

Dinasane

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 Dinasane?

Dinasane contains the active ingredient dienogest. It is used to treat painful symptoms of endometrial lesions (displaced tissue of the lining of the womb).

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

2. What should I know before I use this medicine?

Do not use if you have ever had an allergic reaction to dienogest 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. There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking this medicine.

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

3. What if I am taking other medicines?

Some medicines may interfere with dienogest 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 this medicine?

Follow all directions given to you by your doctor and other health professionals carefully:

- Take one tablet daily at about the same time each day, without any break.
- Follow the direction of the arrows on the blister pack until all the tablets have been taken.
- You must take the tablets continuously without regard to vaginal bleeding. This means that after the first pack has been finished you should start the next without interruption.
- Swallow the tablet whole with water.

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

5. What should I know while using this medicine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using this medicine.• Tell your doctor you are using this medicine well in advance of any expected hospitalisation or surgery.• To avoid becoming pregnant, you should use non-hormonal contraceptive precautions, such as a condom or another barrier method.• Call your doctor straight away if you experience unexplained abdominal complaints that are different to the symptoms you commonly experience from your endometriosis.
Things you should not do	<ul style="list-style-type: none">• Do not use sex-hormone containing contraceptives, or use rhythm or temperature contraception methods, while taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets below 25°C.• Protect from light.

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur.

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.

Dinasane

Active ingredient(s): *dienogest*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dinasane. **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 this medicine.**

Where to find information in this leaflet:

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

1. Why am I using Dinasane?

Dinasane contains the active ingredient **dienogest**. It is a progesterone hormone.

This medicine name is used to treat **painful symptoms of endometrial lesions (displaced tissue of the lining of the womb)**. Taking this medicine leads to the shrinking of the endometrial tissue and reduces associated complaints such as pelvic pain and painful monthly bleedings.

2. What should I know before I use this medicine?

Warnings

Do not use this medicine if:

- you are allergic to dienogest, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have or have had a blood clot in the blood vessels of the legs, the lungs, the heart, the brain, or other parts of the body, or you are concerned about an increased risk of blood clots
- you have or have had diabetes mellitus with blood vessel damage
- you have or have had severe liver disease and your liver function has not returned to normal
- you have or have had cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- you have or have had liver tumours (benign or malignant)
- you have or have had unexplained vaginal bleeding
- you are pregnant or think you might be pregnant
- you are breastfeeding.

If any of the conditions listed above appear while taking this medicine, stop taking it at once and tell your doctor.

Check with your doctor if you:

- smoke
- are overweight
- have diabetes or had diabetes temporarily during previous pregnancy
- have high blood pressure or develop high blood pressure while taking this medicine
- have suffered from depression
- have had an ectopic pregnancy (the embryo develops outside the womb)
- have an impaired function of the fallopian tubes
- develop a liver disease while taking this medicine. Symptoms may include yellowing of the skin or eyes or itching all over the body. Inform your doctor also if such symptoms occurred during a previous pregnancy.
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) – if so, avoid exposure to the sun or ultraviolet radiation
- you or anyone in your immediate family has had blood clots in the legs or lungs, a heart attack, a stroke, breast cancer or high cholesterol
- take any medicines for any other condition.

If you have any of the conditions listed above you may need to be kept under close supervision. Your doctor can explain this to you.

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

Check with your doctor if you are pregnant or intend to become pregnant. The possibility of pregnancy should be ruled out before starting this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

Do not give this medicine to a child.

This medicine is not for use in female children before the first menstrual bleed.

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/foods may interfere with dienogest and affect how it works. These include:

- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbamazepine, topiramate, felbamate
- medicines used to treat depression such as fluoxetine, fluvoxamine
- diltiazem, verapamil which are medicines used to treat high blood pressure, chest pain or irregular heartbeats
- medicines used to treat tuberculosis such as rifampicin, rifabutin
- medicines used to treat HIV or hepatitis C virus (HCV)
- medicines used to treat fungal infections such as ketoconazole, itraconazole, fluconazole, voriconazole
- some antibiotics (e.g. erythromycin, clarithromycin)
- cimetidine, an antacid
- herbal medicines containing St. John's Wort
- grapefruit.

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

4. How do I use this medicine?

How much to take

- Take one tablet daily at about the same time each day, without any break.
- Follow the instructions provided and use this medicine until your doctor tells you to stop.

When to take this medicine

- It does not matter if you take the medicine before or after food.

How to take it

- Follow the direction of the arrows on the blister pack until all the tablets have been taken.
- You can start taking the tablet on any day of your menstrual cycle.
- You must take the tablets continuously without regard to vaginal bleeding. This means that after the first pack has been finished you should start the next without interruption.
- Swallow the tablet whole with water.

If you forget to take this medicine

This medicine should be used regularly at the same time each day. This medicine may not work as well if you miss tablets or have vomiting and/or diarrhoea within 3-4 hours after tablet taking.

If you miss your dose at the usual time, you should take one tablet only, as soon as you remember. Then continue to take the tablet at your usual time the next day.

If you have vomiting and/or diarrhoea after taking the tablet, you should take one tablet, and then continue to take the tablet at your usual time the next day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much dienogest

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

5. What should I know while using this medicine?

Things you should do

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Tell your doctor you are using this medicine well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking this medicine several weeks before surgery, or at the time of immobilisation and when you can start taking it again.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- **become pregnant while taking this medicine.** If in an exceptional case you should become pregnant during the use of this medicine, there is a higher likelihood in users of progestogen containing preparations like dienogest to have an ectopic pregnancy (the embryo develops outside the womb).
- **you experience unexplained abdominal complaints that are different to the symptoms you commonly experience from your endometriosis.** In this case an ectopic pregnancy must be considered.

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

Things you should not do

- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Contraception methods

- To avoid becoming pregnant, you should use non-hormonal contraceptive precautions, such as a condom or another barrier method.
- You must not use sex-hormone containing contraceptives of any form (tablet, patch, intrauterine system) while taking this medicine.
- Do not use rhythm or temperature methods. These methods can be unreliable.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how this medicine affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Keep your tablets below 25°C. Protect from light.

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.

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
Head complaints: <ul style="list-style-type: none"> headache or migraine Food related: <ul style="list-style-type: none"> weight gain 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Mood issues: <ul style="list-style-type: none"> mood changes, including depression, irritability, nervousness, problems sleeping, loss of interest in sex Stomach complaints: <ul style="list-style-type: none"> nausea, abdominal pain, wind, swollen tummy or vomiting Skin problems: <ul style="list-style-type: none"> acne, hair loss Muscle issues: <ul style="list-style-type: none"> back pain unusual weakness Women's health: <ul style="list-style-type: none"> breast discomfort hot flushes uterine/vaginal bleeding including spotting 	
Menstrual bleeding patterns: <ul style="list-style-type: none"> Dienogest treatment affects the menstrual bleeding pattern in the majority of women. If bleeding is heavy and continuous over time, this may lead to anaemia. 	Speak to your doctor if bleeding is heavy and continuous over time. Your doctor may advise you to stop taking this medicine.
Bone mineral density (BMD): <ul style="list-style-type: none"> The long term use of this medicine may affect the bone mineral density (BMD) of adolescents (12 to < 18 years). 	Ask your doctor for their advice to improve your bone health and reduce your risk of bone loss (osteoporosis).

Serious side effects

Serious side effects	What to do
Blood clot (thrombosis): Thrombosis is the formation of a blood clot which may block a blood vessel. It may occur in the deep veins of the legs (causing deep venous thrombosis), arteries of the lungs (causing pulmonary embolism), blood vessels of the heart (causing a heart attack), or the brain (causing a stroke).	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>Possible signs of a blood clot include:</p> <ul style="list-style-type: none"> • an unusual cough • pain in the chest, arm or below the breastbone • discomfort radiating to the back • breathlessness and/or difficulty breathing • swelling, pain or tenderness of one leg • sudden weakness, numbness or bad ‘pins and needles’ of the face, arm or leg, especially on one side of the body • sudden trouble walking, dizziness, loss of balance or coordination • severe, sudden stomach pains • a fainting attack, or you collapse • unusual headaches or migraines that are worse than usual • sudden problems with your speech, understanding or eyesight. 	<p>If you notice possible signs of a blood clot, stop taking this medicine and consult your doctor immediately.</p>
<p>Liver tumours:</p> <ul style="list-style-type: none"> • Benign or malignant liver tumours may lead to internal bleeding 	<p>Contact your doctor immediately if you have severe pain in your abdomen.</p>
<p>Breast cancer:</p> <ul style="list-style-type: none"> • Lumps in breasts 	<p>Contact your doctor if you feel any lump in your breast.</p>

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. 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 this medicine contains

Active ingredient (main ingredient)	Dienogest 2 mg
Other ingredients (inactive ingredients)	Lactose monohydrate Potato starch

	Microcrystalline cellulose Povidone Purified talc Crospovidone Magnesium stearate
Potential allergens	Lactose monohydrate

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

This medicine does not contain gluten, tartrazine or any other azo dyes.

What this medicine looks like

Dinasane 2 mg tablets:

White to off-white, round, flat faced bevelled edge tablets debossed with “NC” on one side and “22” on other side.

Blister packs of 2 x 14, 6 x 14 or 12 x 14 tablets (AUST R 336683).

Not all pack sizes may be available.

Who distributes this medicine

This medicine is supplied in Australia by:

Arrotex Pharmaceuticals

15-17 Chapel St

Cremorne VIC 3121

Australia

This leaflet was prepared in March 2021.