

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**CLOMILEN 50 mg tablets**  
Clomiphene citrate

**Read all of this leaflet carefully before you start taking this medicine**

- 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 other. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**In this leaflet:**

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

**1. WHAT IS CLOMILEN AND WHAT IS IT USED FOR**

Clomilen consists in a sexual hormone called Clomiphene citrate. Clomiphene citrate is a substance that stimulates ovulation and belongs to a group of medicines called Selective Oestrogen Receptor Modulator (substance that modifies the effect of female sex hormones).

Clomilen is used to stimulate the release of eggs from the ovary (ovulation) in women who would like to get pregnant.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLOMILEN**

**Do not take Clomilen:**

- If you are allergic to the active substance or any other ingredient of this medicine (listed in Section 6 below).
- If you are pregnant.
- If you have liver function disorders.
- If you have unusual menstrual bleeding.
- If you have a cyst on your ovary (cavities filled with liquid in the ovaries).
- If you have an organic damage in the skull (for example pituitary tumour).
- If you have uncontrolled disorders of the thyroid or adrenal function.
- If you have oestrogens dependant neoplasms (benign or malignant tumours).
- If you have visual disorders during the treatment or if you experienced these disorders during previous treatments.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Clomilen

- In some cases, a too strong stimulation of the ovaries can occur (ovarian hyperstimulation syndrome). In that case, the administration of Clomilen should be temporarily stopped and your dose and the duration of your next treatment should be adapted. In order to detect hyperstimulation, it is important to consult your doctor in case of pelvic or stomach pains or swelling in the stomach, or weight gain. Only him/her can take the adequate measures.
- Taking Clomilen increases the risk of multiple pregnancies.

- Caution should be exercised :
  - In case of certain type of cancer
  - In case of thrombophlebitis (inflammation of a vein) and history of thrombophlebitis (obstruction of a vein).
  - In case of severe and untreated hypertension (increase in arterial pressure)
- If you are breast-feeding: Clomilen might reduce milk product; it is recommended not to breast-feed while you take Clomilen.
- If you have visual disorders (as spots or flashes). **In that case, stop the treatment and contact your doctor.**
- If you have benign excrescences in the womb (uterine fibromas), their volume might increase during the treatment with Clomilen.
- If you already had hyperlipidaemia (excess of fats in the blood) or if this has already been observed in your family and if you take high doses of Clomilen or if you are treated for a duration longer than the normal duration, you can develop hyperlipidaemia.
- If you take other medicines, read the section "Other medicines and Clomilen".

### **Other medicines and Clomilen**

Please tell your doctor or pharmacist if you take or have recently taken any other medicines.

The concomitant use of Clomilen and certain other hormones increase the risk of excessive stimulation and of multiple pregnancies.

Clomilen should be used under close monitoring of a gynaecologist.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### *Pregnancy*

Do not take this medicine if you are pregnant.

In order to avoid taking Clomilen during pregnancy, your doctor should exclude pregnancy before initiating or repeating the treatment with Clomilen.

#### *Breast-feeding*

It is recommended not to use Clomilen during breast-feeding. In some patients, a decreased in the milk production has been observed.

### **Driving and using machines**

Clomilen has a limited influence on the ability to drive or use machinery.

In some patients, visual disorders have been observed.

These disorders may be dangerous while driving or using machinery, especially in case of changing lights.

### **Clomilen contains lactose**

If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Clomilen.

## **3. HOW TO TAKE CLOMILEN**

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

Clomilen can be used only **under close monitoring of a gynaecologist** and **after excluding pregnancy**.

The recommended dose for an initial treatment is a single tablet per day during 5 days, from the fifth day of the cycle.

The efficacy of the treatment (occurrence of an ovulation) is assessed by the body temperature curve or any other adequate mean (plasma levels of progestin, ultrasound).

If no ovulation occurs, consult your doctor.

It is important to make coitus and fertility period coincide.

The examination of the uterine mucosae can be useful, especially to make ovulation and artificial insemination coincide.

Your doctor will tell how long you should take Clomilen.

An extended treatment is unadvised. If the treatment is efficient, it is generally within the 6 first cycles.

#### **If you take more Clomilen than you should**

If you take more Clomilen than you should, tell your doctor or your pharmacist.

The symptoms of an overdose are: nausea, vomiting, flushes, visual disturbances or flashes, vision of black spots, increase of the volume of the ovaries with abdominal pains (that can occur in the days that follow stopping the treatment). Weight gain and significant liquid retention in the abdomen may also be observed.

Patients of child-bearing age who have taken high doses should be monitored during 2 to 3 weeks in order to detect any increase in the ovarian volume (monitoring with ultrasound and hormones monitoring, as oestrogens).

#### **If you forgot to take Clomilen**

If you forgot 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 Clomilen**

Keep taking Clomilen 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, Clomilen can cause side effects, although not everybody gets them.

The following side effects may occur:

#### **The side effects that are generally observed with the highest doses are:**

- Increase in the volume of the ovaries, cyst, endometriosis (formation of uterine mucosae out of the uterus)
- Flushes

**Talk to your doctor** if you have stomach pains, weight gain, stomach disturbances or swelling after taking Clomilen.

### Other side effects are:

- *Visual disorders:* blurred vision, spots or flashes or consecutive images, decreased visual acuity and rarely cataract (total or partial opacification of the lens or the lens capsule) and optic neuritis (inflammation of the nerve of the eye). **Stop the treatment and consult your doctor.** These undesirable effects are generally observed after taking high doses and usually disappear a few days after stopping the treatment.
- Cramps of the retina vessels that might cause a temporary loss of vision in an eye. Modification of the retina functioning causing a vision decrease or abnormalities. Detachment of the bottom part of the vitreous body.
- *Skin reactions:* dermatitis (inflammation of the skin), rash (skin eruption), urticaria, reddening, allergic reactions, bruising, hair loss. The hair loss is very rare and reversible after stopping the treatment.
- *Nervous system disorders:* light-headedness (undetermined frequency), nervousness (nervous tension) or insomnia, tiredness, depression, sensitivity disorders (for instance, tingling, numbness, itching) and convulsions.
- *Gastro-intestinal disorders:* digestive intolerance, weight gain, hyperlipidaemia (excess of fats in the blood), sometimes with pancreatitis likely to be life threatening (pancreas inflammation).
- Breast tension, frequent but low quantity urination, heavy and prolonged menstrual bleeding (hypermenorrhoea), bleeding between menstrual periods and insufficient production of uterine mucous, stomach pains.

After taking Clomilen, the risk of multiple pregnancies, including intra- and extra-uterine (in and out of the uterus).

Isolated cases of occurrence or worsening of certain hormone-dependant tumours have been observed.

Increase in certain hepatic values (transaminases).

### 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 the leaflet. You can also report side effects directly via their national reporting system.

### 5. HOW TO STORE CLOMILEN

Keep out of the sight and reach of children.

Store in original container below 30 °C.

Do not use 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. CONTENT OF THE PACK AND OTHER INFORMATION

#### What Clomilen contains

- The active substance is clomiphene citrate.  
Each tablet contains 50 mg clomiphene citrate.

- The excipients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose, maize starch, pregelatinised starch, purified water, sodium starch glycolate

**What Clomilen looks like and contents of the pack**

White to off-white, round shaped, flat, bevel-edged, uncoated tablets. Scored on one side and embossed "C50" on the other. They are supplied in PVC and aluminium blister packs. Pack size 10 tablets.

**Marketing Authorisation Holder and Manufacturer**

***Product license holder***

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