

# AERODIOL(R)

Oestradiol hemihydrate 150 micrograms/actuation

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about AERODIOL(R).

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks.

Your doctor has weighed the benefits they expect AERODIOL(R) will have for you against the risks of you taking it.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine - you may need to read it again.**

### What AERODIOL(R) is used for

The menopause occurs naturally in the course of a woman's life, usually between the ages of 45 and 55.

Around the time of the menopause, the body slowly stops producing oestrogen, a type of hormone produced by the ovaries. This results first in irregular periods and then ultimately in periods stopping completely. At the same time, a number of uncomfortable symptoms can occur such as hot flushes, night sweats and vaginal dryness. Oestrogens can be given to reduce or eliminate these symptoms.

AERODIOL(R) is a type of hormone replacement therapy (HRT).

AERODIOL(R) is a nasal spray used to prevent or relieve your menopausal symptoms on a short-term basis. It delivers a natural female sex hormone called oestradiol that belongs to the oestrogen family.

AERODIOL(R) replaces the oestrogen your body lacks after the menopause.

With AERODIOL(R), the replacement oestrogen is given as a nasal spray, which is absorbed through the lining of your nose. As it does not have to pass through your stomach and liver to get into your system, it allows you to take a much lower dose of oestrogen than would be needed in a tablet and helps to avoid some unpleasant side effects.

AERODIOL(R) is not a contraceptive and should not be used as such.

**Ask your doctor if you have any questions about why AERODIOL(R) has been prescribed for you.**

### Before you use AERODIOL(R)

#### **When you must not use it**

**Do not use AERODIOL(R) if you have an allergy to:**

- \* Oestradiol hemihydrate, the active substance in AERODIOL(R)
- \* Any of the other ingredients listed at the end of the leaflet

- \* Any medicine containing the same active ingredient (oestradiol)

**Do not use AERODIOL(R) if you have:**

- \* Severe liver disease
- \* Know or suspected malignant breast or other oestrogen-dependent tumours
- \* Unexplained vaginal bleeding
- \* Active venous thromboembolic disease or history of venous thrombosis (blood clots in blood vessels).

**Do not take this medicine if you are pregnant or breastfeeding.**

**If you still have an uterus, it is essential to take another type of drug called a progestogen with AERODIOL(R).**

In this case your doctor will give you a progestogen in order to protect the lining of the womb from over-stimulation by oestrogen.

**Do not use AERODIOL(R) after the expiry date (EXP) printed on the pack.**

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

**Do not use AERODIOL(R) if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

**Do not use AERODIOL(R) to treat any other complaints unless your doctor says it is safe.**

**Do not give this medicine to anyone else.**

## **Before you start**

Your doctor should perform a complete medical and gynaecological examination before you use AERODIOL(R) and at regular intervals and make a record of your family's medical history.

### **Tell your doctor if you have:**

- \* A family history of breast cancer.
- \* Nodules, lumps or cysts in your breast or any other benign breast condition
- \* Conditions affecting the lining of the womb such as fibroids, endometriosis and endometrial hyperplasia
- \* Frequent nosebleeds
- \* Severe diabetes
- \* High blood pressure
- \* Kidney failure
- \* Liver disorders such as porphyria (a rare disease with increased excretion of pigments urine and faeces)
- \* Gallstones
- \* Disease with fits or convulsion called epilepsy
- \* Asthma
- \* Prolactinoma (pituitary gland tumour)
- \* Otosclerosis (disorder of the ear that causes hearing loss)
- \* Migraine or severe headache

### **Your doctor may want to take special precautions if you have any of these conditions.**

Tell your doctor if you are likely to have an increased risk of developing blood clots in your blood vessels. The risk increases as you get older and it may also be increased if:

- \* Anyone in your immediate family has ever had blood clots
- \* You are overweight
- \* You have systemic lupus erythematosus (a disease affecting the skin and major organs)
- \* You have a history of repeated miscarriage
- \* You are obliged to stay in bed for a long period such as after an operation

**If you have not told your doctor about any of these things, tell them before you start using AERODIOL(R).**

## **Taking other medicines**

**Tell your doctor or pharmacist about other medicines including medicines that you buy without a prescription from pharmacy, supermarket or health food shop.**

**Some medicines can interfere with the action of AERODIOL(R).**

### **These include:**

- \* Some medicines to help you to sleep (barbiturates)
- \* Some medicines for epilepsy (carbamazepine, phenobarbitone, phenytoin, primidone, felbamate, oxcarbazepine, topiramate)
- \* Some medicine to fight against fungus (griseofulvin)
- \* Some medicines to treat tuberculosis (rifampicin, rifabutin)

If you are taking corticosteroids (e.g. for hay fever) or vasoconstricting agents (to unblock your nose) administered by nasal route, you should not use AERODIOL(R) immediately afterwards.

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## **Using AERODIOL(R)**

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**Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### **How much to use**

The recommended dose is a single dose of 300 mcg per day administered as one spray into each nostril. Dosing should preferably take place at the same time every day.

The dose should be adapted to suit your individual requirements. Your doctor may change the dose after 2 or 3 cycles according to your needs.

AERODIOL(R) like other HRT, is meant for short-term relief of menopausal symptoms. Your doctor may prescribe the treatment using one of two ways:

- as cyclical treatment for 21 to 28 days per month, followed by a treatment-free period of 2 to 7 days.
- as continuous treatment everyday without stopping.

For women who have not had a hysterectomy (operation to remove the womb), a progestogen treatment (another hormone) should be taken with AERODIOL(R) for at least 12 days per cycle of treatment. It is important not to forget to take this treatment.

Bleeding resembling a period may occur during the treatment-free period. This bleeding is normal and should be light. Tell your doctor if you experience heavy or irregular bleeding.

**In all cases, strictly comply with your doctor's directions.**

**If you think that the effect of AERODIOL(R) is too strong or too weak, talk to your doctor or pharmacist.**

## **How to use AERODIOL(R)**

Follow the instructions below:

Remove the protective cap, which should be replaced after each use.

### **Priming:**

Before using for the first time, prime the pump by making 3 firm sprays into the air in a well-ventilated area. This procedure should only be carried out when a bottle is used for the first time.

### **Instructions for use:**

Hold the bottle upright and bend your head slightly forward, ensuring that the tip is inside your nostril. Push the pump down firmly.

**Do not inhale when spraying.**

## Recommendations:

For maximum efficacy:

- \* Use AERODIOL(R) at the same time everyday,
- \* If you have a runny nose (due to a cold or hay fever for example), blow your nose a few minutes before administration and avoid blowing your nose for the next 15 minutes,
- \* If your nose is severely blocked, AERODIOL(R) may be administered temporarily in the mouth between the cheek and the gum above the upper teeth. In such case, the usual dose should be doubled.
- \* Avoid blowing your nose, or sniffing for fifteen minutes following administration,
- \* If your nose runs significantly after administration, dab with a paper tissue, avoiding blowing your nose.

After use, replace the protective cap, pushing it all the way down.

**Never try to dismantle the pump.**

### ***If you forget to take AERODIOL(R)***

If you forget to take a dose less than 12 hours after the usual time, take it as soon as possible and take the next dose at your normal time.

Do not take a double dose next time. If you are more than 12 hours late, do not take the dose.

### ***If you take more AERODIOL(R) than you should (overdose)***

**Telephone your doctor or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too much AERODIOL(R) even if there are no signs of discomfort or poisoning.**

The general effects of taking an overdose of this treatment are:

- \* breast tenderness
- \* abdominal bloating

- \* nausea
- \* aggressiveness

If you have any of these symptoms when you use AERODIOL(R), tell your doctor. You will not need any treatment as these symptoms will disappear when the dose is reduced.

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## **While you are using AERODIOL(R)**

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- Follow your doctor's instructions, particularly for the progestogen treatment that is needed with this treatment if you have an intact uterus.
- Tell your doctor if the symptoms persist despite taking the treatment or if you think that the effect is too strong.
- Tell your doctor well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using AERODIOL(R).
- Tell any other doctor, dentist or pharmacist who treat you that you are using AERODIOL(R).
- Discuss the benefits and risks of continuing HRT with your doctor every 6 months.

AERODIOL is meant for the short-term relief of menopausal symptoms. Taking HRT for more than 5 years may increase the risk of breast cancer or ovarian cancer (cancer of the ovaries).

Every woman is at risk of getting breast cancer or ovarian cancer whether or not she takes HRT however these cancers have been found slightly more often in women using HRT than in women of the same age who have never used HRT. AERODIOL has not been associated with the same higher chance of having these cancers, nevertheless, if you are concerned about the risk of breast cancer or ovarian cancer, discuss the risk compared to the benefits of treatment with your doctor.

**Tell your doctor if you experience painful swelling of a leg, sudden pain in the chest or difficulty in breathing as these are thromboembolic symptoms.**

**In the very unlikely event that you discover you are pregnant while taking AERODIOL(R), stop taking the treatment and tell your doctor.**

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AERODIOL(R).**

AERODIOL(R) helps most people with symptoms of the menopause, but it may have unwanted side-effects in a few people.

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

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

Tell your doctor if you notice any of the following side effects and if they worry you.

The most frequently reported side effects are nasal reactions: prickling-tingling sensation, sneezing and runny nose. They are usually short-lived and mild.

Other undesirable effects may occur such as headache, breast tenderness, nausea, irregular bleeding, nose bleeds, changes in sexual desire.

More rarely reported are fluid retention (oedema), weight changes, dizziness, fatigue, leg cramps, migraine, abdominal cramps or bloating, menstrual pain, increased thickness of the womb lining, benign breast tumours, high blood pressure, acne, skin rash.

Tell your doctor immediately and stop taking your treatment if you notice any of the following:

- \* signs that blood clots may have formed such as unusual pains or swelling in your arms or legs, pains or a feeling of heaviness in your chest, sudden shortness of breath, coughing blood, fainting
- \* signs of jaundice such as yellow colour to the skin or eyes
- \* migraine-type headache
- \* sudden visual disturbances
- \* significant increase in blood pressure

There are serious side effects. You may need urgent medical attention. These side effects are very rare.

Tell your doctor if you notice anything else that makes you feel unwell.

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## After using AERODIOL(R)

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### **Storage**

Store below 30 degrees C but not in the fridge or freezer.

Keep out of the reach and sight of children

### **Disposal**

Return any unused medicines to your pharmacist.

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## Product description

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### **What it looks like**

AERODIOL(R) is contained in a colourless bottle equipped with a metering pump fitted with a nasal applicator and protected by a plastic bottle and a transparent blue plastic dust cover.

The plastic holder has AERODIOL(R) written in blue on it.

### **Ingredients**

Each spray of AERODIOL(R) contains

150 mcg of oestradiol hemihydrate.

There are 60 sprays in AERODIOL(R) nasal spray solution.

AERODIOL(R) also contains the following inactive ingredients:

- \* methylbetadex
- \* sodium chloride
- \* sodium hydroxide or hydrochloric acid
- \* purified water.

AERODIOL(R) is registered on the Australian register of Therapeutic Goods.

Australian Register Number: 83232

### **Manufacturer and sponsor**

AERODIOL(R) supplied in Australia by:

**Servier Laboratories (Aust) Pty Ltd**

8 Cato Street

Hawthorn, Victoria 3122

Australia

This leaflet was prepared in July 2007.