

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Estradot?

Estradot contains the active ingredient estradiol. Estradot is used for the short-term relief of symptoms of the menopause. For more information, see Section [1. Why am I using Estradot?](#) in the full CMI.

2. What should I know before I use Estradot?

Do not use if you have ever had an allergic reaction to estradiol, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Estradot?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Estradot and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Estradot?

- 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.

More instructions can be found in Section [4. How do I use Estradot?](#) in the full CMI.

5. What should I know while using Estradot?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Estradot.See your doctor at least once a year for a check-up.Check your breasts each month and report any changes promptly to your doctor.Call your doctor straight away if you become pregnant while using Estradot. It should not be used while you are pregnant.Tell your doctor that you are using Estradot 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.For blood tests, tell the person who takes the blood that you are using Estradot.
Things you should not do	<ul style="list-style-type: none">Do not use this medicine to treat any other complaints unless your doctor tells you to.Do not give it to anyone else, even if their symptoms seem similar to yours.
Looking after your medicine	<ul style="list-style-type: none">Keep your medicine in the original container until it is time to use it.Store it in a cool dry place.

For more information, see Section [5. What should I know while using Estradot?](#) in the full CMI.

6. Are there any side effects?

Common side effects: irregular vaginal bleeding or spotting, tender, painful or swollen breasts, period-like pain, redness, irritation or itching under the patch, 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, 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, increase or decrease in sex drive

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: Do not use Estradot or other estrogens, 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 estrogens 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 estrogens and MPA. There are no comparable data currently available for other doses of conjugated estrogens and MPA or other combinations of estrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing estrogen and progestogen combinations.

Talk regularly with your doctor about whether you still need treatment with Estradot.

Treatment with estrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.

Estradot®

Active ingredient(s): *estradiol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Estradot. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Estradot.**

Where to find information in this leaflet:

- [1. Why am I using Estradot?](#)
- [2. What should I know before I use Estradot?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Estradot?](#)
- [5. What should I know while using Estradot?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Estradot?

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

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

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

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

How it works

Estradiol is a natural female sex hormone called an estrogen. 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 estrogen 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. Estrogens can be given to reduce or eliminate these symptoms.

Estradot 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 estrogen 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

2. What should I know before I use Estradot?

Do not use Estradot if you have an allergy to:

- estradiol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- any other medicine containing estrogen, 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 estrogen (patch, tablet, cream, etc.) again.

Do not use Estradot if you have:

- cancer of the breast or uterus (womb) or any other estrogen 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.

Check with your doctor if you have:

- 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 estrogen (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 still have a uterus (womb), do not use Estradot unless you are also taking another drug called a progestogen.

Women who still have a uterus must take both estrogen and progestogen as part of HRT. This is because estrogen 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 estrogen 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 estrogen.

Tell your doctor if any of these apply to you before you use Estradot.

Your doctor may want to take special precautions if you have or have had any of the above 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 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)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use Estradot if you are pregnant or breastfeeding.

It may affect your baby.

3. What if I am taking other medicines?

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

Tell your doctor if you are taking birth control pills.

Estradot 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.

Some medicines and Estradot may interfere with each other. 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

You may need to take different amounts of your medicines or to take different medicines while you are using Estradot. Your doctor and pharmacist have more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Estradot.

4. How do I use Estradot?

How much to use

- Estradot patches come in five strengths. You will usually start with the Estradot 50 patch. Your doctor will check your progress and may change you to a lower or higher strength, depending on your response to treatment.

When to use Estradot

- If you are not already using HRT, you can start Estradot 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 Estradot.

How to use Estradot

- A leaflet in the carton contains pictures and information on how to apply the patch properly.
- 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 take Estradot

- **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 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 Estradot

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.

If you use too much Estradot

If you think that you have used too much Estradot, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using Estradot?

Things you should do

If you become pregnant while using Estradot, 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 doctor that you are using Estradot 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 that you are using Estradot.

It may interfere with the results of some tests.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Estradot.

Remind any doctor, dentist or pharmacist you visit that you are using Estradot.

Things you should not do

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

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

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine

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.

Getting rid of any unwanted medicine

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • irregular vaginal bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible) Some people may have some irregular bleeding or 	<p>Speak to your doctor if you have any of these less serious side</p>

<p>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.</p> <ul style="list-style-type: none"> • 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 discoloration, 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 	<p>effects and they worry you.</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of allergy such as itching or hives on the skin; shortness of breath or troubled breathing, wheezing or coughing, light-headedness, dizziness, rash, itching, hives, breathlessness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening, swelling of the face throat, lips, tongue, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<p>skin, the area around the eyes or other part of the body</p> <ul style="list-style-type: none"> • 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 such as chest pain, dizziness, nausea, shortness of breath, irregular pulse. • signs or symptoms of a stroke such as collapse, numbness or weakness of the arms and the legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some side effects (e.g. increase in blood sugar level) can only be found when laboratory tests are done.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Estradot contains

Active ingredient (main ingredient)	estradiol
Other ingredients (inactive ingredients)	silicone adhesive acrylic adhesive dipropylene glycol povidone oleyl alcohol Dow BLF 2550 non-removable backing layer Scotchpak 1022 removable release liner

Do not take this medicine if you are allergic to any of these ingredients.

What Estradot looks like

Estradot patches come in five strengths:

Estradot 25 – 2.5 cm² rectangular patches with rounded corners. Each carton contains 2 or 8 patches (AUST R 338056).

Estradot 37.5 – 3.75 cm² rectangular patches with rounded corners. Each carton contains 2 or 8 patches (AUST R 338057).

Estradot 50 – 5 cm² rectangular patches with rounded corners. Each carton contains 2 or 8 patches (AUST R 338058).

Estradot 75 – 7.5 cm² rectangular patches with rounded corners. Each carton contains 2 or 8 patches (AUST R 338059).

Estradot 100 – 10 cm² rectangular patches with rounded corners. Each carton contains 2 or 8 patches (AUST R 338060).

Not all strengths and pack sizes may be available.

Who distributes Estradot

Estradot is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Estradot is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel 0800 726 369

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