

PATIENT INFORMATION LEAFLET

Ovafin Tablet 50mg:

Each tablet contains:

Clomiphene Citrate (USP).....50 mg

Read this entire 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 any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT OVAFIN IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Ovulation stimulants, ATC code: G03BG02

Ovafin 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).

Ovafin (Clomiphene Citrate USP) is indicated for the treatment of ovulatory failure in women desiring pregnancy. Ovafin is indicated only for patients in whom ovulatory dysfunction is demonstrated. Other causes of infertility must be excluded or adequately treated before giving Ovafin.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OVAFIN

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

Do not take Ovafin if:

- You are allergic (hypersensitive) to Clomiphene or any of the other ingredients. Signs 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 on your ovary.
- You are pregnant. You should have a test to make sure you are not pregnant before you take Ovafin.
- Any pregnancy could lead to birth defects or miscarriage. This can happen even if you are not taking Ovafin. You should talk to your doctor about the possible risks before you take Ovafin.
- You have had vision disorders diagnosed by your doctor as being associated with the use of Ovafin (during treatment, or during a previous treatment).

Warnings and precautions

Talk to your doctor or pharmacist 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 had fits or seizures in the past.
- You have 'fibroids' in your womb.
- You have 'polycystic' ovaries.
- Your ovaries are swollen.
- 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 Ovafin.

Other medicines and Ovafin

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 Ovafin can affect the way some other medicines work. Also some medicines can affect the way Ovafin 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 breast-feeding or planning to breast-feed. Ovafin 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.

3. HOW TO TAKE OVAFIN

Always take Ovafin 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 (post-menopausal).

If you take more Ovafin than you should

If you take more Ovafin 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).

If you forget to take Ovafin

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 Ovafin

Keep taking Ovafin 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, Ovafin can cause side effects, although not everybody gets them. Adverse effects appeared to be dose-related, occurring more frequently at the higher dose and with the longer courses of treatment used in investigational studies. At recommended dosage, adverse effects are not prominent and infrequently interfere with treatment.

During the investigational studies, the more commonly reported adverse effects included ovarian enlargement (13.6%), vasomotor flushes (10.4%), abdominal-pelvic discomfort (distention, bloating) (5.5%), nausea and vomiting (2.2%), breast discomfort (2.1%), visual symptoms (1.5%), headache (1.3%) and intermenstrual spotting or menorrhagia (1.3%).

Stop taking Ovafin and see your doctor or 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). 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. (frequency not known)
- Hair thinning (alopecia) has been reported very rarely.
- 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.
- Rare instances of massive ovarian enlargement are recorded. Over-stimulation of the ovary. This can lead to pain in the pelvis, stomach or calves, 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 Ovafin.
- 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. Increase in incidence with increasing total dose. There are rare reports of cataracts and optic neuritis. Your doctor may send you for an eye examination.
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Convulsions have been reported; patients with a history of seizures may be predisposed, transient paraesthesia (frequency not known), dizziness (frequency not known). In investigational patients, CNS symptoms/signs, conditions of dizziness, light-headedness/vertigo (0.9%), nervous tension/insomnia (0.8%) and fatigue/depression (0.7%) were reported. After prescription availability, there were isolated additional reports of these conditions and also reports of other conditions such as syncope/fainting, cerebrovascular accident, cerebral thrombosis, psychotic reactions including paranoid psychosis, neurologic impairment, disorientation and speech disturbance.
- Isolated reports have been received on the occurrence of endocrine-related or dependent neoplasms or their aggravation.
- Mental illness such as 'psychosis' (frequency not known)

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. In some cases 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 behavior
- Rapid or irregular heartbeat
- Skin rash or itching
- Feeling or being sick, Speech problems, 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 and 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 or pharmacist. You can also report side effects via Website: <https://aspin.com.pk/drug-safety/>. Or to DRAP through MED Vigilance E-Reporting System of DRAP available online at <https://primary-reporting.who-umc.org/PK>.

PHARMACEUTICAL INFORMATION

Shelf life

2 years

5. HOW TO STORE

- As prescribed by the physician.
- Store below 30°C.

- Protect from light and moisture.

- Keep out of the sight and reach of children.

- Product contains lactose.

ہدایات :

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

دوا کو روشنی اور نمی سے بچائیں۔ بچوں کی نظر اور پہنچ سے دور رکھیں۔
اس دوا میں لکٹوز ہے۔

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ovafin contains

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

The other ingredients are Lactose monohydrate 200 Mesh, Maize starch, Croscarmellose sodium, Magnesium stearate.

What Ovafin looks like and contents of the pack

White colour, round shape tablet with both sides plain.

Ovafin (Clomiphene Citrate) 50 mg tablets are available in a blister pack of 10's (1 x 10's).

MANUFACTURED BY:



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