

Package leaflet: Information for the user
Clomifene 50mg Tablets
Clomifene Citrate

- if you are pregnant. You should have a test to make sure you are not pregnant before you take Clomifene Tablets
- Do not take this medicine if any of the above apply to you.**

Warnings and precautions

Talk to your doctor or pharmacist before taking

Clomifene Tablets:

- if you are having an early menopause or have been told you are infertile
- if you have stopped having periods because you are under-weight
- if you have had fits or seizures in the past
- if you have 'fibroids' in your womb
- if you have 'polycystic' ovaries
- if your ovaries are swollen
- if you have hypertriglyceridemia (an excess of fats in the blood) or a family history of hypertriglyceridemia.

Your doctor should check for any other causes of fertility problems before starting treatment with Clomifene Tablets. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Clomifene Tablets.

Other medicines and Clomifene Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes medicines you buy with a prescription, including herbal medicines. This is because Clomifene Tablets can affect the way some other medicines work. Also some medicines can affect the way Clomifene Tablets work.

Pregnancy and breast-feeding

- Do not take this medicine if you are pregnant or think you may be pregnant
- Talk to your doctor before taking this medicine if you are breast-feeding or planning to breast-feed. Clomifene Tablets can lower the amount of milk produced. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may notice problems with your eyesight such as blurred vision while taking this medicine. If this happens, do not drive or use any tools or machines.

Clomifene Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.



Read all of this 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.
- If you have further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

1. What Clomifene Tablets is and what it is used for
2. What you need to know before you take Clomifene Tablets
3. How to take Clomifene Tablets
4. Possible side effects
5. How to store Clomifene Tablets
6. Contents of the pack and other information

1. What Clomifene Tablets is and what it is used for

Clomifene Tablets contain a medicine called clomifene citrate. This belongs to a group of medicines called ovulation stimulants. It works by stimulating the release of eggs from the ovary (ovulation).

Clomifene Tablets are used for some types of infertility, in women who are not ovulating properly.

2. What you need to know before you take Clomifene Tablets

Before taking this medicine talk to your doctor about the risks of:

- Becoming pregnant with more than one child at the same time (multiple pregnancies)
- Pregnancies where the baby grows outside of the womb (ectopic)
- A possible increased risk of ovarian cancer
Any pregnancy could lead to birth defects or miscarriage. This can happen even if you are not taking Clomifene Tablets. You should talk to your doctor about the possible risks before you take Clomifene Tablets.

Do not take Clomifene Tablets:

- if you are allergic to clomifene or any of the other ingredients of this medicine (listed in section 6)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have or ever had liver disease
- if you have unusual menstrual bleeding where the cause is not known
- if you have a type of cancer that is made worse by hormones
- if you have a cyst on your ovary

This medicine should not be taken by children, adolescents, men or women who have already gone through the menopause (post-menopausal).

If you take more clomifene than you should

If you take more clomifene than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. You are likely to get over-stimulation of your ovary (see section 4 below).

If you forget to take Clomifene Tablets

If you forget a dose, talk to your doctor as you may need to change your treatment cycle. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Clomifene Tablets

Keep taking Clomifene Tablets until your doctor tells you to stop. If you stop, the treatment may not work.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Clomifene Tablets and go to a hospital straight away if:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have numbness, weakness or paralysis on one side of your body, slurred speech, sudden blurred vision, confusion or unsteadiness. These could be signs of a stroke

Stop taking Clomifene Tablets and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Over-stimulation of the ovary.
This can lead to pain in the pelvis, stomach or calf, swelling or feeling bloated, passing less urine, difficulty in breathing or an increase in weight. If this happens, your doctor may lower your dose of Clomifene Tablets
- Blurring of vision or spots or flashes in front of the eyes. These symptoms usually get better but in some cases they may be permanent. Your doctor may send you for an eye examination.
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Sudden and severe headaches
- Mental illness such as 'psychosis'

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Increased pain with periods, heavy periods or bleeding between periods
- Pain in the lower part of the stomach. This could be a sign of endometriosis or worsening of endometriosis, ovarian cancer or enlarged ovaries
- Thinning of the layer covering the inside of the uterus.
- Increased levels of fat in the blood (hypertriglyceridaemia) which may also cause inflammation of the pancreas.
- Pain in the upper middle or upper left part of the abdomen. This could be a sign of inflammation of the pancreas (pancreatitis).
- Cloudy lenses in the eye (cataracts)
- Fits, feeling faint, disorientated or more tense than normal. Also, balance problems or feeling dizzy (vertigo)
- Feeling tired or difficulty in sleeping (insomnia), depression or change in moods or behaviour
- Rapid or irregular heartbeat
- Speech problems
- Skin rash or itching
- Raised red skin patches with blisters surrounded by rings, sores on the lips, eyes or mouth and fever (erythema multiforme), red or purple skin patches (ecchymosis)
- Feeling or being sick

- Flushing of the skin
- Headaches
- Swelling of the face, around the eyes, lips or tongue
- Painful breasts
- Hair loss or thinning
- Increased levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.
- Numbness or tingling on your skin (paraesthesia)
- Feeling anxious
- Feeling more nervous than usual.

There have been rare reports of ovarian cancer with fertility drugs. Some studies suggest that prolonged use of clomifene may increase this risk. Therefore the recommended duration of treatment should not be exceeded.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clomifene Tablets

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clomifene Tablets contain

The active substance is clomifene citrate. Each tablet contains 50mg of clomifene citrate.

The other ingredients are lactose, maize starch and magnesium stearate.

What Clomifene Tablets look like and contents of the pack
Clomifene tablets are white, round tablets with HG C50 on one side and a breakline on the other side.

They are available in packs of 30 tablets.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)
Please be ready to give the following information:

Product name	Reference number
Clomifene 50mg Tablets	29831/0037

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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