

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Aridol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Aridol against the benefits they expect it will have for you.

**If you have any concerns about taking an Aridol test, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Aridol is used for

Aridol is a **test** to see if you have asthma or not.

Aridol contains the active ingredient mannitol.

Asthma is a condition causing inflammation of the airways, making it difficult to breathe sometimes. People with asthma are often very susceptible to factors in the environment such as exercise, dust, smoke and other irritants.

Your doctor or another specifically trained healthcare professional will ask you to breathe in Aridol, using a small inhaler.

- For people who **do** have **asthma**, their airways will become narrower and so they may find it harder to breathe.
- People who **do not** have **asthma** will not experience their airways becoming narrower when breathing in Aridol. They will still be able to breathe normally.

As part of the test, you will be asked to blow into a tube that will measure the effect of Aridol on your lungs.

This medicine is only used to see whether you have asthma.

**Ask your doctor if you have any questions about why an Aridol test has been ordered for you.**

### Before you start to use it

#### When you must not use it

**Do not take an Aridol test** if you have an **allergy** to:

- mannitol
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction to a medicine may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

#### Do not take an Aridol test:

- if you now have or used to have a swollen or weakened blood vessel around the heart or brain (**aneurysm**);
- if you have **high blood pressure** which is not controlled by medicine;
- if you have had a **heart attack** in the last 6 months;
- if you have had a **stroke** in the last 6 months.

**Do not take an Aridol test after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should do the Aridol test, talk to your doctor.**

#### Before you start to take the test

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

#### Tell your doctor:

- if your **lung capacity** is **reduced** (this will be measured prior to the test);
- if you have previously experienced **difficulty in breathing**, or have **wheezed** or **coughed** during a spirometry test (blowing into a measuring instrument);
- if you are **coughing up blood**;
- if you have air in the pleural space between the chest wall and the lungs, causing chest pain and shortness of breath (**pneumothorax**);
- if you have recently had **stomach, chest or eye surgery**;
- if you experience chest pain (**angina pectoris**);
- if you have **problems performing the spirometry test** (the person doing the test will tell you);
- if you have had an **infection** of the **airways** in the last 2 weeks.

Your doctor may want to take special precautions or delay the test if you have any of these conditions.

If you experience an asthma attack (breathlessness, wheezing and/or cough) during the spirometry test, you may be given a medicine to keep your air passages open and the test will be stopped.

#### Do not take Aridol on your own.

Aridol is only to be given by trained professionals familiar with the use of similar tests and their possible effects.

**Children under the age of 6 should not be given Aridol or perform the test.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

Aridol is not recommended during pregnancy.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is not known if Aridol passes into the breast milk.

If you have not told your doctor about any of the above, tell him/her before you do the Aridol test.

#### Taking other medicines

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

If you are taking medicines to treat asthma or allergies, you may need to stop taking these before the test. These medicines may affect your body's response to Aridol. Your doctor will tell you which medicine(s) to stop and for how long (usually between 6 hours and 4 days before the test).

**Do not drink** coffee, tea or cola, **eat** chocolate or any other foods containing **caffeine** on the day of the test, especially before the test is done.

**Do not take vigorous exercise** on the day of the test, especially before the test is done.

**Do not smoke** for at least 6 hours before the test.

### How to take Aridol

You will be given Aridol via an inhaler (Osmohaler™) by a doctor or another specially trained healthcare professional who will be with you throughout the test. You will not be left on your own.

**You must not put Aridol capsules in your mouth or swallow them.**

Performing the test:

1. You will be asked to sit comfortably on a chair.
2. Initially you will be asked to blow forcefully into a tube (spirometry test).
3. A nose clip will then be put on your nose so you will only be able to breathe in and out of your mouth.
4. After breathing out fully, you will be asked to deeply breathe in the Aridol medicine using a special inhaler (Osmohaler™).
5. You will then hold your breath for five seconds before breathing out.
6. The nose clip will be removed and you will be asked to breathe normally.
7. Next you will be asked to blow forcefully into the tube again. This test measures the effect of Aridol on your lungs.
8. Steps 3-7 may be repeated up to 9 times with more and more Aridol depending on the effect on your lungs (as measured in step 7), until the test is finished.
9. Once the test has finished you may be given a medicine to help you breathe.

If you are unsure about any part of the test, or have questions about the medicine, please talk to the doctor or another specially trained healthcare professional performing the test.

#### If you take too much (overdose)

If you think you may have been given too much Aridol, tell the doctor or healthcare professional performing the test straight away. You may feel that you cannot breathe, become wheezy or cough if you have taken too much Aridol. The doctor may give you oxygen and medicines to help you breathe.

### Side Effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well during or after an Aridol test.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

#### Very common

(likely to affect more than 1 in 10 people):

- Headache

#### Common

(likely to affect less than 1 in 10 but more than 1 in 100 people):

- nausea (feeling sick)
- upper stomach pains
- diarrhoea
- vomiting
- dizziness
- tiredness
- itchy eyes
- runny nose

- cold or flu
- sore or irritated throat
- discomfort when swallowing
- chest tightness
- back pain
- breathlessness
- cough or wheezing

**Tell your doctor if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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### After using Aridol

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#### *Storage*

**Aridol must be kept in a cool, dry place where the temperature stays below 25°Celsius.**

**Do not store medicines in the bathroom or near a sink. Do not leave any medicine on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep medicines where children cannot reach them.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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### Product Description

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#### *What it looks like*

Aridol comes as a powder contained within capsules which are utilised for inhalation.

The capsules are supplied in blister packs. One diagnostic kit, packed in a box, consists of:

- 1 empty capsule
- 1 x 5 mg capsule
- 1 x 10 mg capsule
- 1 x 20 mg capsule
- 15 x 40 mg capsules
- 1 Osmohaler™

The powder is white to off-white.

The empty capsule is clear with two white bands.

The 5 mg capsule is half white, half clear.

The 10 mg capsule is half yellow, half clear.

The 20 mg capsule is half pink, half clear.

The 40 mg capsules are half red, half clear.

#### *Ingredients*

##### **Active Ingredients**

Aridol capsules contain 0 mg, 5 mg, 10 mg, 20 mg or 40 mg of the active ingredient mannitol.

##### **Inactive Ingredients**

The other ingredients of Aridol are

- gelatin,
- titanium dioxide,
- yellow iron oxide and
- red iron oxide (contained in the capsule shells).

#### *Supplier*

Aridol is supplied in Australia by:

##### **Pharmaxis Ltd**

20 Rodborough Road

Frenchs Forest NSW 2086

Tel: (02) 9451 7200

#### *Australian Registration Number*

AUST R 116832

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