

OVA-MIT TABLET

Clomifene citrate (50 mg)

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What Ova-mit is used for

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

How Ova-mit works

Ova-mit 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).

Before you use Ova-mit

- When you must not use it

Do not take this medicine if any of the following apply to you:

- you are allergic (hypersensitive) to clomifene or any of the other ingredients of this medicine (listed in section 8).

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

- if you are having an early menopause or have been told you are infertile.

- if you have or ever had liver disease.
- if you have unusual menstrual bleeding where the cause is not known.
- if you have a type of cancer that is made worse by hormones.
- if you have a cyst on your ovary.
- if you are pregnant. You should have a test to make sure you are not pregnant before you take Ova-mit.
- 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.

- Before you start to use it

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).
- 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 Ova-mit. You should talk to your doctor about the possible risks before you take Ova-mit.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Ova-mit can affect the way some other medicines work. Also some medicines can affect the way Ova-mit works.

How to use Ova-mit

- How much to use

Adult women only:

This medicine should not be taken by children, adolescents and women who have already gone through the menopause (postmenopausal).

- When to use it

Ova-mit should be taken in case you are not ovulating properly, as described in section 'What Ova-mit is used for'.

- How long to use it

Keep taking Ova-mit until your doctor tells you to stop. If you stop, the treatment may not work.

- 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 Ova-mit than you should, contact your doctor immediately or go to the Emergency Department of your nearest hospital. Take the medicine pack with you. This is so the doctor knows what you have

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taken. You are likely to get over-stimulation of your ovary.

While you are using it

- Things you must do

- 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.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

Talk to your doctor or pharmacist before taking Ova-mit.

- if you have had fits or seizures in the past.
- if you have “fibroids” in your womb.
- if you have ‘polycystic’ ovaries.
- if your ovaries are swollen.
- if 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 Ova-mit.

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

- Things to be careful of

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.

- 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. Ova-mit can lower the amount of milk produced.

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.

Ova-mit contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Ova-mit contains ponceau 4R, cochineal red A aluminium lake E124
It may cause allergic reactions.

Side effects

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

Stop taking Ova-mit 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 lips, face, 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 Ova-mit and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Common

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.

Unknown

- 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 Ova-mit.

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- 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:

Very common

- 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

- feeling or being sick.
- increased pain with periods, heavy periods or bleeding between periods.
- painful breasts.
- headaches.
- feeling bloated and distended.

Uncommon

- 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

- fits.
- cloudy lenses in the eye (cataracts).
- reduced vision, pain in the eyes and difficulty to see some colours (optic neuritis).

Not known

- 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).
- problems with your eyesight.
- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects To medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Ova-mit

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C. Protect from light and moisture.

- 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

Light orange, round, flat scored tablets with Remedica’s logo on one side.

- Ingredients

- Active ingredient
Each tablet contains 50 mg clomifene citrate.

- Inactive ingredients
Povidone, cellulose microcrystalline, lactose monohydrate, maize starch, starch pregelatinised, silica colloidal anhydrous, magnesium stearate, talc, quinoline yellow aluminium lake E104, ponceau 4R, cochineal red A aluminium lake E124.

- MAL number

MAL19870690AZ

Manufacturer

Remedica Ltd
Aharon Str.,

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Clomifene citrate (50 mg)

Limassol Industrial Estate,
3056 Limassol, Cyprus

Product registration holder

Eucogen Sdn. Bhd.,
No. 6A, Jalan Sungai Burung U 32/U,
Bukit Rimau, Seksyen 32, 40460
Shah Alam.

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19/01/2023

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