

Dimetriose

Gestrinone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **Dimetriose**. 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 or pharmacist has weighed the risks of you taking **Dimetriose** against the benefits they expect it will have for you.

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 Dimetriose is used for

Dimetriose is a medicine for treating a specific illness called endometriosis, which only occurs in women.

Dimetriose is available only with a doctor's prescription.

Before you take Dimetriose

When you must not take it

Do not take Dimetriose if you have an allergy to Dimetriose or any of the ingredients listed at the end of this leaflet.

Do not take Dimetriose if you are pregnant or intend to become pregnant.

Do not take Dimetriose if you are breast-feeding or plan to breast-feed.

Dimetriose is intended for the treatment of endometriosis in women and therefore should not be taken by men or by children. It is also not recommended for elderly patients.

You should not take **Dimetriose** if you have any of the following:

- *Severe heart, kidney or liver problems.*
- *Metabolic disorder*
- *Vascular disorder – blood circulation problems.*

Do not take Dimetriose after the expiry date (EXP) printed on the pack. If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Dimetriose if the packaging is torn or shows signs of tampering, or if the capsules don't look quite right.

If you are not sure whether you should start taking Dimetriose, contact your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. **Dimetriose** is not recommended for use during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed. Breastfeeding is not recommended whilst you are taking **Dimetriose**

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- *epilepsy*
- *heart or kidney disease*
- *high blood lipid (fat) levels*
- *diabetes*
- *blood clots in the veins (thrombosis).*

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Dimetriose. You may need to have regular checkups with your doctor while taking **Dimetriose**.

Dimetriose is not a contraceptive pill. If contraception is necessary, a barrier method (eg. condoms) must be used during treatment with **Dimetriose**.

Taking other medicines

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

Some medicines and **Dimetriose** may interfere with each other. These include:

- *Anti-epileptic drugs*
- *Rifampicin – an antibiotic*

These medicines may be affected by **Dimetriose**, 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 will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking **Dimetriose**.

How to take Dimetrioise

How much to take

Your doctor or pharmacist will tell you how many capsules you will need to take. This depends on your condition and whether or not you are taking any other medicines.

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

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

How to take it

Swallow Dimetrioise with a glass of water.

When to take it

Your doctor or pharmacist will tell you when and how often you need to take Dimetrioise.

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

If you forget to take it

If you miss one dose, the missed capsule should be taken as soon as possible and the original dose sequence continued.

If you miss two or more doses, stop taking Dimetrioise and start again on the first day of your next menstrual cycle, after ensuring you are not pregnant.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Dimetrioise treatment is limited to a single course of six months.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone Australia 13 11 26, or New Zealand (03) 474 7000), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Dimetrioise. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Dimetrioise

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Dimetrioise.

You must use a barrier form of contraception (eg. condoms) while taking Dimetrioise.

If you become pregnant while taking Dimetrioise, stop taking it and tell your doctor immediately.

Things you must not do

Do not give Dimetrioise to anyone else, even if they have the same condition as you.

Do not take Dimetrioise to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

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

Dimetrioise may cause dizziness in some people. Make sure you know how you react to Dimetrioise before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy

or light-headed. If this occurs do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dimetrioise, even if the problem is not listed below.

Dimetrioise 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.

Tell your doctor or pharmacist if you notice any of the following and it worries you :

- *Menstrual spotting, irregular or heavy bleeding*
- *Skin problems, oily skin or acne*
- *Weight gain*
- *Changed appetite*
- *Hot flushes*
- *Headache*
- *Aches or cramps*
- *Nervousness*
- *Depression*
- *Gastrointestinal disturbances*
- *Changed libido (sex drive)*
- *Changed breast size or breast lumps*
- *Changed voice*
- *Increased body hair*
- *Oedema (excess fluid)*
- *Dizziness or faintness*
- *Lethargy*
- *Sweating*
- *Blurred vision*
- *Back, breast, or pelvic pain*

Other side effects not listed above may occur in some patients

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

After using Dimetrioise

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they will not keep as well.

Keep your capsules in a dark, cool, dry place where the temperature stays below 30°C.

Do not store Dimetriose or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Dimetriose or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Dimetriose is a hard white capsule with a Roussel logo (three short blue bars in a triangular pattern) printed on each half.

Dimetriose is available in a blister pack of 8 capsules

Ingredients

Dimetriose capsules contain:

Gestrinone 2.5mg, (active ingredient), Lactose, Maize starch, Cellulose, Talc, Silica, Magnesium stearate, Gelatin, Titanium dioxide and Blue ink.

Dimetriose does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

- *Aventis Pharma Pty. Ltd.
27 Sirius Rd
Lane Cove NSW 2066*

Australia

- *Aventis Pharma Limited
Auckland, New Zealand*

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