

QuitX[®] Patches (Nicotine)

CONSUMER INFORMATION LEAFLET

IMPORTANT – Please read this leaflet very carefully **BEFORE** you start to use the patches. After reading, if you have any questions, consult your pharmacist or doctor.

QuitX – Controlled Release Nicotine Patch – Transdermal Nicotine

1. Identification

QuitX is available in 3 nicotine dosage strengths:

QuitX STEP 1

52.5mg nicotine patch (release rate 21mg nicotine per 24 hours), AUST R 77927.

QuitX STEP 2

35mg nicotine patch (release rate 14mg nicotine per 24 hours), AUST R 77929.

QuitX STEP 3

17.5mg nicotine patch (release rate 7mg nicotine per 24 hours), AUST R 77930.

There are 7 patches per box.

QuitX Patches contain nicotine, acrylic/acrylate copolymer adhesive, coconut oil – fractionated, methacrylic acid copolymer.

2. What QuitX patches are used for

QuitX patches can help you stop smoking. You probably know that smoking is a very difficult habit to break. There are two sides to quitting smoking. The first is the psychological dependence on cigarettes. You have probably smoked for many years and smoking has become an important part of your life.

The other side is a physical addiction to nicotine. Cigarettes contain nicotine, and your body has become dependent on nicotine. The QuitX patch delivers nicotine into your bloodstream through your skin. Using QuitX will help to gradually reduce the amount of nicotine your body craves each day. This type of treatment is called Nicotine Replacement Therapy (NRT).

It is recommended that QuitX be used in combination with personal counselling. Counselling is available from various groups such as Quit For life. To get the best out of QuitX, we encourage you to enrol in one of these groups.

QuitX is not intended for short periods, *e.g.* plane trips or other times when you cannot smoke. It is designed to help you quit smoking, not as a substitute for smoking.

QuitX works most effectively when you have a strong personal commitment to stop smoking. You cannot rely on QuitX alone to break the habit.

Each nicotine patch helps relieve many nicotine withdrawal symptoms and cravings (such as early morning), which you would otherwise have when you stop smoking.

3. Before Using QuitX Patches

When you must not use it

There are some people for whom QuitX Patches may not be suitable. Do not use QuitX Patches if:

- you have a generalised skin condition or disorder
- you are a non-smoker
- you are an occasional smoker
- you are under 12 years of age
- you are allergic to nicotine or to any component of the patch
- the expiry date (EXP) printed on the pack has passed
- the packaging is torn or shows signs of tampering.

There are no health benefits to smoking. It is always better to give up smoking and using QuitX can help. In general, any possible side effects associated with NRT are far outweighed by the well established dangers of continuing to smoke.

If you are in hospital because of a heart attack, severe heart rhythm disorders or a stroke, you should try to quit smoking without using NRT unless your doctor tells you to use it. Once you are discharged from the hospital, you may use NRT in consultation with your doctor.

If you have had allergic reactions that involve swelling of the lips, face and throat (angioedema) or itchy skin rash (urticaria), using NRT can sometimes trigger this type of reaction.

If you have allergic eczema or dermatitis you may get a reaction to the patch.

Before you start to use it

Some conditions require special precautions before using QuitX patches. Consult your doctor if you have any of the following conditions:

- severe high blood pressure
- chest pain (angina), even if it is well controlled
- recent heart attack
- an irregular heartbeat
- recent stroke
- other heart or blood vessel disease
- diabetes requiring insulin
- serious kidney or liver problems
- uncontrolled, overactive thyroid
- stomach ulcer
- tumour of the adrenal gland.

- you are pregnant or trying to become pregnant
- you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell them before using QuitX Patches.

If you have diabetes you should monitor your blood sugar levels more often than usual when starting QuitX Patches as you may find your insulin or other medication requirements alter.

If you are pregnant or breastfeeding then you should try to quit smoking without the use of QuitX Patches if possible. However it is better to stop smoking using NRT than to continue smoking.

If you are pregnant

Smoking during pregnancy has risks such as poor growth of your baby before birth, premature birth or still birth. Stopping smoking is the best way to improve both your health and that of your baby. The earlier you stop smoking, the better.

Ideally, if you are pregnant, you should stop smoking without using NRT.

However, if you have tried and this hasn't worked, NRT may be recommended to help you stop smoking. This is because it is better for your developing baby than if you carry on smoking. The decision to use NRT should be made as early on in your pregnancy as possible and you should aim to use it for only 2-3 months.

Products that are taken intermittently, such as gum, are preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness. If you are going to use QuitX Patches, make sure you remove the patches before going to bed.

Your doctor can discuss the benefits and risks of using QuitX Patches during pregnancy should you need further help.

If you are breastfeeding

Tobacco smoking causes breathing difficulties and other problems in babies and children. If you need to use NRT to help you quit, the amount of nicotine your baby may receive is much smaller and less harmful than breathing in second hand smoke. QuitX Patches should not be used while breastfeeding. You should use NRT products that are taken intermittently (*e.g.* gum) and breastfeed just before you take the product. This helps your baby to get the smallest amount of nicotine possible.

QuitX Patches may be used by adolescents between the ages of 12 and 18 years.

NRT should only be used in this age group if a counselling program is used as the same time. QuitX Patches should be used for no longer than 12 weeks in this age group except on the advice of a doctor or pharmacist.

Tell your pharmacist or doctor if you are taking any other prescription or

non-prescription medicines, as using QuitX (or stopping smoking) may change their effect.

If you require further advice, you should talk with your doctor or pharmacist.

4. How to Use QuitX Patches

How to get started

It is probably best to nominate a specific day that you will stop smoking. It may be helpful to:

- Try to choose a day when you will not be where others are smoking
- Choose a day with as little stress as possible
- Choose a day not too far in the future.

Tell your family and friends that you have set this target "quit day".

This is the day you take control of your habit and become a non-smoker.

Prepare to stop smoking by trying to reduce the number of cigarettes you smoke each day. You should stop smoking completely while using QuitX.

How much to use

The QuitX course lasts for three months and one patch is used each day for the three months. Each patch is worn for one day (24 hours).

As your course progresses, the aim is to use a lower strength patch as your body's desire for nicotine decreases.

QuitX patches come in 3 nicotine dosage strengths. QuitX STEP 1 (21mg/24 hours), QuitX STEP 2 (14mg/24 hours) and QuitX STEP 3 (7mg/24 hours).

The correct strength for you depends on how many cigarettes you smoke each day. There are two sets of instructions here. Instruction A is for people who smoke 20 or more cigarettes each day and Instruction B is for people who smoke less than 20 cigarettes each day. Choose the correct Instructions for you.

QuitX patches are designed to be used as part of a 12 week "weaning off" nicotine program. This consists of the 4-4-4 week program:

STEP 1 - The first 4 weeks – Patch delivering 21mg of nicotine over 24 hours.

STEP 2 - The second 4 weeks – Patch delivering 14mg of nicotine over 24 hours.

STEP 3 - The last 4 weeks – Patch delivering 7mg of nicotine over 24 hours.

If you have a previous medical condition your doctor may choose to vary the dosage as appropriate.

Instruction A

If you smoke 20 or more cigarettes each day

Weeks 1 - 4:

- Stop cigarette smoking and use one QuitX STEP 1 patch each day for 4 weeks.
- After 4 weeks you should no longer be smoking cigarettes and can move on to QuitX STEP 2. However if you are still smoking, consult your doctor or pharmacist.

Weeks 5 - 8:

- Use one QuitX STEP 2 patch each day for another 4 weeks.
- After week 8, if you are still a non-smoker, you can move on to QuitX STEP 3. But if you have smoked during weeks 5 - 8, consult your doctor or pharmacist.

Weeks 9 - 12:

- Use one QuitX STEP 3 patch each day for another 4 weeks.
- After week 12 you should stop using the patches. You have become a non-smoker. Congratulations!

Instruction B

If you smoke less than 20 cigarettes each day, commence treatment with QuitX STEP 2 nicotine patch and remain on this therapy for 4 weeks.

Weeks 1 - 4:

- Stop cigarette smoking and use one QuitX STEP 2 patch each day for 4 weeks.
- After 4 weeks you should no longer be smoking cigarettes and can move on to QuitX STEP 3. But if you are still smoking consult your doctor or pharmacist.

Weeks 5 - 12:

- Use one QuitX STEP 3 patch each day for 8 weeks.
- If you have smoked during your course of treatment in weeks 5 - 8, please consult your doctor or pharmacist before proceeding further.
- Similarly, if you have smoked during your course of treatment in weeks 9 - 12, please consult your doctor or pharmacist.
- After week 12 you should stop using the patches. You have become a non-smoker. Congratulations!

5. How and where to apply the patch

- Cut open the pouch along the dotted line. Keep the sachet for future disposal of the patch.
- Remove the protective liner from the sticky side of the patch.
- Apply the QuitX patch to a clear, dry, non-hairy area of skin free from creams, lotions (including sunscreen products or insect repellents), ointments, oil or powder. Wash and clean the area thoroughly before the application. After a warm bath or

shower, wait until the skin is cool and dry before application of the patch (especially important in hot and humid weather, so as to maximise initial adhesion).

- Do not shave the skin as this could cause irritation.

- The skin should not be broken or inflamed in any way (this includes e.g., sunburn, rash, eczema).

- You may use your chest, back, upper arm or hip. Try to avoid areas where your skin folds when you sit or exercise.

- Place the sticky side of the patch onto the area of skin you have chosen and press firmly with the palm of your hand for at least 20 seconds. Then run your fingers around the edge pressing firmly. Do not try to check if the patch has stuck by lifting the edge. This may make it come loose.

- Once applied, do not remove and re-apply elsewhere as the patch will not re-adhere well.

- When replacing QuitX after 24 hours, choose a different location for the new patch.

- Remove the used patch, fold it in half, sticky side inwards, replace in the original sachet and discard carefully, keeping it out of the reach of children or pets.

- Do not flush down the toilet.

Additional information:

- You can swim, bath or shower with the patch on. However, wait at least until one hour after you apply the patch before undertaking any sweaty or wet activity. This will help maximise patch adhesion.

- Do not use bath oils or shower gels with oily ingredients, either before or after application of the patch, as this could affect patch adhesion.

- Despite using all the precautionary measures noted in this leaflet, be aware that excessive sweating or oily skin can lead to poor patch adhesion. Very hot or humid conditions can also affect adhesion.

- If the patch should fall off, secure it back in place with a medicinal adhesive tape or apply fresh patch and continue. Change the patch at the usual time the following day.

- It is best not to use soap on the patch or skin immediately surrounding the patch.

- Do not smoke (or use nicotine gum) while using the patch – remember there is nicotine in your system for several hours after removing the patch.

- If you forget to change the patch at the usual time, change it when you remember and then change the patch at the usual time the following day.
- It is recommended that you do not apply the patch to a previously used skin site for three days.
- You should wear no more than one QuitX patch at a time.
- QuitX patches should not be used for periods longer than 3 months.

6. While you are using QuitX Patches

Things you must do:

Use QuitX exactly as instructed.

If you follow these recommendations you should get the full benefit of this QuitX Support program.

Stop smoking completely while using QuitX.

You may have increased side effects if you continue to smoke while wearing the patch.

Tell your doctor or pharmacist if you continue to smoke while you are using QuitX.

If you become pregnant while you are using QuitX, tell your doctor immediately.

Your doctor will discuss the benefits and risks of using QuitX Patches during pregnancy and help you decide whether or not you should continue using it.

Tell any doctors, dentists and pharmacists who are treating you that you are using QuitX Patches.

Things you must not do:

Do not stop using QuitX Patches suddenly.

You may get side effects similar to those you would get if you stopped smoking suddenly.

7. Unwanted effects

The nicotine in QuitX Patches can cause reactions like those caused by smoking. These reactions include dizziness, headache, nausea (feeling sick) or sleep disturbances. These reactions are usually mild but tell your doctor or pharmacist if they worry you.

The patch can cause skin irritation. Using a different area of skin to apply the patch each day can reduce this.

However if you have severe redness, swelling, itching, burning sensation or blisters at the patch site, or a rash (*e.g.*, itchy red rash or hives) you should remove the patch and tell your doctor immediately or go to the Accident & Emergency at your nearest hospital. This could be an allergic reaction to QuitX.

Keep QuitX Patches out of Reach of Children at all times

Nicotine is a highly toxic substance and could be life threatening to children. Each QuitX patch is sealed in a child-resistant sachet. Please take particular care to dispose of the used patches carefully.

8. Overdosage

If you smoke or use other products containing nicotine while wearing a QuitX patch, you may suffer an overdose of nicotine.

The signs and symptoms of nicotine overdose include pallor, sweating, nausea, salivation, vomiting, stomach upset, diarrhoea, headache, dizziness, hearing and vision disturbances, tremor, confusion, weakness, fainting and breathing difficulties.

If overdosage is suspected, remove the patch immediately, wash the area liberally with water (do not use soap) and dry. Depending on the severity of the symptoms, seek advice from your pharmacist, doctor or hospital casualty department.

Anyone who chews or swallows a nicotine patch should immediately contact a doctor, hospital or the Poisons Information Centre (Phone 13 1126) for treatment advice.

9. Storage

Store out of reach of children and pets. (New and used QuitX patches contain nicotine which can be harmful). In the event of a child applying or playing with a new or used patch, contact a doctor or Poisons Information Centre immediately.

Store below 25°C. Keep the patch sealed in the pouch until needed. Do not use if seal on pack is broken, or if the package is damaged or shows signs of tampering.

Do not store the patch in the refrigerator, even in very hot weather, as this could lead to a loss of adhesion.

10. Where to go for further information

This leaflet is only a summary of information about QuitX and does not represent a complete statement of all possible reactions that may be experienced by users.

Ask your pharmacist or doctor if you have any questions, or if you experience any difficulties before, during or after using QuitX.

QuitX Patches are supplied in Australia by:
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Medical Information
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