

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 Clomid?

Clomid contains the active ingredient clomifene citrate. About 20% of couples who experience difficulty in conceiving, do so because the woman's ovaries are not producing and releasing an egg each menstrual cycle (anovulation). Your doctor has prescribed Clomid to treat this.

For more information, see Section 1. Why am I using Clomid? in the full CMI.

2. What should I know before I use Clomid?

Do not use if you have ever had an allergic reaction to clomifene citrate 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 Clomid? in the full CMI.

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.

4. How do I use Clomid?

• The recommended dose for the first course of Clomid is one tablet per day for five days at the beginning of your cycle. If ovulation does not occur, your doctor may advise you to increase the dose of Clomid in subsequent treatment cycles.

More instructions can be found in Section 4. How do I use Clomid? in the full CMI.

5. What should I know while using Clomid?

| Things you should do | Remind any doctor, dentist or pharmacist you visit that you are using Clomid. |
|-----------------------------|---|
| Things you should not do | Do not give Clomid to anyone else, even if they have the same condition as you. Do not use Clomid to treat any other complaints unless your doctor tells you to. |
| Driving or using machines | Be careful driving or operating machinery until you know how Clomid affects you. Clomid may cause visual disturbances in some people. |
| Looking after your medicine | Keep your tablets in a cool dry place where the temperature stays below 30°C. Keep your tablets in the pack until it is time to take them. |

For more information, see Section 5. What should I know while using Clomid? in the full CMI.

6. Are there any side effects?

Serious side effects include erythema multiforme (a skin condition with red, often itchy spots, which start on the limbs and sometimes on the face and rest of the body), eye related symptoms (blurred vision, partial or complete loss of vision, double vision) and allergic reaction (symptoms such as difficulty breathing, swelling of the face, lips, throat or tongue).

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.



Active ingredient: clomifene citrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Clomid. 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 Clomid.

Where to find information in this leaflet:

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

1. Why am I using Clomid?

Clomid contains the active ingredient clomifene citrate.

About 20% of couples who experience difficulty in conceiving, do so because the woman's ovaries are not producing and releasing an egg each menstrual cycle (anovulation). Your doctor has prescribed Clomid to treat this.

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

It must be remembered that there are many causes of anovulation, so Clomid may not be effective in all cases.

When taking Clomid there should be 28-32 days from the beginning of one period to the next. Your ovaries should release an egg 6-12 days after a course of Clomid. You should have intercourse around this time to maximise your chances of conception.

If your period does not arrive after the 35th day there are two likely possibilities:

 the dose of Clomid has not been sufficient to produce ovulation,

or

you are pregnant

If your period is overdue, contact your doctor/fertility unit and they will advise you what steps to take.

2. What should I know before I use Clomid?

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

Warnings

Do not use Clomid if:

 you are allergic to clomifene citrate, 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 liver disease or a history of liver problems
- you have hormone-dependent tumours
- you have abnormal uterine bleeding of undetermined origin
- you have ovarian cysts, with the exception of polycystic ovary
- you have had vision disorders diagnosed by your doctor as being associated with the use of Clomid (during treatment, or during a previous treatment)

Check with your doctor if you:

- · have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines or other substances, such as foods, preservatives or dyes
- have pre-existing or a family history of hyperlipidemia (high cholesterol levels) or hypertriglyceridemia (high triglyceride levels in blood)

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Like most fertility medicines, Clomid should not be taken during pregnancy.

To avoid inadvertently taking Clomid 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 Clomid therapy.

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

You should be aware of the potential complications of multiple pregnancy before taking Clomid. Discuss this with your doctor.

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

Like most fertility medicines, Clomid is not recommended while you are breastfeeding.

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.

4. How do I use Clomid?

How much to take

- The recommended dose for the first course of Clomid is one tablet per day for five days at the beginning of your cycle. If ovulation does not occur, your doctor may advise you to increase the dose of Clomid in subsequent treatment cycles.
- Do not take an increased dose unless instructed to do so by your doctor.

 Taking more than what your doctor has prescribed may overstimulate your ovaries, possibly damaging your ovaries and endangering your health.

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

These directions may differ from the information contained in this leaflet.

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

When to take Clomid

- Your doctor will advise you on which day of your cycle to begin to take Clomid.
- Take Clomid at about the same time each day.
- If you do not have regular periods your doctor may prescribe other tablets e.g., norethisterone for a number of days, after which a period may start. Use this bleeding to time your Clomid course.

How long to take Clomid

- Clomid tablets are usually taken daily for five consecutive days at the beginning of your cycle.
- Your doctor will advise you on how many courses of Clomid you should take.
- Long term therapy with Clomid is not recommended. Your doctor will tell you how long you should take Clomid.

If you forget to take Clomid

Clomid should be taken regularly at the same time each 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.

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 use too much Clomid

If you think that you have used too much Clomid, 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 Clomid?

Things you should do

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

Clomid Progress Checks

It will be necessary to monitor your response to Clomid. Methods used to do this include:

- basal body temperature chart
- urine testing

- blood tests
- mucus testing

The most appropriate method for you will be discussed with your doctor.

Things you should not do

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

Driving or using machines

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

Clomid may cause visual disturbances in some people. Make sure you know how you react to Clomid before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision.

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Keep your tablets in the pack until it is time to take them.
 If you take the tablets out of the pack they will not keep well.

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.

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 (EXP).

Do not take Clomid if the packaging is torn or shows signs of tampering.

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 |
|---|--|
| Gynecological hot flushes intermenstrual ("between period") spotting or heavy menstrual periods breast discomfort vaginal discharge | Speak to your doctor if you have any of these less serious side effects. |

| Less serious side effects | What to do | |
|--|------------|--|
| General | | |
| nausea or vomiting headache fatigue dizziness or light-headedness fainting hair loss fever | | |
| Genito-urinary related | | |
| increased frequency of urination | | |
| Eye related | | |
| visual problems | | |
| Heart related | | |
| increased heart ratepalpitations | | |
| Nervous System related | | |
| insomnianervousnessdepressionseizures | | |
| Skin related | | |
| rash itching or skin irritations | | |

Serious side effects

| Serious side effects | What to do |
|--|---|
| Allergic reaction: difficulty breathing shortness of breath swelling of the face, lips, throat or tongue cold, clammy skin Skin related (erythema multiforme): red, often itchy spots, which start on the limbs and sometimes on the face and rest of the body the spots may blister or progress to form raised, red, pale-centered | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any signs of allergic reaction. |
| marks fever sore throat headache diarrhea Eye related: blurred vision, spots or flashes in front of the eyes difficulty in reading | If you experience skin condition side effects, contact your doctor or pharmacist immediately. |
| blindness (partial or complete loss of vision) double vision eye pain Gynecological growth in size of uterine fibroids the chances of ectopic pregnancies (foetus growing | Visual symptoms usually get better but in some cases they may be permanent. Your doctor may need |

| Serious side effects | What to do |
|--|---|
| outside the womb) are higher if you conceive on Clomid. • prolonged Clomid use may be associated with a small increase in the risk of ovarian cancer. | to send you for an eye examination. |
| Gut related | If you experience any |
| abdominal discomfort or pelvic pain, soreness or a "bloated" feeling | of the other serious side effects listed, |
| General | stop taking Clomid and tell |
| hypertriglyceridemia (high triglyceride levels in blood) in patients who have pre-existing or a family history of hypertriglyceridemia. weight gain | your doctor or pharmacist immediately. |

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 Clomid contains

| Active ingredient (main ingredient) | 50 mg clomifene citrate |
|--|---|
| Other ingredients (inactive ingredients) | sucrose lactose monohydrate maize starch pregelatinized maize starch magnesium stearate iron oxide yellow |
| Potential allergens | N/A |

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

What Clomid looks like

Clomid tablets are beige, round, flat faced bevel edged with a score line on one side and M into two concentric circles engraved on the other side.

The 50mg strength is available in boxes of 10 tablets. (AUST R 313131).

Who distributes Clomid

sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113

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