Please note that there are currently 2 leaflets available for the Multi-Action ACTIFED Dry Coughs licence (PL 15513/0010).

It is the same product licence number for both leaflets i.e PL 15513/0010

The information contained within each leaflet is identical apart from the manufacturer details, column format and leaflet dimensions.

The leaflets are differentiated by manufacturer, column format (either 3 column or 6 column) as well as their respective dimensions.

1. PIL 1 (pages 2-5) - 3 column format, dimensions 160 x 210 mm Manufacturer: Delpharm Orleans, 5 avenue de Concy, 45071 Orléans, Cedex 2, France.

Or

2. PIL 2 (pages 6-7) - 6 column format, dimensions 420 x 160 mm Manufacturer: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

This is a combined pdf of both leaflets.

Both these PILs are from different manufacturer as mentioned above and it will be inserted in carton as per its manufactured site. For Delpharma site’s carton, Delpharm PIL (PIL 1) will be inserted and for McNeil (Springdew) site’s carton, McNeil PIL (PIL 2) will be inserted.
Multi-Action ACTIFED®
Dry Coughs
pseudoephedrine, triprolidine,
dextromethorphan

This medicine is used to help relieve symptoms of cold and flu including irritating dry cough and related congestion symptoms.

This medicine is for use by adults and children aged 12 years and over.

Do not use this medicine:
- There are some people who should not use this medicine. To find out if you are one of them see section 2.
- If you have ever had a bad reaction to any of the ingredients.

Speak to your doctor:
- If you suffer from any of the conditions mentioned in section 2. See section 2.
- If you are taking any other medicines.

Follow the dosage instructions carefully. See section 3.

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

What the medicine is for
Multi-Action Actifed Dry Coughs is a medicine which is used to help relieve dry coughs and related congestion symptoms. The liquid contains triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes, pseudoephedrine hydrochloride which is a decongestant that unblocks stuffy noses and dextromethorphan hydrobromide which is an antitussive to help stop coughing.

The medicine is for use in adults and children aged 12 years and over.

2 Before taking this medicine
This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist. This medicine can lead to dependence. Therefore the treatment should be of short duration.

Do not use this medicine…
- If you have ever had a bad reaction to pseudoephedrine, triprolidine, dextromethorphan or any of the other ingredients.
- If you suffer from lung disease.
- If you have diabetes.
- If you have a phaeochromocytoma (a rare tumour that affects your heart rate and blood pressure).
- If you have an overactive thyroid gland.
- If you have glaucoma (increased pressure in the eye).
- If you have severe kidney problems.
- If you have high blood pressure or heart disease.
- If you are taking beta blockers (used to treat high blood pressure).
- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you are taking selective serotonin reuptake inhibitors (used to treat depression and anxiety such as fluoxetine, paroxetine and sertraline).
- For children under 12 years old.

If any of these apply to you, get advice from a doctor or pharmacist without using Multi-Action Actifed Dry Coughs.

Talk to your doctor or pharmacist...
- If you have kidney or liver problems.
- If you are susceptible to glaucoma (increased pressure in the eye).
- If you have blocked arteries or veins (occlusive vascular disease).
- If you have bronchitis, emphysema or asthma or if you have had a cough for a few weeks or a cough with a lot of mucus (phlegm).
- If you are being treated for a thyroid disorder.
- If you have difficulty passing water or prostate problems (which may mean you need to pass water more often).
- If you are or have ever been addicted to opioids, alcohol, prescriptions medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you have been told by your doctor that you are a slow metabolizer of CYP2D6.
- If you are taking medicines such as certain antidepressants or antipsychotics this medicine may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).
- If you are taking any other cough and cold medicines.
- If your child is prone to developing certain allergic reactions (e.g. atopic reactions).
- If you are taking any other medicines, including:

  Sedatives (drugs used to treat anxiety and tension).
If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

### If you experience the following, stop taking this medicine immediately and contact your doctor:

- A feverish generalised redness of the skin (erythema) associated with pustules. (See section 4).
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Sudden abdominal pain or rectal bleeding due to inflammation of the colon (ischemic colitis). (See section 4).
- Sudden loss of vision. Reduction of blood flow to your optic nerve may occur with this medicine. (See section 4).

### If you are pregnant or breast-feeding

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

### Driving and using machines

- **Avoid alcoholic drink.** This medicine may cause drowsiness. If affected, do not operate machinery.
- This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive when taking this medicine if your ability to drive safely is affected.

**Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine. There is further information for patients who are intending to drive in the UK - go to:**

www.gov.uk/drug-driving-law

### Some of the ingredients can cause problems

- Each 5 ml of this medicine contains 2.8 g of sucrose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

- This medicine contains 208 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

- This medicine contains 5 mg sodium benzoate (E211) in each 5 ml.

- Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed).

- The red colouring, Ponceau 4R (E124) in this medicine may cause allergic reactions.

- This medicine contains 1 g sorbitol in each 5 ml. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

**This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’.**

### 3 How to take this medicine

**Check the table that follows to see how much medicine to take.**

- For oral use only.
- **Always shake the bottle** thoroughly before use.
- Do not take more medicine than the label tells you to.
- Do not use to sedate a child.
- Do not overfill the spoon.
Children under 12 years
Do not give to children under 12 years old.

Adults and Children aged 12 years and over

Age Dose
Adults and children aged 12 years and over
Take two large 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day

- Do not take more than 4 doses in 24 hours.
- Leave at least 4 hours between doses.
- If symptoms persist or worsen stop use and talk to your doctor or pharmacist.

If anyone has too much
If anyone has too much contact a doctor or your nearest Accident and Emergency Department (Casualty) taking this leaflet and pack with you.

If you take more of this medicine than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Also, other types of hallucinations, psychotic disorders, seizures, clumsiness, dizziness, speech problems, lack of energy, high blood pressure, tremor, or constricted or dilated pupils.

Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions. Contact your doctor or hospital straight away if you experience any of the above symptoms.

If you forget to take the medicine
If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

Drug Withdrawal
When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

4 Possible side-effects
Like all medicines, Multi-Action Actifed Dry Coughs can cause side-effects, although not everybody gets them.

If you experience any of the following, stop taking this medicine and seek immediate medical help:
- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders or arms), or heart attack.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Feeling unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than normal.
- Hallucinations or paranoid delusions (seeing or hearing things that are not there, irrational thoughts or feelings).
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine (See section 2).
- Sudden onset of severe headache, nausea, vomiting, confusion, fits, visual disturbances
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.
- Sudden loss or reduction of vision which may be due to reduced blood flow to the optic nerve (ischaemic optic neuropathy).

If you experience any of the following, stop using this medicine and talk to your doctor:
- Trouble passing water (especially in men with prostate problems)

Other effects which may occur include:
Very Common (may affect more than 1 in 10 people)
- Headache

Common (may affect up to 1 in 10 people)
- Difficulty sleeping, dizziness, drowsiness or nervousness
- Difficulty performing tasks
- Blurred vision
- Thickened mucus, dry mouth, upset stomach or nausea

Rare (may affect up to 1 in 1000 people)
- Depression or feeling confused
- Tremors, shakiness or slurred speech

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

Drug Withdrawal
When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised
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- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

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Like all medicines, Multi-Action Actifed Dry Coughs can cause side-effects, although not everybody gets them.

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- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine (See section 2).
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- Sudden loss or reduction of vision which may be due to reduced blood flow to the optic nerve (ischaemic optic neuropathy).

If you experience any of the following, stop using this medicine and talk to your doctor:
- Trouble passing water (especially in men with prostate problems)

Other effects which may occur include:
Very Common (may affect more than 1 in 10 people)
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Common (may affect up to 1 in 10 people)
- Difficulty sleeping, dizziness, drowsiness or nervousness
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Rare (may affect up to 1 in 1000 people)
- Depression or feeling confused
- Tremors, shakiness or slurred speech

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

Drug Withdrawal
When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than those indicated
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

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If you experience any of the following, stop using this medicine and talk to your doctor:
- Trouble passing water (especially in men with prostate problems)

Other effects which may occur include:
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- Difficulty performing tasks
- Blurred vision
- Thickened mucus, dry mouth, upset stomach or nausea

Rare (may affect up to 1 in 1000 people)
- Depression or feeling confused
- Tremors, shakiness or slurred speech
Low blood pressure
Sleep disturbances
An increased awareness of the heartbeat (palpitations)

Other effects which may occur but it is not known how often
Anxiety, irritability or feeling jittery or feelings of extreme happiness
Restlessness
A fast or irregular heartbeat
Tingling or numbness of the hands or feet (Pins and needles)
High blood pressure
Dependence and addiction (see section “How do I know if I am addicted?”)
Dry throat or nose or nose bleeds
Red rash
Shallow breathing
Stomach pain, diarrhoea or vomiting
Pain when passing water
Feeling tired

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing this medicine
Do not store this product above 25°C.
Keep the bottle in the outer carton and away from light.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Further Information

What’s in this medicine?
The active ingredients in 5 ml of Multi-Action Actifed Dry Coughs are:
Triprolidine hydrochloride 1.25 mg, pseudoephedrine hydrochloride 30 mg and dextromethorphan hydrobromide 10 mg.
Other ingredients are: Sorbitol, sucrose, sodium benzoate (E211), methyl hydroxybenzoate (E218), Ponceau 4R (E124) (sodium), alcohol, blackberry flavour (ethanol), levomenthol, vanillin and purified water.

What the medicine looks like
Multi-Action Actifed Dry Coughs is a clear red liquid available in 100 ml bottles.

Marketing Authorisation Holder: McNeil Products Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
Manufacturer: Delpharm Orléans, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France
This leaflet was revised January 2022.
Actifed is a registered trade mark.
McNeil Products Limited 2022 ©
Talk to your doctor or pharmacist…

► If you have kidney or liver problems.
► If you are susceptible to glaucoma (increased pressure in the eye).
► If you have blocked arteries or veins (including leg ulcers).
► If you have bronchitis, emphysema or asthma or have had a cough for a few weeks or a cough with a lot of mucus (CFDPG).
► If you are being treated for a thyroid disorder.
► If you have difficulty passing water or prostate problems (which may mean you need to pass water more often).
► If you are or have ever been addicted to opioids, alcohol, antidepressants, or illegal drugs.
► If you are susceptible to atopic reactions (e.g. eczema, hay fever or asthma) or have a history of headaches caused by caffeine or aspirin.
► If you have been told by your doctor that you are a slow metaboliser of these medicines.
► If you are taking medicines such as certain antidepressants or antipsychotics this medicine may interact with these medicines.
► If you are taking medicines such as certain antihistamines (drugs used to treat hay fever), anticholinergic drugs (drugs used to treat irritable dry cough and related congestion symptoms), or medicines for high blood pressure or have had such in the last 2 weeks, drugs for depression known as monoamine oxidase inhibitors (MAOIs) or reversible inhibitors of monoamine oxidase (RIMA).
► If you are taking other cough and cold medicines.
► If you are prone to developing certain allergic reactions (e.g. anaphylaxis).
► If you are taking any other medicines including:
  ► Sedatives (drugs used to treat anxiety and tension).
  ► Hypnotics (sleeping tablets including barbiturates).

Certain drugs for depression such as: norepinephrine-dopamine reuptake inhibitors (NDRIs), which include bupropion.

<table>
<thead>
<tr>
<th>Talk to your doctor or pharmacist…</th>
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  ❘ Sedatives (drugs used to treat anxiety and tension). |
  ❘ Hypnotics (sleeping tablets including barbiturates). |

### 1. Before taking this medicine

This medicine is suitable for most people but a few people should not use it. For example, if you are taking certain other medicines, your doctor or pharmacist will talk to you about this medicine. This medicine can cause side effects that are more likely to appear than usual.

#### 2. How to use this medicine

This is a leaflet for consumers. It includes an introduction to this medicine, a summary of important information, the type of medicine, and any precautions that might be needed.

#### 3. Driving and using machines

This medicine may cause drowsiness if taken with food. If you are driving or using machines, take care.

#### 4. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 5. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 6. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.

This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you are allergic to any of the medicines you are taking, talk to your pharmacist.

Reference to prices is given for guidance only. All prices are subject to change. The amount of this medicine in question is more than 1 ml or 3 ml. The small amount of alcohol in this medicine will not have any noticeable effect.

### 7. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 8. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 9. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.

#### 10. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 11. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 12. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.

#### 13. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 14. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 15. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.

#### 16. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 17. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 18. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.

#### 19. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 20. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 21. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.

#### 22. How to take this medicine

Check the table that follows to see how much medicine to take.

#### 23. For use only

► Always shake the bottle thoroughly before use.

► Do not take more medicine than the label tells you to.

► Do not use beyond the expiry date on the pack.

► Do not give to children.

#### 24. Some of the ingredients can cause reactions

Each 5 ml of this medicine contains 2.8 g of sucrose.
Parents or carers should give this medicine to children at a dosage of 1 tablespoon (5 ml) every 4 to 6 hours, or as directed. If symptoms persist or worsen stop use and talk to your doctor or pharmacist.

If you forget to take the medicine
If you forget to take a dose, take the next dose when needed provided that the next dose was not taken in the last 4 hours ago. Do not take a double dose.

If you take more of this medicine than you should
If you take more of this medicine than you should, you may experience drowsiness. Do not drive or use any tools that require you to be alert and wakeful until you feel better. If you think you have taken too much of this medicine, talk to your doctor or local poison control centre.

If you experience any of the following, stop using this medicine and talk to your doctor:
- Difficulty sleeping, dizziness, drowsiness or nervousness
- Trouble passing water (especially in men with prostate problems)
- Feeling tired
- Stomach pain, diarrhoea or vomiting
- Tingling or numbness of the hands or feet
- Tearing or numbsness of the hands or feet (Pins and needles)
- High blood pressure
- Dependency and addiction (See section "How do I know if I am addicted?")

Reporting of side-effects
By reporting side-effects you can help provide more information on the safety of this medicine. You can report side-effects to this medicine directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for Mhra Yellow Card in the Google Play or Apple App Store. By reporting side-effects, you help your doctor or pharmacist to take care of your health.

5 Storing this medicine
Do not store this product above 25ºC. Keep the bottle in the outer carton and away from light. Keep this medicine out of the reach of children.

6 Further Information
What's in this medicine?
The active ingredients in 5 ml of Multi-Action Actifed Dry Coughs are:

1.25 mg, pseudoephedrine hydrochloride 30 mg, and dextromethorphan hydrobromide 10 mg.
Other ingredients are: Sorbitol, sucrose, excipients (521), methyl hydroxybenzoate (E218), Potassium 4C (E124) (sodium, alcohol), blackberry flavour (ethanol), lemon oil, azodicarbonamide and purified water.

What the medicine looks like
Multi-Action Actifed Dry Coughs is a clear red liquid available in 100 ml bottles.

Manufacturer:
McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

This leaflet was revised March 2022.

If you experience any of the following, stop using this medicine and talk to your doctor:
- Dependence and addiction (see section "How do I know if I am addicted?)
- If you experience any of the following, stop using this medicine and talk to your doctor:
- Difficulty sleeping, dizziness, drowsiness or nervousness
- Trouble passing water (especially in men with prostate problems)
- Feeling tired
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- Dependency and addiction (see section "How do I know if I am addicted?)

Reporting of side-effects
By reporting side-effects you can help provide more information on the safety of this medicine. You can report side-effects to this medicine directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for Mhra Yellow Card in the Google Play or Apple App Store. By reporting side-effects, you help your doctor or pharmacist to take care of your health.