

SEROPHENE®

Clomiphene citrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SEROPHENE.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SEROPHENE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this information with the medicine.

You may want to read it again later.

What SEROPHENE is used for

SEROPHENE is a medicine containing clomiphene citrate. It is used to stimulate the development of ovarian follicles when normal ovulation does not occur.

How does SEROPHENE work?

SEROPHENE appears to work by increasing the output of the hormones FSH (follicle-stimulating hormone) and LH (luteinizing hormone), which stimulate the ovary to cause follicle growth so that an egg may be released at mid-cycle.

SEROPHENE is only available on prescription from your doctor.

SEROPHENE is not addictive. This medicine does not interfere with your ability to drive a car or operate machinery.

Your doctor may have prescribed SEROPHENE for another reason. Ask your doctor if you have any questions about why SEROPHENE has been prescribed for you.

Before you take SEROPHENE

When you must not take it

Do not take SEROPHENE if:

- you are pregnant
- you are breastfeeding
- you have liver disease or a history of liver disease
- you have abnormal menstruation or vaginal bleeding
- you have enlarged ovaries or ovarian cysts not due to polycystic ovary disease
- you are suffering from depression
- you have a blood clot
- you have problems with your eyesight
- you have uncontrolled thyroid disease
- you have problems with your adrenal gland
- you have a pituitary tumour
- you have hormone-dependent tumours.

Do not take SEROPHENE if you are allergic to it or any of the ingredients listed at the end of this leaflet.

SEROPHENE should not be taken by children or the elderly.

Do not take this medicine after the expiry date (EXP) printed on the carton.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take SEROPHENE if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking SEROPHENE, consult your doctor.

Before you start to take it

Tell your doctor if you have had a previous allergic reaction to SEROPHENE or to any other medicines.

SEROPHENE contains lactose. Please tell your doctor if you are sensitive to lactose.

Tell your doctor if you have any other conditions relating to your ovaries or cervix.

If you have not told your doctor about any of the above, tell him/her before you take SEROPHENE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Based on experience, SEROPHENE has not been shown to interfere with the actions of other medicines. Discuss any medicines you may be taking with your doctor.

How to take SEROPHENE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will decide on the best dose for you. Follow the instructions given to you by your doctor.

The usual dose is 1 tablet every day for 5 days. If your doctor does not think that ovulation has occurred after taking this course, he/she may advise you to take 2 tablets each day for 5 days.

Do not take more than 2 tablets each day for 5 days.

How to take it

Take your tablets with a glass of water. If your doctor has told you to take 2 tablets a day, take the tablets together and not at different times of the day.

When to take it

There is no specific time when SEROPHENE tablets should be taken. However, you should try to take the tablets at the same time each day.

How long to take it

SEROPHENE tablets are usually taken for 5 days. It is possible to have more than one treatment cycle of SEROPHENE. However, if you do not fall pregnant after 3 treatment cycles, further treatment is not usually recommended.

If you forget to take it

If you miss a dose tell your doctor and he/she will advise you of the best thing to do given your own special case.

Do not try to make up for missed doses by taking more than one dose at a time.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately contact your doctor or the Poisons Information Centre (in Australia telephone 13 11 26, in New Zealand telephone 0800 764 766) if you are concerned that you have used too much SEROPHENE.

While you are taking SEROPHENE

You may need additional examinations or tests while you are taking SEROPHENE.

Your doctor will advise you of any tests he/she will use while you are taking the medicine.

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using SEROPHENE.

If you plan to have surgery, tell your doctor or dentist that you are using SEROPHENE.

Tell all the doctors, dentists and pharmacists who are treating you that you are using SEROPHENE.

Things you must not do

Do not stop taking SEROPHENE without telling your doctor.

Do not change your dose unless your doctor tells you to. Changing your dose without advising your doctor can increase your risk of unwanted side effects or prevent the medicine from working properly.

Do not give SEROPHENE to any one else, even if their symptoms seem similar to yours or they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SEROPHENE.

SEROPHENE helps most people but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- facial flushes
- mild abdominal pain
- tender breasts
- nervousness
- sleeplessness
- headache
- dizziness
- light-headedness
- increase in amount of urine you pass
- depression
- tiredness
- rash
- skin allergies
- abnormal vaginal bleeding
- weight gain
- hair loss.

Tell your doctor immediately if you notice the following:

- blurred vision

You will need an eye examination. Blurred and other eye problems may increase the dangers of driving and/or increase the dangers of operating machinery.

Tell your doctor immediately or go to the Accident and Emergency section of your nearest hospital if you experience any of the following together:

- severe pain or swelling in your abdomen
- nausea
- vomiting.

You may have hyperstimulation of the ovaries, known as ovarian hyperstimulation syndrome (OHSS). This is a rare but potentially serious side effect of infertility treatment. Without proper hospital management, this condition may even be fatal but this is extremely rare.

In very rare cases a blood clot may form. This will usually be associated with severe ovarian hyperstimulation syndrome (OHSS).

Women taking SEROPHENE may have more than one baby in the same pregnancy. This may affect the outcome of the pregnancy and the health of the newborn babies. As with any pregnancy, complications may occur such as ectopic pregnancy (a pregnancy with the baby outside the womb), miscarriage, stillbirth and birth defects.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking SEROPHENE

Storage

Store your medicine in a cool dry place away from light where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking SEROPHENE or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

SEROPHENE is a white tablet with a score mark on it.

Ingredients

Each tablet of SEROPHENE contains 50 mg of clomiphene citrate as the active ingredient.

Inactive ingredients are:

- lactose
- sodium starch glycollate
- starch
- microcrystalline cellulose

- silica-colloidal anhydrous
- magnesium stearate.

It is available in packs of 10 tablets.

SEROPHENE can be identified by the Australian Registration Number AUST R 56755 that can be found on the carton.

Supplier

SEROPHENE is supplied in Australia by:

Merck Serono Australia Pty Ltd
3-4/25 Frenchs Forest Road
Frenchs Forest 2086

For enquiries call: 1800 633 463

SEROPHENE is supplied in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland

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