

CLOMID[®] TABLET

Clomiphene citrate (50mg)

What is in this leaflet

1. What Clomid is used for
2. How Clomid works
3. Before you use Clomid
4. How to use Clomid
5. While you are using it
6. Side effects
7. Storage and Disposal of Clomid
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Clomid is used for

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

How Clomid works

Clomid contains a medicine called clomiphene citrate. This belongs to a group of medicines called ovulation stimulants. It works by stimulating the release of eggs from the ovary (ovulation).

Before you use Clomid

-When you must not use it

Do not take Clomid if:

- You are allergic (hypersensitive) to clomiphene or any of the other ingredients of Clomid (listed in *Ingredients* below)
- Symptoms of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- 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 (growth) on your ovary
- You are pregnant. You should have a test to make sure you are not pregnant before you take Clomid.

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

-Before you start to use it

Take special care with Clomid and check with your doctor before taking

your medicine if:

- You are having an early menopause or have been told you are infertile
- You have stopped having periods because you are under-weight
- You have fibroids (abnormal growth) in your womb
- You have polycystic (many small growth) ovaries
- Your ovaries are enlarged
- You have hypertriglyceridemia (an excess of fats in the blood) or a family history of hypertriglyceridemia.

Before you take the 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 Clomid. You should talk to your doctor about the possible risks before you take Clomid.

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.

-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.

How to use Clomid

Always take Clomid exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- o 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

-How much to use

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).

-When to use it

Take Clomid at about the same time each day unless your doctor tells you otherwise.

It will help you remember when to take the medicine. If you are not sure when to use it, ask your doctor or pharmacist.

-How long to use it

Keep taking Clomid until your doctor tells you to stop. If you stop, the treatment may not work. Long-term cyclic therapy is not recommended.

-If you forget to use it

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 use too much (overdose)

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.

While you are using it

-Things you must do

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. Tell your doctor immediately if:

- You are pregnant or think you may be pregnant.
- You are breast-feeding or planning to breast-feed. Clomid can lower the amount of milk produced.

-Things you must not do

- Do not give this medicine to anyone else, even if they seem to have the same condition as you.
- Do not stop taking Clomid, or change the dosage, without checking with your doctor.

-Things to be careful of

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.

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.

Side Effect

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. The symptoms 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 Clomid 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 Clomid
- 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)
- 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 symptom 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
- Feeling or being sick
- Flushing of the skin
- Headaches
- Breasts discomfort
- Hair loss or thinning

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

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems /Side Effects /AEFI /Vaccine Safety).

Storage and Disposal of Clomid

-Storage

Keep out of the reach and sight of children.

Do not store in original container 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.

-Disposal

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.

Product Description

-What it looks like

Clomid 50mg Tablets are flat face bevelled edge tablet (beige) with M logo scored line. They are supplied in PVC and aluminium blister packs with 30 scored tablets.

-Ingredients:

-Active ingredient:

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

-Inactive ingredients

- The other ingredients are sucrose, lactose, starch instant, corn starch, magnesium stearate, iron oxide yellow

-MAL Number:

Clomid Tablets 50mg:

MAL19950686AZ

Manufacturer

Patheon France S.A.
40, boulevard de Champaret
38300 Bourgoin-Jallieu,
France.

Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.
Unit TB-18-1, Level 18-1, Tower B,
Plaza 33, No.1 Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of revision

06/03/2017

(CCDS V4 / based on UK SmPC
Nov2013).

Serial Number:

BPFK(R4/1)060317/00013