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Black

LITHO OFFSET

REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

MANUFACTURING SITE

Reference	CH020004	Technical Code	652459
Substrate	WHITE	PC-Spec	PC-0002662
Braille Nr	N/A	Colour Target Ref	N/A

TECHNICAL DETAILS

Component	Leaflet	Plant	Helsingborg
Dimensions	280 x 180 mm	Master Dieline	JJSC_00233_V1
		Date	26-11-2021

					
Profile	Text Limit	Bleed	Fold/Technical	Perforation	Stamping Area

					
Coding (Silent Zone)	Print & Varnish Free	Print Free	Varnish Free	Seal Area	Tamper Evident Label Area


Braille Grid

FONTS USED

AkzidenzGroteskPro-It
AkzidenzGroteskPro-Md
AkzidenzGroteskPro-MdIt
AkzidenzGroteskPro-Regular
MetaPlusBlack-Roman
Wingdings-Regular
ZapfDingbatsStd

SMALLEST TEXT SIZE

6.30 pt

AVE. TEXT SIZE

6.3 pt

LARGEST TEXT SIZE

9.90 pt

652459

Package leaflet: information for the user

nicorette®

15mg Inhaler
Nicotine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nicorette Inhaler is and what it is used for
2. What you need to know before you use Nicorette Inhaler
3. How to use Nicorette Inhaler
4. Possible side effects
5. How to store Nicorette Inhaler
6. Contents of the pack and other information

1 What Nicorette Inhaler is and what it is used for

Nicorette Inhaler is a nicotine replacement therapy (NRT).

It is used to relieve and/or prevent withdrawal symptoms and reduce the cravings you get when you try to stop smoking. It can be used to help you quit smoking completely or to relieve cravings and withdrawal symptoms during times when you cannot smoke, e.g. in smoke free areas such as on a plane or at the cinema.

Nicorette Inhaler can sometimes be used in combination with Nicorette Invisi 10mg and 15mg Patch for the treatment of tobacco dependence as part of a stop smoking programme.

When you stop smoking or cut down the number of cigarettes you smoke, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke (*craving*). This indicates that you were dependent on nicotine.

You may also miss the frequent movements of your hand to your mouth, inhaling, etc. which are known as habitual movements.

When you use Nicorette Inhaler, air is drawn through the inhaler and nicotine is released. The nicotine is absorbed into your body through the lining of your mouth. This relieves the unpleasant withdrawal symptoms. It will also help to stop your craving to smoke. For the best effect, ensure that you use Nicorette Inhaler correctly – see "How to Use Nicorette Inhaler."

The benefits of stopping smoking far outweigh any potential risk from using nicotine from NRT. Each inhalation provides about 13 micrograms of nicotine. It is the toxins in cigarette smoke such as tar, lead, cyanide and ammonia that cause smoking related disease and death, not the nicotine.

2 What you need to know before you use Nicorette Inhaler

Do not use Nicorette Inhaler:

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast feeding, unless advised by your doctor.
- If you are a non-smoker or are under 18 years of age.

Warnings and Precautions

Talk to your doctor, nurse or pharmacist before using Nicorette Inhaler

- if you are in hospital because of heart disease (including heart attack, disorders of heart rate or rhythm, or stroke).
- if you have high blood pressure.
- if you have persistent indigestion or pains in the chest
- if you have a stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus (passage between the mouth and stomach).
- if you have liver or kidney disease.
- if you have a long term throat disease or difficulty breathing due to bronchitis, emphysema or asthma. Nicorette Inhaler may not be suitable for you to use and you may be advised to use a different type of NRT.
- if you have an overactive thyroid gland or have a phaeochromocytoma (a tumour of the adrenal gland that can affect blood pressure) – your doctor will have told you this.
- if you have diabetes – monitor your blood sugar levels more often when starting to use Nicorette Inhaler as you may find your insulin or medication requirements alter.
- If you have a history of epilepsy or seizure.
- **If any of these apply, talk to your doctor, nurse or pharmacist.**
- **Transferred dependence:** Nicotine in any dose form can result in a dependence syndrome after continued use. Transferred dependence can occur with this medicine, but is unusual and is both less harmful and easier to break than smoking dependence.

This product contains small cartridges which could be a choking hazard if a child attempts to swallow one. Keep any unused cartridges in the pack out the sight and reach of children.

Other medicines and Nicorette Inhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including the following medicines as stopping smoking may require these doses of these medicines to be adjusted:

- theophylline to treat asthma
- tacrine for Alzheimer's disease
- clozapine or olanzapine for schizophrenia
- imipramine, clomipramine, fluvoxamine to treat depression
- ropinirole for Parkinson's disease
- pentazocine to treat pain
- flecainide or adenosine to treat irregular or fast heart beats

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are **pregnant**: ideally, you should try to give up smoking without NRT. Do not use Nicorette Inhaler unless advised by your doctor.

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If you are **breast-feeding**: Nicorette Inhaler should not be used during breast feeding, unless advised by your doctor.

3 How to use Nicorette Inhaler

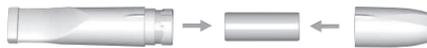
Always use this medicine exactly as described in this leaflet or as your doctor, nurse or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to use Nicorette Inhaler

Follow the instructions below.

Setting up the Inhaler

- 1 Take the sealed plastic tray from the box. Peel back the foil.
- 2 Take the white plastic mouthpiece from the tray.
- 3 Twist the two sections of the mouthpiece until the two marks line up. Then pull the mouthpiece apart.
- 4 Take a cartridge from the tray. Push the cartridge firmly into the bottom of the mouthpiece until the seal breaks.
- 5 Put the top section on the mouthpiece, lining up the two marks. Push together firmly to break the cartridge seal.
- 6 Twist to lock.



Special information about using the Inhaler

Using the Inhaler

- 1 Inhale using the inhaler, either deeply or shallow puffs. Choose the way that suits you. Either way, your body will receive the amount of nicotine required to give craving relief. You may find it takes more effort than inhaling from a cigarette, but the amount of nicotine you absorb through the lining of your mouth is the same whether you take deep or shallow puffs.
- 2 It is up to you how many inhalations (puffs) you take, how often you take them and for how long.
- 3 Once a cartridge is used up, you will need to change it. Most people use between 3 and 6 cartridges a day

Changing a cartridge

- 1 Open the mouthpiece as in step 3 of Setting up the Inhaler. Pull out the cartridge and dispose of it safely.
- 2 Put a new cartridge into the inhaler as in steps 4-6 of Setting up the Inhaler.

Dosage and temperature

Nicorette Inhaler works best at room temperature and it is best not to use the Inhaler in the cold.

In cold surroundings (below 15°C or 59°F) you may have to inhale more often to get the same amount of nicotine as when using the inhaler at room temperature. When you are in surroundings above 30°C or 86°F, you should inhale less often to avoid taking in too much nicotine.

How to stop smoking: your choice

Because smoking is an addiction, you may find it difficult to give up. From time to time you may still have strong urges to smoke but if you follow these recommendations, you have a good chance of quitting.

Some people may find it easier to set a quit date and stop smoking **immediately**. Others who are unable or not ready to stop smoking abruptly, may benefit from gradually

reducing the number of cigarettes they smoke each day until they feel able to stop completely.

If you find it hard to stop smoking using Nicorette Inhaler, you are worried that you will start smoking again without it or you find it difficult to reduce the number of cartridges you are using, talk to your doctor, nurse or pharmacist. Remember Nicorette Inhaler is not intended as a substitute for smoking, it is an aid to give up.

Use one of the four options which follows:

* Stopping Immediately

The idea is to stop smoking immediately and use the inhaler to relieve the cravings to smoke. After achieving this you then stop using the inhaler.

Adults aged 18 years and over

The Inhaler can be used for up to 3 months using the following steps:

- Step 1: Set a date to quit** and stop smoking cigarettes.
Step 2: Over a period of up to 8 weeks, whenever you get a craving to smoke, you use the Inhaler instead. Aim to use between 3 and 6 cartridges per day. Do not use more than 6 per day.
Step 3: After 8 weeks much of your smoking routine will have gone. Over the next 2 weeks start to reduce the number of cartridges used per day by half.
Step 4: During weeks 11 and 12 continue to reduce the number of cartridges per day till you are using none at all.

* Stopping Gradually

The idea is to start by gradually replacing some of your cigarettes with the use of the inhaler. After achieving this you then give up cigarettes completely while using the inhaler. Finally, you give up using the inhaler.

Adults aged 18 years and over

Step 1: Work out how many cigarettes you smoke per day. Set a date to start reducing the number of cigarettes you smoke.

Step 2: Start reducing. Over the next few months, reduce the number of cigarettes you smoke by using Nicorette inhaler when you feel the urge to smoke, until you feel ready to stop completely. Aim to use 3 or more cartridges per day, but not more than 6.

► **If after 6 weeks you have not reduced the number of cigarettes you smoke, ask your doctor, nurse or pharmacist for advice.**

► **You should aim to stop smoking completely by six months from the beginning of treatment.**

Step 3: Stop smoking. Cut out all cigarettes and continue using the inhaler for up to 3 months to relieve your cravings to smoke.

Follow the four steps outlined above for "Stopping Immediately"

► **If you need to use the product for longer than 6 months, ask your doctor, nurse or pharmacist for advice.**

* Combination Therapy

Nicotine replacement therapy often provides sufficient nicotine when used as a single therapy. However, heavy smokers (more than 20 cigarettes a day), people who experience breakthrough cravings or those who have failed with single therapy may benefit from using combination therapy with patch and inhaler. Below is the dosage information for combination therapy. This shows the number of patches and inhaler cartridges you should be using, when you should use them and the maximum amount of time you should be using the therapy for.

turn over →



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Combination therapy for Adults aged 18 years and over

Directions for combination use

Age	Dosage of Invisi Patch	Dosage of Inhaler
Adults aged 18 years and over	<ul style="list-style-type: none">Apply one new 15mg Invisi Patch to the skin when you wake. Do this for the first 8 weeks.Apply one new 10mg Invisi Patch to the skin when you wake. Do this for the next 4 weeks	<ul style="list-style-type: none">as required to relieve cravings (do not exceed 6 cartridges per day).
<ul style="list-style-type: none">Remove the patch 16 hours after application, usually at bedtime.Do not exceed 6 cartridges per day.		

See the following step by step process for giving up smoking using Nicorette Combination Therapy. Make sure that you read the instructions for each step in the information which follows:

Step 1: Use the Nicorette Invisi 15mg Patch and the Inhaler for the first 8 weeks.

Step 2: Use the Nicorette Invisi 10mg Patch and the Inhaler for the next 4 weeks.

Step 3: Stop using the patch and continue with the Inhaler for the next 3 months during which time the habits associated with smoking will be lost

* During times you cannot smoke

If you are a smoker and are in a situation where you are prohibited from smoking or it is inconvenient to smoke (e.g. in a smoke-free area such as on a plane or at the cinema), you can use Nicorette Inhaler to relieve any cravings you may experience.

Adults aged 18 years and over

Dose: As needed. Remember to change your cartridge when necessary and do not use more than 6 cartridges per day.

ⓘ Children under 18 years

Do not give this product to children under 18 years of age.

ⓘ If you have used Nicorette Inhaler too much

If you have used more than the recommended number of cartridges, you may experience nausea (feeling sick), increased salivation, pain in your abdomen, diarrhoea, sweating, headache, dizziness, hearing disturbance or weakness.

- If you do get any of these effects contact a doctor or your nearest hospital Accident and Emergency department immediately. Take this leaflet and the pack with you.

⚠ If a child uses an inhaler or swallows a cartridge

- Contact a doctor or your nearest hospital Accident and Emergency department immediately if a child uses your inhaler, or chews, sucks or swallows a cartridge. Take this leaflet and the pack with you.
Nicotine inhalation or ingestion by a child may result in severe poisoning

4 Possible side-effects

Like all medicines, this medicine can cause side-effects though not everybody gets them. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to stopping smoking (nicotine withdrawal)

You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use Nicorette Inhaler cartridges before you are ready to reduce your nicotine intake.

⚠ These effects include:

- irritability or aggression
- feeling low
- anxiety
- restlessness
- poor concentration
- increased appetite or weight gain
- urges to smoke (craving)
- night time awakening or sleep disturbance
- lowering of heart rate
- dizziness, lightheadedness, blurry vision, nausea
- coughs and colds
- constipation
- mouth ulcers
- bleeding in the mouth
- swelling of the nasal passages and back of the throat

Effects of too much nicotine

It is possible to inhale too much nicotine if you use the inhaler in very warm surroundings. You may also get these effects if you are not used to inhaling tobacco smoke.

⚠ These effects include:

- feeling faint
- feeling sick (nausea)
- headache

Side-effects for Nicorette Inhaler

If you experience any of the following, stop using the Inhaler and seek medical help immediately:

- swelling of the face, lips, tongue, throat or other parts of the body, wheezing or difficulty breathing or swallowing
- chest pain, palpitations, an abnormal or fast heart beat
- pins and needles

Other side-effects include:

Very common side-effects:

(may affect more than 1 in 10 people)

- headache
- irritation of the throat
- nausea
- hiccups

Common side-effects:

(may affect up to 1 in 10 people)

- cough
- stomach pain
- feeling sick (nausea)
- sickness (vomiting)

- diarrhoea
- allergic reactions (swelling of the mouth, lips, throat and tongue, itching of the skin, ulceration and inflammation of the lining of the mouth).
- burning sensation in the mouth
- taste disturbance or loss of taste
- pins and needles
- dry mouth
- indigestion
- excessive gas or wind
- increased salivation
- sore and inflamed mouth
- tiredness (fatigue)

Uncommon side-effects:

(may affect up to 1 in 100 people)

- abnormal dreams
- chest palpitations, fast heart rate or beat
- sudden reddening of the face and/or neck
- high blood pressure
- sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath
- loss or damage to voice
- shortness of breath
- nasal congestion
- sneezing
- throat tightness
- burping (belching)
- swollen, red, sore tongue
- blisters in the mouth
- numbness or tingling of the mouth
- hives (urticaria)
- excessive sweating
- itching
- rash
- pain in jaw
- aching muscles, muscle tenderness or weakness not caused by exercise
- chest discomfort and pain
- General feeling of discomfort or being unwell or out of sorts (malaise)

Rare side-effects:

(may affect up to 1 in 1000 people)

- difficulty in swallowing
- decreased feeling or sensitivity, especially in the mouth
- feeling of wanting to be sick (retching)

Side effects with unknown frequency:

- blurred vision, watery eyes
- stomach discomfort
- dry throat, lip pain
- redness of the skin
- muscle tightness

Not known: frequency cannot be estimated from the available data

- Seizure

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Website: www.hpra.ie

You can also report side effects directly in Malta via:
ADR Reporting at: www.medicinesauthority.gov.mt/adrportal
By reporting side-effects you can help provide more information on the safety of this medicine.

5 How to store Nicorette Inhaler

Cleaning the Inhaler

Clean the empty mouthpiece several times a week by rinsing it in water.

Storing the Inhaler and cartridges

- Keep this medicine out of the sight and reach of children and animals.
- Do not use this medicine after the expiry date which is stated on the carton and blister after 'Use before'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions

Disposal

Dispose of your used Inhaler cartridges safely.

When a cartridge is used up, it is very important that you dispose of the empty cartridge carefully as it still contains some nicotine fixed to the plug. This nicotine is not available for inhalation but could be harmful to children or pets if swallowed or sucked. You can return the empty cartridge to the foil tray then dispose of all the empty cartridges with your household rubbish.

6 Contents of the pack and other information

What Nicorette Inhaler contains

The active substance is nicotine.

The other ingredients are: Levomenthol and Porous plug of polyethylene.

What Nicorette Inhaler looks like and contents of the pack

Nicorette Inhaler consists of a white plastic mouthpiece into which you insert a tube-like cartridge containing 15 mg of nicotine, the active ingredient, held in a porous plug. The plug also contains levomenthol to give the nicotine a slight minty flavour.

Nicorette Inhaler is supplied as either

- a pack containing a mouthpiece and 4 cartridges

or

- a pack containing a mouthpiece and 20 cartridges

Marketing Authorisation Holder and Manufacturer

The Product Authorisation holder is JNTL Consumer Health I (Ireland) Ltd.

Block 5, High Street, Tallaght, Dublin 24, Ireland

The manufacturer is McNeil AB, PO Box 491, Norrbroplatsen 2, SE-251 09 Helsingborg, Sweden

For further information on smoking cessation please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie.

This leaflet was last revised in December 2023