

Clomhexal®

clomiphene citrate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Clomhexal.

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 taking this medicine 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 Clomhexal is used for

This medicine is used to stimulate the ovaries to produce and release an egg during a woman's menstrual cycle (ovulation) in women wishing to become pregnant.

It contains the active ingredient clomiphene citrate.

It works by causing a gland in the brain (the anterior pituitary) to release hormones which stimulate ovulation.

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 reason.

This medicine is not addictive.

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

Before you take Clomhexal

Your doctor will perform a pelvic examination on you before you begin to take Clomhexal. This is to check that you have no medical conditions which may stop you falling pregnant or which might indicate that Clomhexal is not a suitable medicine for you.

When you must not take it

Do not take this medicine if you have an allergy to:

- **clomiphene citrate, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description.**

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.**

Do not take this medicine if you have any of the following medical conditions:

- **abnormal vaginal bleeding of unknown cause**
- **ovarian cysts not due to polycystic ovary disease**
- **mental depression**
- **thrombophlebitis (inflammation of a blood vessel due to a clot)**
- **hormone dependent tumours and pituitary tumours**

- **uncontrolled thyroid or adrenal gland function**
- **liver disease or a history of liver problems.**

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

To avoid inadvertently taking Clomhexal during early pregnancy, you should perform tests during each treatment cycle to determine whether ovulation occurs. You should have a pregnancy test before the next course of Clomhexal therapy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Clomhexal may pass into breast milk and there is a possibility that your baby may be affected.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- **uterine fibroids (growths in the uterus which are not cancer)**
- **polycystic ovary disease. This condition results in many small cysts (fluid-filled sacs) in the ovaries.**

If you have not told your doctor about any of the above, tell him/her before you start taking Clomhexal.

Discuss with your doctor the potential complications of multiple pregnancies before taking Clomhexal.

The chances of multiple pregnancies are higher when you use Clomhexal.

Taking other medicines

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

Clomhexal has not been shown to interfere with the actions of other medicines. However many other medicines should not be taken if you become pregnant. Discuss all medicines you may be taking with your doctor and pharmacist.

How to take Clomhexal

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, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Clomhexal may not work as well.

The usual starting dose is one tablet each day for 5 days.

If ovulation appears to not have occurred after the first course of therapy, your doctor may advise you to increase your dose of Clomhexal in subsequent treatment cycles.

Do not take an increased dose unless instructed to do so by your doctor.

Taking more than your doctor prescribes may overstimulate your ovaries. This could damage your ovaries and endanger your health.

How to take it

Swallow the tablets whole with a full glass of water.

If your doctor has told you to take two tablets each day, take the tablets together and not at different times of the day.

When to take Clomhexal

Your doctor will advise you on which day of your cycle to begin to take Clomhexal.

Take your medicine at about the same time each day.

It will help you remember when to take it.

How long to take Clomhexal

Continue taking your medicine for as long as your doctor tells you.

Clomhexal is usually taken for 5 consecutive days at the beginning of your cycle.

It is possible to have more than one course of treatment with Clomhexal. However long-term therapy is not recommended. Your doctor will tell you how many courses of Clomhexal you should take.

If you forget to take it

If you forget to take a dose, tell your doctor and he/she will advise you of what to do given your own special case.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Clomhexal. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- **abdominal or pelvic discomfort, pain or a bloated feeling**
- **nausea and vomiting**
- **diarrhoea.**

While you are taking Clomhexal

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do some tests to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Clomhexal 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.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause visual disturbances, especially in brightly lit environments. Visual disturbances such as blurring, spots or flashes may occur in some people. This medicine may also cause tiredness, dizziness or light-headedness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Clomhexal.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of 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 you notice any of the following and they worry you:

- hot flushes
- intermenstrual (between period) spotting or heavy menstrual periods
- nausea or vomiting
- breast soreness or discomfort
- headache
- insomnia, tiredness, dizziness or light-headedness
- rash or skin irritations
- increased frequency of urination
- hair loss
- fever
- vaginal discharge
- weight gain.

Tell your doctor or pharmacist as soon as possible if you notice any of the following:

- severe abdominal or pelvic pain, discomfort or swelling
- visual blurring, spots or flashes. If visual problems occur, stop taking Clomhexal.

The above list includes serious side effects that may require medical attention.

The chances of ectopic pregnancies (foetus growing outside the womb) are higher if you become pregnant whilst taking Clomhexal.

There is a higher chance of multiple pregnancies from clomiphene therapy.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- seizures.

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

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

After taking Clomhexal

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Clomhexal or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Clomhexal 50mg - white, round, biconvex tablets with a break mark on one side.

Available in blister packs of 5 tablets.

Ingredients

Active ingredients:

- Clomhexal 50mg - 50mg clomiphene citrate.

Inactive ingredients:

- lactose
- maize starch
- microcrystalline cellulose
- povidone
- colloidal anhydrous silica
- magnesium stearate.

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

Supplier

Clomhexal is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
Level 4, 100 Harris St
Pymont NSW 2009
Tel: 1800 634 500

This leaflet was revised in January 2009.

Australian Register Number

50mg tablets: AUST R 66173 (blisters)