

Package leaflet: Information for the user

Clomifene 50mg Tablets

Clomifene citrate



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 are and what they are 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 are and what they are 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).

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
- if you are pregnant. You should have a test to make sure you are not pregnant before you take Clomifene Tablets
- if you have had vision disorders diagnosed by your doctor as being associated with the use of Clomifene Tablets (during treatment, or during a previous treatment).

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.

3. How to take Clomifene Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water. Do not crush or chew your tablets
- Do not take more than two tablets in one day
- Do not take the tablets for more than five days at a time
- If you feel the effect of your medicine is not working, do not change the dose yourself, but ask your doctor.

The usual dose is:

Adult women only:

- Your doctor will tell you when in your menstrual cycle to start taking the tablets
- For the first course of treatment, take one tablet a day for five days
- If you do not have a period after the first course of treatment your doctor will increase your dose to two tablets a day for five days
- You should start this second course at least 30 days after the first course
- You will not usually take more than three courses of treatment. If ovulation does not happen after three courses talk to your doctor.

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 Tablets 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 notice any of the following serious side effects – you may need urgent medical treatment

- You have an allergic reaction (such as anaphylaxis and angioedema). The symptoms may include: a rash, itching, difficulty breathing, shortness of breath, swelling of your face, lips, throat or tongue, cold clammy skin, palpitations, dizziness, weakness or fainting
- 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
- 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
- Eye symptoms may include blurring of vision or spots or flashes in front of the eyes, difficulty in reading, blindness (partial or complete loss of vision), double vision and eye pain. 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 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
- 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.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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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