

## Package leaflet: Information for the user

### Provocholine® 100 mg powder for nebuliser solution methacholine chloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Provocholine is and what it is used for
2. What you need to know before you take Provocholine
3. How to take Provocholine
4. Possible side effects
5. How to store Provocholine
6. Contents of the pack and other information

### 1. What Provocholine is and what it is used for

#### What Provocholine is

Provocholine contains a medicine called 'methacholine chloride'. It works on the airways, causing them to tighten and become narrower or retract. The product is for diagnostic use only.

Provocholine has been specially supplied for administration only by healthcare professionals in an asthma clinic or lung function testing laboratory.

#### What is Provocholine used for

Provocholine is used in adults (aged 17 and over). It is used as part of a breathing test called a 'methacholine challenge test'.

Your doctor or nurse will do this test to help decide if you have asthma.

### 2. What you need to know before you take Provocholine

#### Do not take Provocholine if:

- you are allergic to methacholine chloride or other parasympathomimetic agents
- you have asthma or are wheezing
- you have already done a 'methacholine challenge test' with Provocholine on the same day - you should not have more than one test on the same day.
- you have had a heart attack in the last 3 months
- you have a slow heart rate called 'bradycardia'
- you have a specific condition in your aorta, the body's main artery called an 'aortic aneurysm'
- you are taking medicines that belong to a group called 'beta-blockers'
- you have uncontrolled high blood pressure
- you have an illness called 'myasthenia gravis' and are being treated with medicines that belong to a group called 'cholinesterase inhibitors'
- you have had recent eye surgery
- you are at risk of elevated intracranial pressure

Do not take Provocholine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before taking Provocholine.

## Warnings and precautions

Talk to your doctor or nurse before taking Provocholine if:

- you have epilepsy
- you have problems with your heart and blood vessels
- you have an ulcer
- you have thyroid disease
- you have a blockage in your water-works (called 'obstructed urinary tract')
- you have problems with a nerve in your body called the 'vagus nerve'.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before taking Provocholine.

## Children

Not recommended for use in children and adolescents under 17 years of age.

## Other medicines and Provocholine

Medicines for asthma such as bronchodilators or corticosteroids, taken by mouth or via inhalers must be interrupted before testing with Provocholine. Tell your doctor or nurse if you are taking or have recently taken these medicines, or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

- This is because some medicines may affect the safety of a breathing test with Provocholine.
- Also, some other medicines can affect the results of a breathing test with Provocholine.

Discuss with your doctor if you should stop taking these medicines before you have your test. Your doctor or nurse will tell you how long you need to stop the other medicines for.

In particular, do not take this medicine and tell your doctor or nurse if you are taking any of the following medicines:

- beta-blockers to lower your blood pressure
- cholinesterase inhibitors to treat a condition called 'myasthenia gravis'.

If any of the above apply to you, or you are not sure, talk to your doctor or nurse before taking Provocholine.

## Pregnancy, breast-feeding and fertility

Do not take Provocholine if you are pregnant, think you might be pregnant or are planning to have a baby. This is because it may harm the unborn baby.

- You and your partner must use effective methods of contraception if you are able to become pregnant.

Do not breast-feed if you are taking Provocholine. It is not known whether this medicine may pass into the mother's milk.

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

## Driving and using machines

Provocholine has no influence on the ability to drive and on the use of machines.

### 3. How to take Provocholine

Provocholine has been specially supplied for administration only by healthcare professionals in an asthma clinic or lung function testing laboratory.

## About the Methacholine Challenge Test

Provocholine is given by a doctor or nurse as part of a breathing test called a 'methacholine challenge test'.

- You inhale the medicine - your doctor or nurse will show you how to do this before the test begins.
- You will normally be given a number of doses during the test. You start with a low dose and the dose is then gradually increased. The doses are given in this order:
  - 0.03125 mg/mL → 0.0625 mg/mL → 0.125 mg/mL → 0.25 mg/mL → 0.5 mg/mL → 1 mg/mL → 2 mg/mL → 4 mg/mL → 8 mg/mL → 16 mg/mL.
  - Once your lung function (how your lungs are working) has reached the target level, the test will be stopped at that dose.

### When will the test be stopped?

#### The test will be stopped if:

- your lung function reaches to the target level
- you have reached the highest dose of Provocholine - but your lung function has not dropped to the target level
- your doctor or nurse decides you are not able to carry on with the test because of side effects.
- At the end of the test, you may be given a medicine called a 'reversal agent'. The reversal agent will cause the airways to expand and dilate (i.e. it will reverse the airways constriction effect of Provocholine). Your doctor or nurse will measure how your lungs are working to make sure your breathing is back to normal before you are sent home.

If you have any further questions on the use of this product, ask your doctor or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Uncommon:** may affect up to 1 in 100 people

- itching
- headache
- throat irritation
- feeling light-headed
- chest tightness, cough or wheezing.

#### Other side effects if given by mouth or injection:

- fainting
- heart attack
- low blood pressure
- feeling or being sick
- chest pain or pressure.

#### Side effects of the 'reversal agent' that may be given after the test:

- feeling weak
- feeling drowsy
- flushing or headache
- increased heart rate or unusual heart beat
- pain or discomfort in your chest (angina)
- increased blood pressure
- unusual taste in the mouth
- drying or irritation of the throat
- feeling or being sick (nausea and vomiting)
- feeling nervous, irritable or difficulty sleeping
- feeling very dizzy (vertigo)
- tremors or cramps in your muscles.

Tell your doctor or nurse if you notice any of the side effects listed above during or after the test. If any of the side effects become serious, tell your doctor or nurse straight away.

## Reporting of side effects

If you get any side effects, talk to your doctor 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Provocholine

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 vial label or carton after "Exp.". The expiry date refers to the last day of that month.

Store un-reconstituted vials of powder at room temperature (below 30°C).

Once the medicine has been mixed with solvent, the solution should be used straight away. Any unused liquid should be disposed of safely. Do not refrigerate or freeze the reconstituted solution.

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 to protect the environment.

**NOTE: Provocholine is a diagnostic drug. It should never be removed from the asthma clinic or lung function testing laboratory.**

## 6. Contents of the pack and other information

### What Provocholine contains

- The active substance is methacholine chloride.
- There are no other ingredients in Provocholine.

### What Provocholine looks like and contents of the pack

- Provocholine is a white powder for nebuliser solution.
- Provocholine is supplied in an amber coloured glass vial. Each carton contains 6 vials.

### Marketing Authorisation Holder

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### Manufacturer

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### Distributor

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For any information about this medicine, please contact the local distributor.

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