



MEDLEY PHARMACEUTICALS

SERMED

(Clomiphene Citrate)

50mg Tablets

WHAT IS IT LEAFLET?

This leaflet answers some common questions about Sermed. It does not contain all the available information. It does not take the place of talking to your doctor. All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sermed against the benefits he/she expects it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

WHAT IS SERMED FOR IT?

About 20% of couples, who experience difficulty in conceiving, do so because the woman's ovaries are not producing and releasing an egg each menstrual cycle (an ovulation). Your doctor has prescribed Sermed. To treat this. Sermed acts by causing a gland in the brain (the anterior pituitary) to release hormones which stimulate ovulation. It must be remembered that there are many causes of an ovulation, so Sermed may not be effective in all cases. When taking Sermed there should be 28-32 days from the beginning of on period to the next. Your ovaries should release an egg 6-12 days after a course of. Sermed You should have intercourse around this time to maximize your chances of conception. If your period does not arrive after the 35th day there are two likely possibilities: • the dose of Sermed has not been sufficient to produce ovulation, or • you are pregnant If your period is overdue, contact your doctor/fertility unit and they will advise you what steps to take. This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE SERMED:

Your doctor will perform a pelvic examination on you before you begin to take Sermed. This is to check that you have no physical conditions which may stop you falling pregnant or which might indicate that Sermed is not a suitable drug for you.

WHEN YOU MUST NOT TAKE IT:

Do not take Sermed if you have an allergy to Sermed or any of the ingredients listed at the end of this leaflet. Do not take Sermed if you are pregnant like most fertility medicines, Sermed should not be taken



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during pregnancy. To avoid inadvertently taking Sermed during early pregnancy, you should perform tests during each treatment cycle to determine whether ovulation occurs. You should have a pregnancy test before the next course of Sermed therapy. Do not take Sermed if you have any of the following conditions:

- Liver disease or a history of liver problems
- Hormone-dependent tumors
- Abnormal uterine bleeding of undetermined origin
- Ovarian cysts, with the exception of polycystic ovary do not take Sermed after the expiry date (EXP) printed on the pack. If you take this medicine after the expiry date has passed, it may not work as well. Do not take Sermed if the packaging is torn or shows signs of tampering. If you are not sure whether you should start taking Sermed, contact your doctor or pharmacist.

BEFORE YOU START TO TAKE IT:

Tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- any other substances, such as foods, preservatives or dyes Tell your doctor or pharmacist if you have pre-existing or a family history of hyperlipidemia (high cholesterol levels) or hypertriglyceridemia (high triglyceride levels in blood). Tell your doctor or pharmacist if you are breast-feeding. Like most fertility medicines, Sermed is not recommended while you are breast-feeding. The chances of multiple pregnancies are higher when you use Sermed. You should be aware of the potential complications of multiple pregnancy before taking Sermed Discuss this with your doctor

How TO TAKE SERMED:

Packaging Fold the blister package of 10 tablets in half lengthwise so that the 5 tablets on each side of the platform 'face' one another. This will perforate the backing foil along the middle of the platform. To remove a tablet from the platform, peel the backing foil from the middle of the platform towards the outer edge. How much to take the recommended dose for the first course of Sermed is one tablet per day for five days at the beginning of your cycle. If ovulation does not occur, your doctor may advise you to increase the dose of Sermed in subsequent treatment cycles. Do not take an increased dose unless instructed to do so by your doctor. Taking more than your doctor prescribes may over stimulate your ovaries, possibly damaging your ovaries and endangering your health. Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.



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When to take it your doctor will advise you on which day of your cycle to begin to take Sermed. If you do not have regular periods your doctor may prescribe other tablets eg. Norethisterone for a number of days, after which a period may start. Use this bleeding to time your Sermed course. Take Sermed at about the same time each day. This will help you remember when to take the tablets. How long to use it Sermed tablets are usually taken daily for five consecutive days at the beginning of your cycle. Your doctor will advise you on how many courses of Sermed, you should take. Long term therapy with Sermed is not recommended. Your doctor will tell you for how long you should take Sermed. If you forget to take it does not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints. If you take too much (overdose) immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Sermed. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Sermed Progress Checks It will be necessary to monitor your response to Sermed. Methods used to do this include:

- Basal body temperature chart
- Urine testing
- Blood tests
- Mucus testing

The most appropriate method for you will be discussed by your doctor. While you are using Sermed Things you must not do not give Sermed to anyone else, even if they have the same condition as you. Do not use Sermed to treat any other complaints unless your doctor tells you to. Things to be careful of be careful driving or operating machinery until you know how Sermed affects you. Sermed may cause visual disturbances in some people. Make sure you know how you react to Sermed before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or have blurred vision. Side effects tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sermed. Sermed helps many people with infertility, 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

SIDE EFFECTS:

Tell your doctor or pharmacist if you notice any of the following:

- hot flushes • intermenstrual ("between period") spotting or heavy menstrual periods • nausea or vomiting • breast discomfort • headache • insomnia, nervousness, depression, fatigue, dizziness or



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light-headedness • rash or skin irritations • increased frequency of urination • hair loss • fever • vaginal discharge • seizures • visual problems • increased heart rate • palpitations If any of the following happen, stop taking Sermed and tell your doctor or pharmacist immediately: • blurred vision, spots or flashes • abdominal discomfort or pelvic pain, soreness or a "bloated" feeling • weight gain The chances of ectopic pregnancies (fetus growing outside the womb) are higher if you conceive on Sermed. Sermed may cause uterine fibroids to grow in size. Prolonged Sermed use may be associated with a small increase in the risk of ovarian cancer. Hypertriglyceridemia (high triglyceride levels in blood) has been observed in patients who have pre-existing or a family history of hypertriglyceridemia.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything 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 using Sermed Storage Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they will not keep well. Keep your tablets in a cool dry place where the temperature stays below 25°C. Do not store Sermed or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills. Heat and dampness can destroy some medicines. Keep it where children cannot reach it. A locked cupboard at least one-half meters above the ground is a good place to store medicines. Disposal if your doctor or pharmacist tells you to stop taking Sermed or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

HOW SUPPLIED:

Sermed (Clomiphene citrate) Tablets 50mg: Alu Alu pack of 10's packing.

STORAGE:

Store below 30°C.

Protect from sunlight and moisture.

The expiration date refers to the product correctly stored in the required conditions.

Keep out of reach of children.

To be sold on prescription of a registered medical Practitioner only.

Please read the contents carefully before use.

This package insert is continually updated from time to time



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