NIQUITIN TRANSDERMAL PATCH

Nicotine (7mg, 14mg, 21mg)

What is in this leaflet

1. What NiQuitin Transdermal Patch is used for
2. How NiQuitin Transdermal Patch works
3. Before you use NiQuitin Transdermal Patch
4. How to use NiQuitin Transdermal Patch
5. While you are using it
6. Side effects
7. Storage and Disposal of NiQuitin Transdermal Patch
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What NiQuitin Transdermal Patch is used for

Nicotine patches are indicated as an aid to stop smoking, by treatment of tobacco dependence through the relief of nicotine withdrawal symptoms including cravings. Nicotine patches should preferably be used in conjunction with a behavioural support programme as this normally improves the success rate. Nicotine patches may be used in combination with other forms of NRT where appropriate. Permanent cessation of tobacco use is the eventual objective.

How NiQuitin Transdermal Patch works

Nicotine transdermal patch is a transdermal delivery system acting as nicotine replacement therapy in smoking cessation. It acts temporarily to replace much of the nicotine from cigarettes to reduce motivation to smoke and reduce nicotine withdrawal symptoms including nicotine craving associated with quitting, and thus easing the transition from cigarette smoking to complete abstinence. Following transdermal application, the skin rapidly absorbs nicotine released initially from the patch adhesive.

Before you use NiQuitin Transdermal Patch

- *When you must not use it*

Do not use if you are allergic to nicotine or any of the other ingredients in the patches.

Take special care

- If you have liver or kidney disease, consult a healthcare professional before using the product.
- If you have diabetes you should monitor your blood sugar levels more often than usual when starting to use the nicotine patch. Your insulin or medicine requirements may change.
- If you are in hospital because of a heart attack, severe heart rhythm problems or a stroke, you should try to quit smoking without using any NRT products unless your doctor tells you to use them. Once you are discharged from hospital, you can use NRT as normal.
- If you have any heart problems, you should consult a healthcare professional before using Pre-cessation or Combination NRT (Nicotine Replacement Therapy).
- If you get skin redness, swelling or rash you should stop using the patch and consult a healthcare professional.
- If you have dermatitis you may get a reaction to the patch.

If you are quitting with the Pre-cessation regimen (i.e. use of the nicotine patch prior to quitting smoking) and experience any untoward effects, you should stop smoking. If the effects do not get better, you should remove the patch; you can start using it again when you feel better.

Nicotine patches should not be used in children under 18.

Keep all medicines out of the reach and sight of children.

Each transdermal patch contains 36mg nicotine, equivalent to 5.1mg/cm^2 of nicotine releasing 10mg and delivering over 24hours.

If you are pregnant, you should stop smoking without using NRT. However, if you have tried and this has not worked, NRT may be recommended by a healthcare professional to help you stop smoking.

Women who are breast-feeding may use the nicotine patch since the level of nicotine in breast milk is small and less hazardous than cigarette smoke

- *Before you start to use it*

Come up with your own quit smoking plan, or seek the help of a healthcare professional. NRT can help relieve your cravings and withdrawal symptoms so that you can focus on quitting smoking and, eventually, NRT.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use NiQuitin Transdermal Patch

- *How much to use*

Adults (including the elderly) and adolescent aged 18 years and over: One patch should be applied daily, preferably on waking.

A new patch should be applied to a different place on skin that is dry, clean and hairless. It should be pressed firmly on the skin with the palm of hand for 10 seconds. The same skin site should not be used for at least 7 days. Areas where the skin creases should be avoided.

Do not apply to skin which is red, broken or irritated.

When applying the patch, avoid touching the eyes and nose.

When you have finished, always wash your hands with water.

Water will not harm the nicotine transdermal patch, if it has been applied properly. The user can bathe, swim or shower for short periods while wearing the nicotine transdermal patch. It is recommended that the patch be worn for 24 hours to optimise the effect against morning cravings.

When you take off a patch, fold it in half with the sticky side inwards and place it in the sachet from which you have just taken your new patch. Throw the sachet containing the used

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patch away carefully, making sure it is out of the reach of children or pets.

Abrupt cessation of smoking:
Stop smoking at initiation of treatment. Completing the full program will allow the user to gradually reduce his/her level of nicotine and significantly increases his/her chances of quitting successfully. Use according to the following schedule:

Over 10 cigarettes a day	**Step 1** (21 mg delivered): Initial treatment period 6 weeks
	Step 2 (14 mg delivered): Stepdown treatment period 2 weeks
	Step 3 (7 mg delivered): Stepdown treatment period 2 weeks
10 cigarettes a day or less (Light Smokers)	**Step 2** (14 mg delivered): Initial treatment period 6 weeks
	Step 3 (7 mg delivered): Stepdown treatment period 2 weeks

For optimum results, the 10 week treatment course (8 weeks for light smokers), should be completed in full. Treatment with NiQuitin Transdermal Patch may continue beyond 10 weeks if it is needed to stay cigarette free.
If you are still using the patch after 9 months, talk to a healthcare professional for advice.
If the user resumes smoking, he/she may use the patch again in a future attempt at quitting smoking.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking NiQuitin Transdermal Patch for as long as your doctor recommends.

- *If you forget to use it*

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose. Consult your doctor or pharmacist on what you should do if you are unsure.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

Do not apply to skin which is red, broken or irritated.
When applying the patch, avoid touching the eyes and nose.
When you have finished, always wash your hands with water.
If you get skin redness, swelling or rash you should stop using the patch and consult a healthcare professional.
If you are still using the patch after 9 months, talk to a healthcare professional for advice.
Keep out of sight and reach of children.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give NiQuitin Transdermal Patch to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects
Side effects are listed below –they are grouped based on the likelihood with which they can occur.
Very common (affects more than1 in 10 people)

- Skin reactions in the area where you apply the patch
- Sleep disturbances including insomnia and abnormal dreams
- Feeling /being sick
- Headache
- Dizziness

Common (affects between1 in 10 and 1 in 100 people)

- Nervousness
- Trembling
- Shortness of breath
- Cough
- Sore or swollen throat
- Indigestion
- Stomach pains
- Diarrhoea
- Constipation
- Sweating
- Dry mouth
- Joint, muscle, chest and limb pains
- Tiredness or weakness
- Palpitations (feeling your heart beat)

Very rare (affects less than1 in 10,000 people)

- Sensitivity of the skin to sunlight
- Severe allergic reaction symptoms of which include sudden wheeziness or tightness of chest, rash and feeling faint.

You may get slight redness and itching, burning and tingling of the skin where a patch has been. This usually disappears quickly after removal of the patch. Rarely, a more severe reaction at the sticking site, may occur. If this happens stop using the patch and tell your doctor.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of NiQuitin Transdermal Patch

- *Storage*

Store below 30°C.

- *Disposal*

When you take off a patch, fold it in half with a sticky side inwards and place it in the sachet from which you have just taken your new patch. Throw the sachet containing the used patch away carefully, making sure it is out of the reach of children or pets. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Pinkish tan backing with the marking NCQ7, silver coloured underside with a transpartent slit release lines. Nomical dimensions of 2.5cm x 2.8cm.

- *Ingredients*
  - Active ingredient
    Nicotine
  - Inactive ingredients
    Polyisobutylene Adhesive Lamanite, polyethylene/aluminium/polyethylene terephthalate/ethylene vinyl acete, Ethylene Vinyl Acetate Copolymer, Nitrogen, Brown Ink, Polyester Film

- *MAL number*

MAL20001551ACRZ
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Manufacturer
GlaxoSmithKline Dungarvan Limited
Knockbrack, Dungarvan,
Co. Waterford,
Ireland.

Packed By
Sterling Drug (Malaya) Sdn Bhd
Lot 89, Jalan Enggang,
Ampang/ Ulu Kelang Industrial Estate,
54200 Selangor Darul Ehsan

Product Registration Holder
DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm
No. 1, Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor,
Malaysia.

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