

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Clomid® 50mg Tablets**

clomifene citrate

Is this leaflet hard to see or read? Phone 01 4035600 for help

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

**In this leaflet:**

1. What Clomid is and what it is used for
2. What you need to know before you take Clomid
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**1. What Clomid is and what it is used for**

Clomid contains 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). Clomid is used for some types of infertility, in women who are not ovulating properly.

**2. What you need to know before you take Clomid**

**Before you take the medicine talk to you 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)
- Ovarian Hyperstimulation Syndrome
- Problems with your vision

Any pregnancy could lead to birth defects or miscarriage. This can happen even if you are not taking Clomid. You should talk to your doctor about the possible risks before you take Clomid.

**Do not take this medicine and tell your doctor if:**

× You are allergic (hypersensitive) to clomifene or any of the other ingredients of Clomid (listed in Section 6 below).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- × You are having an early menopause or have been told you are infertile
- × You have or ever had liver disease
- × You have unusual menstrual bleeding where the cause is not known
- × You have a type of cancer that is made worse by hormones
- × You have a cyst on your ovary

- × You are pregnant. You should have a test to make sure you are not pregnant before you take Clomid
- × You have had visual problems diagnosed by your doctor as being associated with Clomid use (current or during previous treatment course).

Do not take this medicine if any of the above apply to you.

### **Take special care with Clomid**

#### **Check with your doctor or pharmacist before taking your medicine if:**

- You have had fits or seizures in the past
- You have 'fibroids' in your womb
- You have 'polycystic' ovaries
- Your ovaries are swollen
- You have a hormone dependent cancer
- 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 Clomid.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Clomid.

### **Warnings and precautions**

You should stop treatment immediately and tell your doctor if you have a sensation of blurred vision or other visual disorders. A full eye examination should be performed.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Clomid can affect the way some other medicines work. Also some medicines can affect the way Clomid works.

### **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 breastfeeding or planning to breast-feed. Clomid 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**

Clomid has moderate effects on the ability to drive and use machines. Visual disorders were sometimes observed in some patients. You may notice problems with your eyesight such as blurred vision while taking this medicine. These may be a hazard when driving a vehicle or operating machines, especially in changing lighting. If this happens, do not drive or use any tools or machines.

### **Important information about some of the ingredients of Clomid**

This medicine contains lactose and sucrose, which are types of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Clomid.

### 3 How to take Clomid

Always take Clomid exactly as your doctor has told you. You should 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 (postmenopausal).**

#### If you take more Clomid than you should

If you take more Clomid 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 Clomid

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 Clomid

Keep taking Clomid 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 product, ask your doctor or pharmacist.

### 4. Possible side effects

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

#### Stop taking Clomid and see your doctor or go to a hospital straight away if:

- You have an allergic reaction (such as anaphylaxis and angioedema). The signs may include: a rash, itching, swallowing problems, 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

- You are pregnant and you have vaginal bleeding and abdominal pain. These could be signs of an ectopic pregnancy (see section 2 above)

The frequency of the above side effects is not known (cannot be estimated from the available data)

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

**Common** (may affect up to 1 in 10 people)

Blurring of vision or spots or flashes in front of the eyes.

**Rare** (may affect up to 1 in 1000 people)

- Reduced vision, pain in the eyes and difficulty to see some colours. This could be a sign of optic nerve inflammation (optic neuritis)

**Not known** (frequency cannot be estimated from the available data)

- Over-stimulation of the ovary leading 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 Clomid
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Mental illness such as 'psychosis'
- Problems with your eyesight
  - Reduced visual acuity
  - Optic nerve ischaemia (optic neuropathy)
  - Detachment of retina or vitreous
  - Clot of retinal blood vessels (central retinal vein occlusion)
  - Double vision
  - Eye pain
  - Accommodation disorders

Visual conditions usually get better but in some cases they lead to reversible or irreversible, partial or total, visual impairment (blindness). Your doctor may send you for an eye examination.

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

**Very common** (may affect more than 1 in 10 people)

- Flushing of the skin
- Pain or discomfort in the lower part of the stomach, weight gain, swelling. This could be a sign of enlarged ovaries.

**Common** (may affect up to 1 in 10 people)

- Feeling or being sick
- Increased pain with periods, heavy periods or bleeding between periods
- Painful breasts
- Headaches
- Feeling bloated and distended

**Uncommon** (may affect up to 1 in 100 people)

- Feeling more tense than normal.
- Having balance problems or feeling dizzy (vertigo)
- Feeling tired or having difficulty in sleeping (insomnia),

- Feeling depressed or having change in moods or behaviour

**Rare** (may affect up to 1 in 1000 people)

- Fits
- Cloudy lenses in the eye (cataracts)

**Not known** (frequency cannot be estimated from the available data)

- Pain or discomfort in the lower part of the stomach, weight gain, swelling. This could be a sign of endometriosis (where the cells lining the interior of the womb are found in other parts of the body, for example in the muscles of the womb) or worsening of endometriosis and ovarian cancer
- Massive Ovarian enlargement
- Multiple pregnancies e.g. twins
- Increased levels of fat in the blood (hypertriglyceridaemia)
- Increased liver enzymes. This can be seen in blood tests.
- Pain in the upper middle or upper left part of the abdomen. This could be a sign of inflammation of the pancreas (pancreatitis) which may be caused by high levels of fat in the blood
- Palpitations (tachycardia)
- Lesions of the skin of the legs, arms, palms, hands, feet and inside the mouth (erythema multiforme)
- Feeling faint or having loss of consciousness
- Feeling dis-orientated and having speech problems
- Skin rash or itching
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Feeling anxious (anxiety)
- Nervousness
- Bruising
- Swelling of the face, around the eyes, lips or tongue
- Hair loss or thinning

### **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 HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie)

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

### **5. How to store Clomid**

Keep out of the sight and reach of children. Store in the original container in order to protect from light. Do not store above 25°C. Do not use Clomid after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Clomid contains**

- Each tablet contains 50mg of the active substance, clomifene citrate

- The other ingredients are sucrose, lactose monhydrate, soluble starch, maize starch, magnesium stearate, iron oxide yellow (E172), purified water.

#### **What Clomid looks like and contents of the pack**

Clomid 50mg Tablets are beige and round marked with M in two circles. They are supplied in PVC and aluminium blister packs. Pack sizes 5, 30 or 100 tablets.

#### **Marketing Authorisation Holder and Manufacturer**

##### Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

**This leaflet was last revised in May 2023.**