

Package leaflet: information for the user  
Clomiphene Citrate CF 50 mg, tablets  
clomiphene citrate

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Clomiphene Citrate CF and what is it used for?
2. When should you not use this medicine or be extra careful with it?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

1. What is Clomiphene Citrate CF and what is it used for?

The active substance in this medicine is clomiphene and it belongs to the group of anti-estrogens (female sex hormones). Clomiphene promotes ovulation.

This medicine is used in the treatment of infertility due to the absence of ovulation in women who wish to become pregnant.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You are pregnant.
- Your liver is not functioning normally or has not functioned normally in the past. You should not use this medicine until your liver function has recovered.
- You have abnormal vaginal bleeding of unknown origin.
- You have hormone-dependent tumors or if there is a suspicion that you have them.
- You have fluid-filled cysts in your ovaries (ovarian cysts), except in the case of polycystic ovary syndrome (PCOS), a hormonal disorder in the ovaries where ovulation becomes irregular or absent.
- Your pituitary gland or your ovaries are not functioning properly.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

Before starting the treatment, it must be confirmed that any other possible cause of infertility or absence of menstruation is excluded.

For each new treatment with this medicine, your doctor must confirm that you are not pregnant.

- Your doctor may conduct tests on your body temperature, liver function, and ovaries.
- Both before and during the treatment, hormonal effects must be monitored daily. Since the safety of continued regular treatment has not been established, the treatment may be applied a maximum of 6 times.
- Inform your doctor if you experience abdominal pain, weight gain, or a swollen abdomen. Treatment with clomiphene citrate should be stopped until the ovaries have returned to their pre-treatment size. Fluid-filled cysts in the ovaries (polycystic ovaries) may enlarge. The doctor will prescribe the lowest possible dose of this medicine, and the duration of treatment may be reduced if necessary.
- Contact your doctor if you experience lower abdominal pain, nausea, diarrhea, or a swollen abdomen. Treatment with clomiphene citrate, whether or not in combination with adrenal hormones (gonadotropins), can cause excessive stimulation of the ovaries (Ovarian Hyperstimulation Syndrome).
- The use of this medicine increases the chance of multiple pregnancies.
- There is an increased risk of ectopic pregnancy after treatment with this medicine.
- If you have benign tumors in the uterus (uterine fibroids), they may enlarge due to treatment with this medicine.
- If you have high levels of fats in the blood and this also occurs in family members, your doctor will regularly check the concentration of a certain type of fat (triglycerides) in the blood. This also applies if you use higher dosages of this medicine or use this medicine for longer than recommended.
- Sometimes during treatment with clomiphene citrate, visual disturbances such as blurred vision or color spots may occur. If these symptoms occur, treatment with clomiphene citrate should be discontinued and an ophthalmological examination should be performed. If this symptom has occurred, no new treatments with clomiphene citrate should be undertaken.

Are you using any other medicines?

Are you using any other medicines besides Clomiphene Citrate CF, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

There are no known interactions of the active substance (clomiphene) in this medicine with other medicines.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

Do not use this medicine during pregnancy. Your doctor will need to determine if you are pregnant before treatment.

### Breastfeeding

It is not known whether this medicine is excreted in breast milk. This medicine can reduce the amount of breastfeeding. Women who are breastfeeding should only use this medicine after consulting their doctor.

### Driving and using machines

The use of clomiphene citrate can lead to visual disturbances. This should be taken into account when driving vehicles and operating machines.

### Clomiphene Citrate CF contains lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

This medicine should only be used under the supervision of your doctor. Your doctor will give you clear instructions on the number of tablets and the number of days you should use this medicine. You must follow these instructions exactly and not change the treatment without the explicit permission of your doctor.

The recommended dosage is:

1 tablet (50 mg) once daily for 5 days.

The usual dosage is 50 mg (1 tablet) per day, for 5 days starting on the 5th day of the normal or induced menstruation (cycle). When menstruation is absent, your doctor may determine the day you start with this medicine. It is best to take the tablets with water.

It may happen that after these 5 days an ovulation has occurred, but you are not pregnant. In that case, you can repeat this treatment in consultation with your doctor.

If no ovulation occurs, the dosage can be increased to 100 mg (2 tablets) per day, for 5 days, in consultation with your doctor.

1 time daily 2 tablets (100 mg) for 5 days.

If ovulation occurs at this dose but is not followed by pregnancy, the treatment may be repeated up to six times.

If no ovulation occurs at this dose, the treatment may be repeated twice more.

Have you used too much of this medicine?

If you have used too much of this medicine, contact your doctor immediately.

Symptoms of overdose may include: nausea, vomiting, hot flashes, visual disturbances such as blurred vision and color spots, eye disease with a blind spot (scotomata), enlargement of the

ovaries with (lower) abdominal pain, weight gain, and abdominal swelling due to fluid retention (ascites).

Have you forgotten to take this medicine?

If you have forgotten a tablet, take it as soon as possible, possibly with the next dose. However, you should not combine more than two doses.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Very common (occur in more than 1 in 10 users)

- hot flashes
- enlarged ovaries
- overstimulation of the ovaries.

Common (occur in less than 1 in 10 users)

- headache
- abdominal pain, bloating, pressure pain, nausea, vomiting
- tender breasts
- heavy menstruation
- irregular bleeding during the menstrual cycle
- dizziness.

Sometimes (occur in less than 1 in 100 users)

- depression, fatigue
- blurred vision, loss of a part of the visual field (blind spot), light flashes, seeing colored spots. Symptoms often occur for the first time or are exacerbated after exposure to a brightly lit environment. Cases of prolonged visual disturbances are known after discontinuation of treatment with this drug. The visual disturbances may be permanent, especially after long-term treatment or a high dosage with this drug.
- hives (urticaria), itching, skin inflammation due to an allergic reaction
- increased urge to urinate
- weight gain.

Rarely (occur in less than 1 in 1000 users)

- seizures or convulsions
- clouding of the lens capsule in the eye
- inflammation of the optic nerve
- moderate hair loss

Not known (cannot be determined from the available data)

- elevated levels of fats (triglycerides) in the blood
- stroke, anxiety, mood swings, tension, insomnia
- detachment of the posterior part of the vitreous body

- spasm of the blood vessels in the retina which can lead to temporary vision loss in one eye, changes in the functioning of the retina causing reduction or abnormalities in vision
- accelerated heartbeat (tachycardia), palpitations
- multiple pregnancies where the pregnancy can be both intrauterine and ectopic simultaneously
- ectopic pregnancy
- proliferation of the endometrium
- decrease in thickness of the endometrium
- sensation of tingling, itching, or prickling without any apparent cause (paresthesia). These are transient.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. How do you store this medicine?

Keep out of the sight and reach of children.

Store below 25°C. Store in the original packaging.

Do not use this medicine after the expiry date. You can find it on the packaging after "Do not use after" or "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

#### 6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is clomiphene citrate. One tablet contains 50 mg clomiphene citrate.

The other substances in this medicine are lactose, potato starch, povidone K90 (E1201), talc (E553b), colloidal anhydrous silica (E551), magnesium stearate (E470b), quinoline yellow (E104).

What does Clomiphene Citrate CF 50 mg look like and how much is in a package?

Clomiphene citrate CF 50 mg is a yellow, round tablet with a diameter of 10 mm.

Clomiphene citrate CF 50 mg is available in:

- PVC/Al blister packaging: push-through strips of 10 tablets per strip packed in multiples of 10 tablets
- Polypropylene tablet container with polyethylene lid: 50, 100, 200, 250, 500, and 1000 tablets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer  
Marketing authorization holder Centrafarm B.V.  
Van de Reijtstraat 31-E 4814 NE Breda  
Netherlands

Manufacturer  
Centrafarm Services B.V.  
Van de Reijtstraat 31-E  
4814 NE Breda

Netherlands Tiofarma B.V.  
Hermanus Boerhaavestraat 1  
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Registered under:  
RVG 53363 Clomiphene citrate CF 50 mg, tablets

This leaflet was last approved in October 2025.

More information about this medicine is available on the website of the CBG ([www.cbg-meb.nl](http://www.cbg-meb.nl)).