

# Lyllana<sup>®</sup>

## ***Estradiol***

**0.025 mg/day, 0.05 mg/day, 0.075 mg/day, 0.1 mg/day transdermal patches**

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## **What is in this leaflet**

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Please read this leaflet carefully before you start using Lyllana.

This leaflet answers some common questions about Lyllana. 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 using Lyllana against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

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## **What Lyllana is used for**

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Lyllana is a type of treatment called hormone replacement therapy (HRT). It is a stick-on patch that contains a hormone called estradiol.

Lyllana is used for the short-term relief of symptoms of the menopause.

HRT is not used for the long-term maintenance of general health or to prevent heart disease or dementia.

Lyllana is not suitable for birth control and it will not restore fertility.

## ***How it works***

Estradiol (also known as oestradiol) is a natural female sex hormone called an oestrogen. It is the same hormone that your ovaries were producing before the menopause.

The menopause occurs naturally in the course of a woman's life, usually between the ages of 45 and 55. It may happen sooner if the ovaries are removed by surgery (e.g. total hysterectomy).

After menopause, your body produces much less oestrogen than it did before. This can cause unpleasant symptoms such as a feeling of warmth in the face, neck and chest, "hot flushes" (sudden, intense feelings of heat and sweating throughout the body), sleep problems, irritability and depression. Some women also have problems with dryness of the vagina causing discomfort during or after sex. Oestrogens can be given to reduce or eliminate these symptoms.

Lyllana releases estradiol in a continuous and controlled way just as your ovaries were doing before. Because the medicine does not have to pass through your stomach and

liver, 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.

**Ask your doctor if you have any questions about why Lyllana has been prescribed for you.**

Your doctor may have prescribed Lyllana for another reason.

This medicine is available only with a doctor's prescription.

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## **Before you use Lyllana**

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

**Do not use Lyllana or other oestrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.**

A study called the Women's Health Initiative indicated increased risk of heart attack, stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated oestrogens 0.625 mg and the progestogen medroxyprogesterone acetate (MPA).

The researchers stopped the study after 5 years when it was determined the risks were greater than the benefits in this group. The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged 65-79 years taking conjugated oestrogens and MPA.

There are no comparable data currently available for other doses of conjugated oestrogens and MPA or other combinations of oestrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing oestrogen and progestogen combinations.

**Do not use Lyllana if you have an allergy to:**

- estradiol (also known as oestradiol), the active ingredient
- any of the other ingredients listed at the end of this leaflet
- any other medicine containing oestrogen, including the birth control pill

Some of the symptoms of an allergic reaction 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.

If you had a severe skin reaction in the past, you could have a very serious reaction if you use any type of oestrogen (patch, tablet, cream, etc.) again.

Do not use Lyllana if you have:

- cancer of the breast or uterus (womb) or any other oestrogen dependent cancer, or you have had this condition in the past
- ever had blood clots in the veins or lungs. You may have had painful inflammation of the veins or blockage of a blood vessel in the legs, lungs, brain or heart
- a condition that increases the tendency for you to get blood clots
- abnormal vaginal bleeding that has not been investigated
- severe liver problems
- a condition called porphyria, this condition affects your liver

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

**Do not use Lyllana if you are pregnant.**

It may affect your developing baby.

**Do not use Lyllana if breast-feeding**

It may affect your baby.

**If you still have a uterus (womb), do not use Lyllana unless you are also taking another medicine called a progestogen.**

Women who still have a uterus must take both oestrogen and progestogen as part of HRT. This is because oestrogen stimulates the growth of the lining of the uterus (called the endometrium). Before menopause this lining is removed during your period through the action of a natural progestogen. After menopause, taking oestrogen on its own as HRT may lead to irregular bleeding and to a disorder called endometrial hyperplasia. Your doctor will prescribe a progestogen to protect the lining of the uterus from the effects of oestrogen.

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist for disposal.

If you are not sure whether you should start using Lyllana, talk to your doctor.

***Before you start to use it***

**Tell your doctor if you have or have had any of the following medical conditions:**

- a family history of breast cancer
- nodules, lumps or cysts in your breasts or any other benign breast condition (not cancer)
- endometriosis (a disorder of the uterus that may cause painful periods and abnormal bleeding)
- fibroids or other benign tumours of the uterus (not cancer)
- had one or more pregnancies where you lost the baby before birth
- high blood pressure
- heart disease
- kidney or liver problems
- diabetes
- epilepsy
- migraine or other severe headaches
- gall bladder disease
- asthma
- hearing loss due to a problem with the bones in the ear called otosclerosis
- a high level of triglycerides in the blood
- a disorder called systemic lupus erythematosus (SLE)
- a bone disease causing high calcium levels in the blood
- very low calcium levels in the blood
- had a problem in the past with jaundice (a liver problem) or itching skin when you took an oestrogen (e.g. the birth control pill or HRT) or during pregnancy

- a skin condition that could be made worse by applying the patch
- hypothyroidism (a condition in which your thyroid gland fails to produce enough thyroid hormone and for which you are treated with thyroid hormone replacement therapy). Your doctor will then have to monitor your thyroid hormone levels regularly
- severe allergic reactions
- hereditary angioedema or episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract

**If you have not told your doctor about any of the above, tell them before you start using Lyllana.**

**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 in the blood vessels of the legs or lungs
- you are overweight
- you have varicose veins
- you have a disorder called systemic lupus erythematosus (SLE)

### ***Taking other medicines***

**Tell your doctor if you are taking birth control pills.**

Lyllana is not a contraceptive. Since pregnancy may be possible early in the menopause while you are still having menstrual periods, you should ask your doctor to suggest another (non-hormonal) method of birth control.

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Lyllana.**

Some medicines may interfere with Lyllana. These include:

- herbal medicines containing St. John's Wort
- some medicines to help you sleep, including barbiturates and meprobamate
- some medicines for epilepsy, including phenytoin, phenobarbitone and carbamazepine
- phenylbutazone, a medicine for pain and inflammation
- some antibiotics and other anti-infective medicines, including rifampicin, ketoconazole, erythromycin, rifabutin, nevirapine, efavirenz, ritonavir and nelfinavir
- lamotrigine (anti-seizure/anti-epilepsy medicine)

These medicines may be affected by Lyllana, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Lyllana.

## How to use Lyllana

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### ***When to start it***

If you are not already using HRT, you can start Lyllana at a convenient time for you. If you are already using a different type of HRT, your doctor can advise you when to switch to Lyllana.

### ***How much to use***

Lyllana patches come in four strengths.

You will usually start with the Lyllana 0.025 mg/day patch. Your doctor will check your progress and may change you to a different strength, depending on your response to treatment.

### ***How to use it***

#### **Step 1: Pick the days you will change your patch.**

- You will need to change your patch 2 times a week or every 3 to 4 days.
- Use the calendar printed inside your carton to choose the 2 days you will change your patch (See Figure 1).
- Remember to change your patch on the same 2 days you marked on your calendar.
- If you forget to change your patch on the correct date, apply a new patch as soon as you remember, and continue to follow your original schedule



Figure 1

#### **Step 2: Remove the Lyllana patch from the pouch.**

- Remove the patch from its protective pouch by tearing at the notch (do not use scissors, See Figure 2).
- Do not remove your patch from the protective pouch until you are ready to apply it



Figure 2

**Step 3: Remove half of the adhesive liner (See Figure 3).**

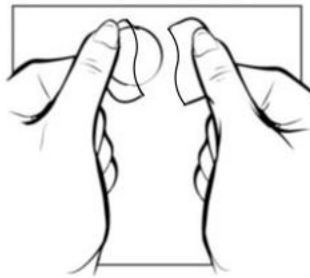


Figure 3

**Step 4: Placing the patch on your skin.**

- Hold the part of the patch that still has the adhesive liner on it
- Avoid touching the sticky half of the patch with your fingers
- Apply the exposed sticky half of the patch to a clean, dry area of skin on your lower abdomen or buttocks (See Figures 4 and 5).



Figure 4



Figure 5

**Note:**

- Avoid the waistline, since clothing and belts may cause the patch to be rubbed off
- Apply to a different area of your abdomen or your buttocks each time. Do not use the same application site twice in the same week.
- Do not apply the patch to your breasts
- Only apply the patch to skin that is clean, dry, and free of any powder, oil, or lotion
- You should not apply the patch to injured, burned, or irritated skin, or areas with skin conditions (such as birth marks, tattoos, or that is very hairy)

**Step 5: Press the patch firmly onto your skin.**

- Remove the remaining half of the adhesive liner and press the entire patch into place with the palm of your hand for 10 seconds
- Rub the edges of the patch with your fingers to make sure that it will stick to your skin (See Figure 6).



Figure 6

**Note:**

- Showering will not cause your patch to fall off
- If your patch falls off reapply it. If you cannot reapply the patch, apply a new patch to another area (See Figures 4 and 5) and continue to follow your original placement schedule
- If you stop using your Lyllana patch or forget to apply a new patch as scheduled, you may have spotting, or bleeding, and recurrence of symptoms

**Step 6: Throwing away your used patch.**

- When it is time to change your patch, remove the old patch before you apply a new patch
- To throw away the patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place this container in the trash.
- Used patches should not be flushed in the toilet

You will have a patch on all the time. You will apply a new patch twice weekly (every 3 or 4 days). There are 8 patches in the carton, enough for a 4-week cycle.

If you have not had a hysterectomy (operation to remove the uterus), you must take another type of hormone called a progestogen as well as using the patches. A progestogen helps to protect the lining of the uterus. If you have not been asked to take a progestogen, talk to your doctor.

***How long to use it***

**Continue using your medicine for as long as your doctor tells you.**

**If you want to continue using HRT for longer than a few months, discuss the possible risks and benefits with your doctor.**

You may have an increased risk of developing breast cancer, heart disease, stroke, blood clots on the lungs and dementia. On the other hand, the risk of hip fractures and bowel cancer may be reduced. If you have had a hysterectomy but still have your ovaries, there may also be a small increase in the risk of developing cancer of the

ovaries. Women taking oestrogens (also known as estrogens) alone, or in combination with progestogens, may have a higher risk of ovarian cancer that may appear within 5 years of use and slowly diminishes over time after discontinuation. Your doctor can discuss these risks and benefits with you, taking into account your particular circumstances.

### ***If you forget to use it***

**Apply a new patch as soon as you remember, and then go back to your usual schedule.**

If you have trouble remembering when to use or replace your patches, ask your pharmacist for some hints.

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## **While you are using Lyllana**

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### ***Things you must do***

**If you become pregnant while using Lyllana, tell your doctor immediately.**

It should not be used while you are pregnant.

See your doctor at least once a year for a check-up. Some women will need to go more often. Your doctor will:

- check your breasts and order a mammogram at regular intervals
- check your uterus and cervix and do a pap smear at regular intervals
- check your blood pressure and cholesterol level

**Check your breasts each month and report any changes promptly to your doctor.**

Your doctor or nurse can show you how to check your breasts properly.

**Tell your surgeon or anaesthetist that you are using Lyllana 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 it.**

The risk of developing blood clots in your blood vessels may be temporarily increased as a result of an operation, serious injury or having to stay in bed for a prolonged period. If possible, this medicine should be stopped at least 4 weeks before surgery and it should not be restarted until you are fully mobile.

**If you are about to have any blood tests, tell the person who takes the blood and your doctor that you are using Lyllana.**

It may interfere with the results of some tests.

**If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Lyllana.**

**Tell any other doctors, dentists or pharmacists who treat you that you are using Lyllana.**



### ***Things you must not do***

**Do not use this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give Lyllana to anyone else, even if their symptoms seem similar to yours.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Lyllana affects you.**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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## **In case of overdose**

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### ***If you use too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have used too much Lyllana.**

Do this even if there are no signs of discomfort or poisoning.

Because of the way this medicine is used, an intentional overdose is unlikely.

Swallowing a patch may cause nausea and vomiting.

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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 using Lyllana.**

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 these lists 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 or pharmacist if any of the side effects get serious, or if you notice any side effects not listed in this leaflet.**

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- signs of allergy such as itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, skin reddening, swelling of the face, lips, tongue, around the eyes or other part of the body; shortness of breath, wheezing or troubled breathing
- signs or symptoms of blood clots, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood
- pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting
- a yellow colour to the skin or eyes, itching, dark coloured urine or light coloured bowel motions
- signs of a skin reaction, such as redness, swelling, painful sores or lumps, areas of skin that bleed or weep fluid
- signs or symptoms of a heart attack, chest pain, dizziness, nausea, shortness of breath, irregular pulse.
- signs or symptoms of a stroke: collapse, numbness or weakness of the arms and the legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice any of the following and they worry you:**

- irregular vagina bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible). Some people may have some irregular bleeding or spotting during the first few months of treatment. The bleeding usually becomes lighter and less frequent over time, and eventually stops. If you have heavy bleeding or continue to have bleeding or spotting after a few months of treatment, tell your doctor so that the treatment can be re-evaluated if necessary.
- tender, painful or swollen breasts
- period-like pain
- redness, irritation or itching under the patch (signs of application site reaction includes bleeding, bruising, burning, discomfort, dryness, skin boils, oedema, erythema, inflammation, irritation, pain, tiny solid skin bumps, rash, skin discolouration, skin pigmentation, swelling, hives, and blisters)
- itching or inflammation of the vagina or discharge of vaginal fluid
- swelling of the lower legs, ankles, fingers or abdomen due to fluid retention
- nausea (feeling sick), vomiting, abdominal cramps, bloating
- headache, migraine
- dizziness
- depression
- eye irritation when wearing contact lenses
- uncontrollable jerky movements
- changes in weight
- spotty darkening of the skin, especially on the face
- changes in hair growth (either hair loss or excessive hairiness)
- increase or decrease in sex drive

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

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects (e.g. increase in blood sugar level) can only be found when laboratory tests are done.

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## After using Lyllana

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### **Storage**

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place where the temperature stays below 25°C.
- Do not store Lyllana or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

### **Keep the patches 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.

### **Disposal**

**Fold used patches in half with the sticky side inwards. Dispose of them where children cannot reach them.**

Used patches still contain some estradiol which could harm a child.

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any patches that are left over.**

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## Product description

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### **What it looks like**

0.025 mg/day patch - A 1.89 cm<sup>2</sup> circular patch consisting of an adhesive layer on a translucent backing film printed with "Estradiol 0.025 mg/day" in brown colour and protected with removable, transparent, oversized, S-cut release liner.

0.05 mg/day patch - A 3.78 cm<sup>2</sup> circular patch consisting of an adhesive layer on a translucent backing film printed with "Estradiol 0.05 mg /day" in brown colour and protected with removable, transparent, oversized, S-cut release liner.

0.075 mg/day patch - A 5.66 cm<sup>2</sup> circular patch consisting of an adhesive layer on a translucent backing film printed with "Estradiol 0.075 mg/day" in brown colour and protected with removable, transparent, oversized, S-cut release liner.

0.1 mg/day patch - A 7.55 cm<sup>2</sup> circular patch consisting of an adhesive layer on a translucent backing film printed with "Estradiol 0.1 mg/day" in brown colour and protected with removable, transparent, oversized, S-cut release liner.

Each carton contains 8 patches (enough for 4 weeks of treatment).

## ***Ingredients***

### Active ingredient:

Lyllana patches release approximately 0.025, 0.05, 0.075 or 0.1 mg of estradiol per day as the active ingredient.

### Inactive ingredients:

The following inactive ingredients are also used to make the patch:

Backing layer:

- Polyester and ethylene vinyl acetate copolymer film printed with brown ink

Adhesive containing estradiol:

- Acrylic adhesive
- Silicone adhesive
- Oleyl alcohol
- Dipropylene glycol
- Povidone

Release liner:

- Fluoropolymer coated polyester film

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## **Sponsor Details**

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Lyllana is supplied in New Zealand by:

Wellmed.NZ Limited

Level 1

50 Customhouse Quay

Wellington 6011

NEW ZEALAND

Phone: 0800 488 866

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## **Date of Preparation**

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This leaflet was prepared on 25 September 2024.