PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

NICORETTE® Transdermal Patch 10 mg

NICORETTE® Transdermal Patch 15 mg

NICORETTE® Transdermal Patch 25 mg

Nicotine.

Read all of this leaflet carefully because it contains important information for you.

NICORETTE® Transdermal Patch is available without a doctor's prescription, for you to help you stop smoking. Nevertheless, you still need to use NICORETTE® Transdermal Patch carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NICORETTE® Transdermal Patch with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What NICORETTE® Transdermal Patch is and what it is used for

NICORETTE® Transdermal Patch helps you to give up smoking by relieving nicotine craving, as well as the unpleasant withdrawal effects that smokers experience when they stop smoking. NICORETTE® Transdermal Patch is most effective if you use it while you participate in a behaviour modification programme to help you stop smoking.

2. What you need to know before you use NICORETTE® Transdermal Patch

Do not use NICORETTE® Transdermal Patch if:

- You are hypersensitive (allergic) to nicotine or any of the other ingredients or components of NICORETTE® Transdermal Patch.
- You have just suffered a heart attack or within 3 months after having a heart attack.
- You have a severe heart condition that effects your heart rate or rhythm.
- You have severe chest pain (angina pectoris/Prinzmetal's variant angina).
- If you recently had a stroke.
- You are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with NICORETTE® Transdermal Patch

Ask your doctor or pharmacist for advice before using NICORETTE® Transdermal Patch if:

- You have recently had a serious cardiovascular event like a stroke or heart attack.
- You have persistent indigestion or pains in the chest.
- You have uncontrolled high blood pressure.
- You have diabetes (high blood sugar). You will have to monitor your blood sugar levels more often when you use NICORETTE® Transdermal Patch. Your doctor may have to adjust your medicine as a result of stopping smoking.
- You have been diagnosed with Buerger's disease (a condition that causes extreme pain in your lower arms or legs due to blockages of your arteries and veins) or if your arteries are

blocked and you have reduced blood flow to your extremities.

- You have severe or moderate liver or severe kidney disease.
- You have been told you have phaeochromocytoma (a tumour of your adrenal glands.
- You have an overactive thyroid gland.
- You have a stomach ulcer, an ulcer in your small intestines, inflammation of your stomach or inflammation of your oesophagus (the passage between your mouth and your stomach).
- You suffer from heart failure.
- You are younger than 18 years of age.
- You do not smoke.

Stop using NICORETTE® Transdermal Patch if you experience a severe or persistent skin reaction during treatment.

Transferred dependence can occur but is unusual and is both less harmful and easier to break than smoking dependence.

Do not smoke while you are using NICORETTE® Transdermal Patch.

Remove NICORETTE® Transdermal Patch before you undergo magnetic resonance imaging (MRI) procedures.

If you are using NICORETTE® Transdermal Patch in combination with nicotine 2 mg chewing gum or oromucosal spray you must read the patient information leaflet of each product respectively.

Other medicines and NICORETTE® Transdermal Patch

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

NICORETTE® Transdermal Patch is not likely to interact with other medicines, however tell your doctor if you are taking:

- Adenosine (used to treat an irregular heart beat).

Stopping smoking may interfere with other medicines.

This is especially important if you take medicines containing:

- Caffeine (stimulant found in coffee and some medicines)
- Theophylline (for asthma)
- Imipramine, clomipramine (for depression or mood disorders)
- Tacrine (used to treat Alzheimer's disease)
- Clozapine, olanzapine (used to treat schizophrenia)
- Ropinirole (used to treat restless leg syndrome)
- Flecainide (used to treat an abnormal heart rate)
- Pentazocine (used to treat severe pain)
- Fluvoxamine (used to treat anxiety disorders)
- Glutethimide (for insomnia)
- Furosemide (for water retention associated with heart failure)
- Propanolol (for high blood pressure)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using NICORETTE® Transdermal Patch, as it may cause harm to your baby.

Take adequate precautions to avoid becoming pregnant while using NICORETTE® Transdermal Patch.

Your doctor may wish to consider a pregnancy test before starting therapy with NICORETTE® Transdermal Patch. Do not take NICORETTE® Transdermal Patch if you are pregnant or breastfeeding.

Driving and using machines

NICORETTE® Transdermal Patch can cause dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how NICORETTE® Transdermal Patch affects you.

3. How to use NICORETTE® Transdermal Patch

Do not share your medicines with any other person.

Always use NICORETTE® Transdermal Patch exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of NICORETTE® Transdermal Patch is too strong or to weak, tell your doctor or pharmacist.

How to apply NICORETTE® Transdermal Patch:

NICORETTE® Transdermal Patch should be applied to clean, dry intact areas of hairless skin, for example on the hip, upper arm, or chest. These areas should be varied each day and the same site should not be used on consecutive days.

1. Wash your hands before applying the patch.
2. Cut open the pouch with scissors along the side, as indicated. Select a clean, dry, hairless intact area of skin, such as the hip, upper arm or chest.
3. Peel one part of the silvery aluminium backing away as far as possible. Avoid touching the sticky surface of the patch with your fingers, as far as possible.
4. Apply the sticky part of the patch carefully onto the skin and peel off the remaining half of the silvery aluminium backing.
5. Press the patch firmly onto the skin with your palm or finger-tips.
6. Rub your fingers firmly round the edge to ensure that the patch sticks firmly.

NICORETTE® Transdermal Patch can be used in combination with 2 mg nicotine gum or 1 mg/spray nicotine oromucosal spray. Each product should be used as per their individual instructions.

If you use more NICORETTE® Transdermal Patch than you should

Symptoms of overdosage are those of acute nicotine poisoning and include nausea, increased salivation, stomach pain, vomiting, diarrhoea, sweating, headache, shaking (tremor), dizziness, faintness, disturbed hearing, confusion and marked weakness.

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the NICORETTE® Transdermal Patch with you so the doctor will know what you have used.

Nicotine in high doses can be very dangerous and sometimes fatal if used by children.

4. Possible side effects

NICORETTE® Transdermal Patch can have side effects.

Not all side effects reported for NICORETTE® Transdermal Patch are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using NICORETTE® Transdermal Patch, please consult your doctor, pharmacist or other health care provider for advice.

NICORETTE® Transdermal Patch may cause side effects similar to those associated with nicotine from smoking or other tobacco use.

These are mainly dose-dependent. Most of the possible side effects occur during the first weeks after start of treatment.

If any of the following happens, stop using NICORETTE® Transdermal Patch and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NICORETTE® Transdermal Patch. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Side effects occurring less frequent:

- Changes in the way your heart beats, for example if you notice it beating faster,
- chest pain,
- shortness of breath (bronchospasm).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- Dizziness,
- headache,
- stomach discomfort, nausea (feeling sick), vomiting (being sick), constipation,
- redness of your skin.

Side effects occurring less frequent:

- Difficulty sleeping, abnormal or vivid dreams,
- feeling irritated,
- paraesthesia (numbness, tingly or burning sensation of your skin),

- hives,
- feeling tired,
- flushing,
- high blood pressure,
- excessive sweating,
- muscle pain,
- reaction at the site where you apply the patch,
- weakness, general feeling of discomfort.

The following side effect may occur, but the frequency is not known:

- Pain in your extremities.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of NICORETTE® Transdermal Patch.

For further information, please contact the Johnson and Johnson call centre on 0860 410032 (landline).

5. How to store NICORETTE® Transdermal Patch

Store at or below 25 °C.

Store all medicines out of reach of children, before and after use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

When NICORETTE® Transdermal Patch is no longer needed, dispose of it carefully where children or animals cannot get it.

6. Contents of the pack and other information

What NICORETTE® Transdermal Patch contains

Each patch contains nicotine equivalent to 1,75 mg per 1,0 cm^2.

The following systems are available:

	NICORETTE® Transdermal Patch 10 mg	**NICORETTE® Transdermal Patch 15 mg**	**NICORETTE® Transdermal Patch 25 mg**
Content of nicotine per patch	15,75 mg	23,62 mg	39,37 mg
Average dose of nicotine delivered during 16 hours	10 mg	15 mg	25 mg
Medicine releasing area	9 cm^2	13,5 cm^2	22,5 cm^2

The amount of nicotine released from each cm^2 of the patch is constant and therefore the dose administered is determined by the size of contact area of the system.

The other ingredients are:

Triglycerides, medium-chain

Basic butylated methacrylated copolymer

Polyethyleneterephtalate-film (PET)

Acrylate matrix

Acrylic adhesive solution

Potassium hydroxide

Croscarmellose sodium

Aluminium acetylacetonate

Release liner

Polyethylenterephthalate (PET) film single-side aluminised, both sides siliconised.

What NICORETTE® Transdermal Patch looks like and contents of the pack

Beige, semi-transparent patch consisting of pre-coated backing layer, nicotine source layer, and a skin contact adhesive layer on a pre-coated aluminised and siliconised release liner. Print on patch in light brown ink.

Cartons containing 7, 14 and 28 sealed, childproof pouches of NICORETTE® Transdermal 10 mg, 15 mg and 25 mg patches.

Holder of certificate of registration

Johnson & Johnson,

241 Main

Road, Retreat,

7945,

South Africa.

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Nicorette Transdermal Patch 10 mg: 45/32.16/0952

Nicorette Transdermal Patch 15 mg: 45/32.16/0953

Nicorette Transdermal Patch 25 mg: 45/32.16/0954

Access to the corresponding Professional Information

The latest electronic Professional Information may be found at the SAHPRA website: https://www.sahpra.org.za/pi-pil-repository/.

Alternatively, you may directly contact Johnson & Johnson (Pty) Ltd.:

Consumer Contact Centre:

0860 410032 (South Africa Only)

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