

**Leaflet: Consumer/Patient Information Clomed****50 mg tablets**

Clomiphene citrate

Please read this leaflet carefully and completely before you start using this medicine as 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 only for you. You must not give it to other people. It may make them ill, even if they have the same signs of illness as you.
- If you experience any side effects, ask your doctor or pharmacist. This includes any possible side effects not mentioned in this leaflet. See section 4.

What you find in this leaflet:

1. What Clomed is and what it is used for
2. What you need to know before using Clomed
3. How to use Clomed
4. Possible side effects
5. How to store Clomed
6. Packaging contents and other information

1. What Clomed is and what it is used for

Clomed contains a medicine called clomiphene citrate. It belongs to a group of medicines called ovulation stimulants.

The effect of Clomed is to trigger egg development (so-called ovulation stimulation).

Therapeutic indications for women :

- Stimulation of egg development in the case of pituitary or ovarian disorders and after prolonged administration of oral contraceptives (which caused lack of menstrual cycle).
- Elimination of pathological increase in milk secretion (galactorea) after birth.

2. What you should know before using Clomed**Do not use Clomed:**

- if you are allergic to clomiphene or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant. You should take a pregnancy test to make sure you are not pregnant before

to use Clomed

- if you have liver disease or liver function disorders
- if you have ovarian cysts (excluding polycystic ovary syndrome) or loss of pituitary function
- if you have thyroid or adrenal gland function disorders
- if you have uterine bleeding of unknown cause or undiagnosed bleeding
- if you have recent or pre-existing visual impairment
- if you have a type of cancer that can be made worse by hormones (hormone-dependent tumours)
- if you have early menopause or have been told you are infertile.

Warnings and precautions

Before using Clomed, ask your doctor or pharmacist:

- If you stop having your period because you are underweight (have a lower than normal body weight).
- If you have or have had seizures or convulsions in the past.
- If you have uterine fibroids.
- If you have polycystic ovaries.
- If your ovaries are swollen.
- If you have hypertriglyceridaemia (excess fat in the blood) or a family history of hypertriglyceridaemia. Your doctor should check for any cause of infertility problems before starting

Clomed treatment.

Before using this medicine discuss the following risks with your doctor:

- The possibility of becoming pregnant with more than one child (multiple pregnancy).
- Pregnancy in which the baby develops outside the uterus (ectopic pregnancy).
- Increased risk of ovarian cancer.
- Ovarian hyperstimulation syndrome (excessive ovarian activity).
- Clomed may cause visual (vision) disturbances. Visual disturbances caused by Clomed are generally reversible; however, cases of prolonged visual disturbances have been reported even after cessation of treatment. Visual disturbances may be irreversible, especially with increasing doses or duration of treatment.

Any pregnancy can end in birth defects or miscarriage. This can happen even if you do not use Clomed.

Children and adolescents

This medicine should not be used in children and adolescents.

Clomed with other medicines

Tell your doctor or pharmacist if you are using, have recently used, or may use any other medicines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant, or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Do not use this medicine if you are pregnant or think you are pregnant. Before using Clomed you should take a pregnancy test to make sure you are not pregnant.

Administration during breastfeeding can only be done after careful assessment of the risk/benefit ratio by the doctor.

Clomed may reduce lactation.

Driving vehicles and operating machinery

This medicine may cause visual disturbances such as blurred vision, therefore, limitations on driving or using machinery should be assessed individually by your doctor.

Clomed contains lactose

If your doctor has advised you that you are intolerant to certain categories of carbohydrates, please ask him or her before taking this medicine.

3. How to use Clomed

Always use this medicine exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you are not sure. The recommended dose should be used once a day before a meal.

Treatment in women should always be preceded by a gynaecological examination because of the risk of adverse reactions. Clomed should only be used strictly for the established therapeutic indication and under permanent medical supervision.

In the case of infertility, the dosage and duration of treatment depend on the sensitivity (ability to respond) of the ovaries.

In the case of regular periods, it is recommended to start treatment on the 5th day of the menstrual cycle (or on the 3rd day of the cycle in the case of early ovulation/follicular phase shorter than 12 days). If you do not have menstrual cycles, treatment can be started at any time.

Scheme No. 1: 50 mg/day over a period of 5 days, meanwhile

the development of the egg must be monitored by clinical examinations and laboratory investigations. Egg development (ovulation) usually occurs between the 11th and 15th day of the menstrual cycle.

If there is no development of the egg by applying this treatment, Scheme 2 is applied.

Schedule 2: daily doses of 100 mg should be taken over a period of 5 days starting on the 5th day of the next menstrual cycle. If no egg development occurs after this treatment, the same schedule (100 mg/day) can be repeated. If the lack of ovulation persists, a 3-month treatment can be repeated after a 3-month break. Further treatment is unnecessary.

You should not increase the dose above 100 mg/day or the duration of treatment beyond 5 days.

Treatment should be started at low doses (25mg/day) if ovarian cysts (so-called polycystic ovarian syndrome) develop.

In case of absence of post-contraceptive menstrual cycle, a daily dose of 50 mg should be administered; therapeutic effects usually appear on the fifth day of treatment, even if schedule 1 is applied.

This medicine should not be given to women who are menopausal (post-menopausal).

Use in children and adolescents

This medicine should not be given to children and adolescents.

If you use more Clomed than you should

If you use more Clomed than you should, seek medical advice or go to a hospital emergency department immediately. Take the medicine pack with you. You must do this so that the doctor knows which medicine you have used. You may cause hyperstimulation of your ovary (see section 4 below).

Symptoms observed after using more tablets than necessary are: nausea, vomiting, flushing of the face, sweating, visual disturbances (blurred vision, bright spots, gaps in the visual field), increased size of the ovaries with pelvic or abdominal pain.

In case of an overdose, it is recommended to remove the active substance and administer supportive treatment. Notify your doctor immediately in case of an overdose.

If you forget to use Clomed

If you miss a dose, talk to your doctor as you may need to change your course of treatment. Do not take a double dose to

compensate for the forgotten tablet. Continue treatment in the same way and doses as prescribed. If you use this medicine irregularly compared to how it was prescribed then the expected effect may not be achieved.

If you stop using Clomed

In women the drug is taken for 5 days during menstruation. If you stop taking before the expected therapeutic effect will not be achieved.

If you have any further questions about this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this drug can cause side effects, although they do not occur in all people.

Stop using Clomed tablets and tell your doctor or go to hospital immediately if:

- You have an allergic reaction. Symptoms may include: a fleeting rash on the skin, trouble swallowing or breathing, swelling of the lips, face, throat or tongue (angioedema).
- You have numbness, weakness or paralysis on one side of the body, slurred speech, sudden blurred vision, confusion or change. These may be signs of a stroke brain.
- You are pregnant and have vaginal bleeding and abdominal pain. These could be signs of an ectopic pregnancy (see 2 above).

The frequency of the adverse reactions mentioned above is not known (cannot be estimated from available data).

Stop taking Clomed tablets and see your doctor immediately if you experience any of the following serious side effects - you may need urgent medical treatment:

Frequent (can affect up to 1 in 10 people)

- Blurred vision, spots or bright spots in the eyes after images. These symptoms generally improve but in some cases they may be permanent. Your doctor may ask for an eye examination.

Frequency unknown (cannot be estimated from available data)

- Ovarian hyperstimulation. This can lead to pelvic, abdominal or calf pain, swelling or bloating, decreased urinary volume, shortness of breath or weight gain. If these symptoms occur your doctor

will lower your dose of Clomed.

- Liver problems that can cause yellowing of the eyes or skin (jaundice).
- Unexpected and severe headaches.
- Mental disorders such as "paranoid psychoses".

Tell your doctor or pharmacist if any of the following side effects become serious or last for more than a few days:

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

- Reddening of the skin
- Pain or discomfort in the lower abdomen, weight gain, oedema. This may be a sign of ovarian growth.

Frequent (can affect up to 1 in 10 people)

- Feeling or feeling sick
- Increased intensity of menstrual pain, heavy bleeding or bleeding between periods
- Breast pain
- Headaches
- Feeling bloated and swollen

Less common (may affect up to 1 in 100 people)

- Nervous tension more pronounced than normal
- Balance problems or dizziness (lightheadedness)
- Tiredness or sleep problems (insomnia)
- State of depression

Rare (may affect up to 1 in 1000 people)

- Seizures
- Dark parts of the eye (cataracts)
- Impaired vision, pain in the eyes and difficulty distinguishing some colours (optic neuritis)

Very rare (may affect up to 1 in 10,000 people)

- Hair loss or thinning

Frequency unknown (frequency cannot be estimated from available data)

- Pain in the lower stomach, weight gain, oedema. This may be a sign of endometriosis (when the lining cells inside the uterus are found in other parts of the body, for example in the muscles of the uterus) or

its worsening and ovarian cancer

- Increased ovarian growth
- Multiple pregnancies, e.g. twins
- Levels increased by fats in blood (hypertriglyceridaemia)

- Pain in the upper middle or upper left part of the abdomen. This could be a sign of inflammation of the pancreas (pancreatitis), which can be caused by an increased level of fat in the blood
- Rapid or irregular heartbeat
- Palpitations
- Skin sores on the legs, arms, palms, hands, soles and inside the mouth (erythema polymorph)
- Vision disorders
- Feeling faint or loss of consciousness
- Feeling disoriented and speech problems
- A fleeting skin rash or itching
- Bruising
- Swelling of the face, around the eyes, lips or tongue
- Abnormal liver function test values
- Endocrine tumours or hormone-dependent tumours
- Increased liver enzyme values revealed by blood tests. This may mean that your liver is not working properly.
- Numbness or tingling in the skin (paresthesia)
- State of anxiety
- Change in mood or behaviour

The sensation of heat waves observed during treatment disappears after treatment is stopped. Especially in rare diseases (so-called Stein-Leventhal) cystic ovarian enlargement may occur. Your doctor may ask to check your body temperature and depending on the results may decide when to stop treatment. The possibility of

twin pregnancies and ectopic pregnancies is higher in women treated with clomiphene than in the normal population. There have been rare cases of ovarian cancer following the use of fertility drugs. Some studies suggest that prolonged treatment with clomiphene may increase this risk. It is therefore recommended that the recommended treatment period should not be exceeded.

Reporting adverse reactions

If you experience any side effects, ask your doctor or pharmacist. This includes any possible side effects not mentioned in this leaflet. You can also report adverse reactions directly through the national reporting system, details of which are published on the website of the Medicines and Medical Devices Agency: www.amdm.gov.md or e-mail: pharmacovigilenta@amdm.gov.md

By reporting adverse reactions, you can help provide additional information on the safety of this medicine.

5. How to store Clomed

Store at temperatures below 25°C in original packaging.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date written on the label or box after EXP.

The expiry date refers to the last day of the month in question. Do not use this medicine if you notice discolouration of the tablets.

Do not dispose of any medicine in water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Clomed contains

- *The active substance* is clomiphene citrate. Each tablet contains clomiphene citrate 50 mg.
- *The other ingredients* are: magnesium stearate, stearic acid, gelatin, talc, potato starch, lactose monohydrate (100 mg).

What Clomed looks like and what it contains Square tablets, with flat surfaces and chamfered edges, white or almost white in colour, marked on one side with 'B' and 'P' on one side and a dividing line on the other. Box of 1 Al/PVC blister pack of 10 or 20 tablets/box of 3 Al/PVC blister packs of 20 tablets together with user leaflet.

Owner certificate by registration and manufacturer

Holder of the registration certificate

SC Balkan Pharmaceuticals SRL,
7/A Industrial Street, MD-2091, or. Singera,
Republic of Moldova

Manufacturer

SC Balkan Pharmaceuticals SRL,
7/A Industrial Street, MD-2091, or. Singera,
Republic of Moldova

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Detailed information on this medicine is available on the Medicines Agency website and Medical Devices (AMDM) <http://nomenclator.amdm.gov.md/>