

Sandrena gel

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.

1. Why am I using Sandrena?

Sandrena contains the active ingredient estradiol (as hemihydrate). Sandrena is a Hormone Replacement Therapy (HRT).

For more information, see Section [1. Why am I using Sandrena?](#) in the full CMI.

2. What should I know before I use Sandrena?

Do not use if you have ever had an allergic reaction to estradiol or estradiol hemihydrate 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, are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Sandrena 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 Sandrena?

- The usual starting dose is one 0.5 g or 1 g sachet per day
- Sandrena should be applied gently on dry and clean skin. It should not be swallowed.

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

5. What should I know while using Sandrena?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Sandrena.• Attend your scheduled appointments and have periodic check-ups, especially examinations of the breasts.• Cover the application area with clothing as soon as the gel has dried to prevent accidental transfer of the gel to others (e.g., child or spouse or pet).
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give this medicine to anyone else, even if their signs of illness are the same as yours.
Driving or using machines	<ul style="list-style-type: none">• Sandrena is not expected to affect your ability to drive or use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.

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

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. Ask your doctor if you have any further questions about side effects. Tell your doctor if you experience any side effects, including those not listed in this leaflet.

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.

Sandrena gel

Active ingredient(s): *estradiol (as hemihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sandrena. **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 Sandrena.**

Where to find information in this leaflet:

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

1. Why am I using Sandrena?

Sandrena contains the active ingredient **estradiol (as hemihydrate)**.

Sandrena is a Hormone Replacement Therapy (HRT). It is used for the short-term relief of menopausal complaints. During and after menopause, the production of sex hormones produced by the body decreases. Women may then suffer from complaints such as hot flushes, night sweats, vaginal irritation, depression, and loss of sexual desire. Sandrena can be used for the short-term relief of menopausal complaints. It can also relieve these symptoms in women who have had their ovaries removed.

2. What should I know before I use Sandrena?

Warnings

Do not use Sandrena if:

- you have any **unexplained vaginal bleeding**
- you have or ever had heart disease or blood vessel problems, such as a **heart attack, stroke or angina**
- you have or have ever had a **liver disease** and your liver function tests have not returned to normal
- you have a **tumour** (e.g., a breast tumour or a tumour in your womb), or if you are suspected of having it
- you are **pregnant** or think you may be pregnant
- you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
- you have or have ever had a **blood clot in a vein** (thrombosis), such as in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)
- you have a **blood clotting disorder** (such as protein C, protein S, or antithrombin deficiency)

- you have a rare blood problem called "**porphyria**" which is passed down in families (inherited)
- you are **allergic** to **estradiol** or estradiol hemihydrate or any of the other ingredients of this medicine Sandrena (listed in section 7).

Before you start using Sandrena:

Tell your doctor if you have ever had any of the following problems, as these may return or become worse during treatment with Sandrena. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots
- increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- fluid retention due to cardiac or kidney problems
- hereditary or acquired angioedema.

Your doctor will conduct a complete gynaecological examination before commencement with Sandrena.

If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely use Sandrena without a progestogen.

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 Sandrena if you are pregnant or think you may be pregnant, or breast-feeding. If you become pregnant, stop using Sandrena and contact your doctor.

Sandrena is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

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.

Some medicines may interfere with the effect of Sandrena. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine)
- Medicines for **tuberculosis** (such as rifampicin, rifabutin)
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Herbal remedies containing **St. John's wort** (*Hypericum perforatum*).

HRT can affect the way some medicines work:

- A medicine for epilepsy (**lamotrigine**), as this could increase frequency of seizures.
- Medicines for **Hepatitis C virus (HCV)** (such as combination regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin as well as a regimen with glecaprevir/pibrentasvir or sofosbuvir/veloatasvir/voxilaprevir) may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using Combined Hormonal Contraceptives (CHCs) containing ethinylestradiol. Women using other estrogens, such as estradiols and ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin, had a similar rate of ALT elevation. Sandrena contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Sandrena with this HCV combination regimen. Your doctor will advise you.

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

4. How do I use Sandrena?

How much to use

The usual starting dose is one 0.5 g or 1 g sachet per day. Your doctor or pharmacist will tell you exactly how much to use.

If you have an intact womb, your doctor will normally also prescribe another medicine containing the hormone progestogen. This is normally for 12 to 14 days in each monthly cycle. After each course of progestogen, you will usually have a withdrawal bleed, like a period.

How to apply the gel

- Sandrena should be applied gently on dry and clean skin. It should not be swallowed.

Where to apply the gel

- Do not apply the gel to your breasts, face or on irritated skin.
- Apply the gel to your lower body or thighs.
- Alternate the application site each day.

Follow these instructions:

1. Apply the gel once a day to the skin on your lower body or thighs.
2. Alternate the application site each day.
3. Spread the gel over an area 1–2 times the size of your hand.
4. Allow the gel to dry for a few minutes.
5. Wash your hands after applying the gel. Avoid contact of the gel with your eyes. The gel may irritate your eyes.
6. Do not wash the area where you have applied the gel for at least one hour.

If you forget to use Sandrena

- Apply the missed dose when you remember, unless you are more than 12 hours late.
- If you are more than 12 hours late just skip the missed dose.
- Missed doses may cause some bleeding between your periods. This is called breakthrough bleeding.

If you use too much Sandrena

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

You should immediately:

- phone the Poisons Information Centre in Australia (**by calling 13 11 26**), or the National Poisons Centre in New Zealand on 0800 POISON (**0800 764 766**)
- 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. You may feel bloated, anxious or irritable, or your breasts may feel tender. Nausea, vomiting and withdrawal bleeding may also occur in some women.

5. What should I know while using Sandrena?

Things you should do

- Attend your scheduled appointments so that your doctor can check on your progress. Tell your doctor if you do not feel better or if you feel worse.
- Regularly check your breasts for any changes. See your doctor if you notice any changes such as:
 - dimpling of the skin
 - changes in the nipple
 - any lumps you can see or feel

Go for regular breast screening, as recommended by your doctor.

- If you need a blood test, tell your doctor or the laboratory staff that you are using Sandrena, because this medicine can affect the results of some tests.
- If you are going to have surgery, tell the surgeon that you are using Sandrena. You may need to stop using Sandrena about 4 to 6 weeks before the operation to reduce the risk of a blood clot. Ask your doctor when you can start using Sandrena again.

Call your doctor straight away if:

- you notice yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
 - painful swelling and redness of the legs
 - sudden chest pain
 - difficulty in breathing

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

Things you should not do

- Do not stop using this medicine suddenly. Keep using Sandrena, even if you seem to be better. If you stop too early or too suddenly your problem may return.
- Do not give this medicine to anyone else. It may harm them, even if their signs of illness are the same as yours.

Possible transfer of estradiol

During close skin contact estradiol gel may transfer to others (e.g. child, spouse, pets) if the application area has not been covered with clothing. Therefore, these precautions should be followed:

- wash your hands with soap and water after application
- cover the application area with clothing as soon as the gel has dried
- shower the application site before skin contact with others.

If the gel has accidentally transferred to others, wash the exposed area with soap and water.

Contact your doctor or veterinarian in case of any symptoms of side-effects.

Driving or using machines

Sandrena is not expected to affect your ability to drive or use machines.

Looking after your medicine

- Store below 25°C.

Follow the instructions on 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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"> • breast pain or tension • headache • fatigue • nausea • vomiting • stomach cramps • flatulence • dizziness • palpitations • swelling from water retention • weight increase • varicose veins • vaginal discharge • lethargy • depression • nervousness • hot flushes • itch of application site • pain • increased sweating • unscheduled or breakthrough bleedings 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • thrombosis (red, painful or swollen leg, difficulty breathing, chest pain, headache or pain elsewhere in your body, dizziness, fainting, disturbances in vision, swollen ankles) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
<ul style="list-style-type: none"> jaundice (yellowing of the eyes or skin). 	notice any of these serious side effects.

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.

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 (Australia) or to <https://pophealth.my.site.com/carmreportnz/s/> (New Zealand). 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 Sandrena contains

Active ingredient (main ingredient)	Estradiol (as hemihydrate)
Other ingredients (inactive ingredients)	Carbomer, trolamine, propylene glycol, purified water and ethanol
Potential allergens	Contains 58.50% v/v alcohol

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

What Sandrena looks like

Sandrena is a smooth opalescent gel.

It is available in 0.5 g or 1 g sachets in packs containing 28 or 91 sachets.

AUST R: 93609 (1.0 g sachet)

AUST R: 93608 (0.5 g sachet)

** Not all presentations and/or pack sizes are available.*

Who distributes Sandrena

In Australia
Orion Pharma (Aus) Pty Limited
Level 24, Tower 3
300 Barangaroo Avenue,
Sydney, NSW 2000,
Australia
Telephone: 1800 861 913

In New Zealand

Orion Pharma (NZ) Limited

c/o Max Health Ltd

PO Box 44452

Pt Chevalier, Auckland 1246.

Telephone: (09) 815 2664

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