

## QuitX<sup>®</sup> 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 are QuitX patches 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.

QuitX is a program consisting of nicotine patches and a QuitX Support Booklet. You should receive the QuitX Support Booklet when you buy your first pack of patches. If you don't have the booklet, ask your pharmacist or write or telephone us and we will send it to you as quickly as possible.

The QuitX Support Booklet contains more help for you to quit smoking, but it is not a substitute for 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

QuitX Patches should not be used by children under 18 years or by non-smokers.

There are also some people for whom QuitX Patches may not be suitable. Do not use QuitX Patches if you have any of these conditions:

- Recent heart attack
- Angina (chest pain) that is not well controlled or is getting worse
- An irregular heartbeat
- Recent stroke
- Pregnancy or breastfeeding
- A generalised skin disorder
- Allergy to nicotine or to any component of the patch.

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.

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
- Other heart or blood vessel disease
- Diabetes requiring insulin
- Kidney or liver problems
- Overactive thyroid
- Stomach ulcer
- Tumour of the adrenal gland.

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

### 4. Using QuitX Patches

#### How to get started

*Make sure you have your QuitX Support Booklet.*

This booklet will be a valuable reference in support of your decision to quit smoking.

*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.**

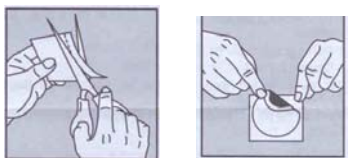
*Weeks 1 - 4:*

- 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.

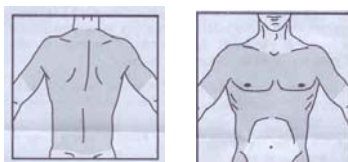
*Weeks 5 - 12:*

- 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.*

*Stop using QuitX Patches immediately if you become pregnant.*

You should not use this program while you are pregnant or if you are breastfeeding.

Tell all of the 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 overdosage 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:  
Alphapharm Pty Limited  
ABN 93 002 359 739  
Chase Building 2  
Wentworth Park Road  
Glebe NSW 2037  
Phone: (02) 9298-3999

Medical Information  
Phone: 1800 028 365

® = Registered Trade Mark

This leaflet was prepared on 27 September 2004.