthcare professional. Smoking reduction: Use the microtab between smoking episodes to reduce smoking. A quit attempt should be made as soon as the smoker feels ready but no later than 6 months. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months. **Adolescents (12 to 18 years):** No more than 40 tablets should be used each day. Smoking cessation: As adult dosage, but treatment should be used for up to 8 weeks before gradually reducing over 4 weeks. Treatment should be stopped when daily consumption is down to one or two tablets. If further treatment is required, consult a healthcare professional. Smoking reduction: Only after consulting a healthcare professional.

Contraindications: Hypersensitivity **Precautions:** Unstable cardiovascular disease, diabetes mellitus, GI disease, renal or hepatic impairment, phaeochromocytoma, uncontrolled hyperthyroidism. Stopping smoking may alter the metabolism of certain drugs. Transferred dependence is rare and less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children. **Pregnancy & lactation:**

Smoking cessation during pregnancy should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional. **Side effects:** Very common: headache, cough, throat irritation, hiccups, nausea. Common: rhinitis, hypersensitivity, burning sensation, dizziness, dysgeusia, paraesthesia, palpitations, sore mouth and throat, abdominal pain, diarrhea, dry mouth, dyspepsia, flatulence, salivary hypersecretion, stomatitis, vomiting, fatigue. Uncommon: abnormal dreams, tachycardia, flushing, hypertension, bronchospasm, dysphonia, dyspnea, nasal congestion, sneezing, throat tightness, eructation, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral, pain in jaw, hyperhidrosis, pruritus, rash, urticaria, asthenia, chest discomfort and pain, malaise. Rare: dysphagia, hypoaesthesia oral, retching, allergic reactions including angioedema. Very Rare: reversible atrial fibrillation. Unknown: anaphylactic reaction, blurred vision, lacrimation increase, dry throat, gastrointestinal discomfort, lip pain, muscle tightness, erythema. Please refer to Summary of Product Characteristics for detailed information **NHS price: 100 pack: £15.23 Legal category: GSL PL holder: McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG PL number: 15513/0178 Date of prep: 05 Sept 2017**

Nicorette Nasal Spray (nicotine) Prescribing Information

Presentation: A metered spray bottle containing 10ml of a 10mg/ml solution of nicotine for intranasal use. Each 50 microlitres delivers 0.5mg nicotine. **Uses:** Relief of nicotine withdrawal symptoms as an aid to smoking cessation. It is also indicated in pregnant and lactating women. **Dosage:** The patient should make every effort to stop smoking completely during treatment with Nicorette Nasal Spray. **Adults (over 18 years):** The frequency of use depends on the previous smoking habit of the individual and the level of their nicotine dependence. 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. The daily limit of use is 32mg of nicotine (64 sprays) which is the equivalent of two sprays to each nostril every hour for 16 hours. Use should be restricted to 3 months. For the first 8 weeks as required to a maximum of one spray into each nostril twice an hour for 16 hours per day. For the subsequent 2 weeks, reduce usage by half. Final 2 weeks, reduce usage to zero. Adults who use NRT beyond 9 months should seek advice from a healthcare professional. **Adolescents (12 to 18 years):** As adult dosage, but therapy should not exceed 12 weeks without consulting a healthcare professional. **Contraindications:** Children under 12 years of age and hypersensitivity to any of the ingredients. **Precautions:** Unstable cardiovascular disease, diabetes mellitus, GI disease, renal or hepatic impairment, phaeochromocytoma, uncontrolled hyperthyroidism, bronchial asthma. Stopping smoking may alter the metabolism of certain drugs. Should not be used whilst driving or operating heavy machinery. Transferred dependence is rare and less harmful and easier to break than smoking dependence. May enhance the haemodynamic effects of, and pain response to, adenosine. Keep out of reach and sight of children and dispose of with care. May initially cause nasal irritation. Care should be taken not to spray the eyes whilst administering the spray. **Pregnancy & lactation:** Smoking cessation during pregnancy should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended to assist a quit attempt after consulting a healthcare professional. **Side effects:** Very common: Rhinorrhoea. Common: Headache, dizziness, paraesthesia, palpitations, cough, throat irritation, dyspnoea, epistaxis, nausea, vomiting, hyperhidrosis, pruritus, rash, chest discomfort and

pain. Uncommon: hypersensitivity, abnormal dreams, flushing, hypertension, fatigue, malaise. Very rare: reverse atrial fibrillation. Not known: anaphylactic reaction, lacrimation increased, tachycardia, nasal discomfort, oropharyngeal discomfort and pain, sneezing, GI discomfort, angioedema, erythema, urticaria, asthenia. Please refer to Summary of Product Characteristics for detailed information **NHS Cost**: £16.18 **Legal category**: GSL PL holder: McNeil Products Ltd, Roxborough Way, Maidenhead, Berkshire, SL6 3UG **PL number**: 15513/0180 **Date of preparation**: 26th June 2016