

SUNOLUT TABLET

Norethisterone (5mg)

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What Sunolut Tablet is used for

Low dose for:-

- abnormal uterine bleeding
- short menstrual period
- menstrual periods with abnormally heavy or prolonged bleeding uterus disorder
- bleeding or perforation of blood vessels
- perimenopause syndrome
- postpone menstrual period

High dose for:

- breast cancer treatment

How Sunolut Tablet works

The active ingredient in this medicine is norethisterone. Norethisterone is synthetic progesterone hormone. It is a female sex hormone that regulates the progesterone hormone imbalance which lead to irregular or heavy menstrual bleeding.

Before you use Sunolut Tablet

- When you must not use it

Do not use Sunolut Tablet if:-

- You have hypersensitivity to norethisterone or any ingredients in this product listed at the end of this leaflet.
- You have or past history of have clotting in any blood vessel or stroke.
- You have or suspected for breast cancer.
- You have abnormal vaginal bleeding, the cause of which is unknown.
- You have missed miscarriage.

- Before you start to use it

You should check with your doctor if you have the following :-

- Liver problem
- Diabetes
- Seizure
- Migraine
- Asthma
- Heart or kidney problem

Pregnancy and breastfeeding

Please consult your doctor before start to use Sunolut Tablet if you are pregnant, plan to become pregnant, breastfeeding. Your doctor will have weighed the risks of you taking Sunolut Tablet against the benefits they expect it will have for you.

The use of norethisterone during the first four months of pregnancy is not recommended. Norethisterone may interfere with lactation by decreasing the quantity and quality of breast milk.

- Taking other medicines

Some medicines and Sunolut Tablet may interfere with each other. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- Antibiotic to treat bacterial infection (such as rifampicin, isoniazid, ampicillin, tetracycline, neomycin, penicillin, chloramphenicol, sulphonamides, nitrofurantoin).
- Barbiturates, tranquillizers and hypnotics.
- Medicines for seizure such as phenytoin, primidone.
- Anti- histamine, treatment for allergy.
- Oral anticoagulants, medicine to prevent blood clot.
- Pain killer.
- Medicines for migraine
- Tricyclic, anti-depressants.
- Vitamins.
- Medicines for diabetes.
- Theophylline, medicine for asthma.

How to use Sunolut Tablet

- How much to use

You should take Sunolut Tablet exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Low dose:

For abnormal uterine bleeding, menstrual periods with short cycle, abnormally heavy or prolonged bleeding and bleeding or perforation of blood vessels, take 1 tablet three times daily for 10 days. Take one tablet twice daily starting from day 19 to 26 after your last period to prevent bleeding.

Endometriosis treatment: Take 1 tablet three times daily for a minimum of 6 months. If spotting occurs increase dose to 4 or 5 tablets a day. The dose should be reduce to initial quantity once bleeding has stopped.

Postpone menstrual period: Take 1 tablet three times daily starting three days before the period starts.

Perimenopause syndrome treatment: 1 tablet daily from days 16 to 25 of the menstrual period cycle.

High dose:

The initial dose is 8 tablets per day and increase to 12 tablets if there is no regression.

- When to use it

Take Sunolut Tablet when needed and according to your doctor's prescription.

- How long to use it

It is important to take Sunolut Tablet as long as your doctor prescribes. Duration of this treatment may be continue for six to nine months or when breakthrough bleeding problems persist.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose likely such as nausea, vomiting, breast enlargement and vaginal bleeding.

While you are using it

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Sunolut Tablet.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.

- Do not give Sunolut Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how Sunolut Tablet affects you.

Side effects

Like all medicines, Sunolut Tablet can cause side effects, although not everybody gets them. Side effects include breakthrough bleeding, change in menstrual flow, swelling due to water retention, changes in weight, changes in vaginal discharge, jaundice (yellowing of the skin and whites of your eye), rashes on the skin, skin hyperpigmentation, nausea, headache, and visual disturbance.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other side effects while taking this medication.

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

Storage and disposal of Sunolut Tablet

- Storage

Store at or below 30°C.

- 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

Round, white, convex, plain tablet with single score on one side and “SW” debossed on other side.

- Ingredient(s)

- Active Ingredient
Norethisterone

- Inactive Ingredients

- Lactose
- Starch
- Magnesium Stearate
- Polyvinylpyrrolidone
- Isopropyl Alcohol
- Deionised Water

- MAL number

MAL19871925AZ

MAL20051305ASZ

Manufacturer

(MAL19871925AZ)

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4, Taman
Perindustrian Tampoi Indah, 81200
Johor Bahru, Johor, Malaysia.

(MAL20051305ASZ)

Sunward Pharmaceutical Pte.Ltd
No.11,Wan Lee Road
627943, Singapore.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
No. 9,11 & 17, Jalan Kempas 4, Taman
Perindustrian Tampoi Indah, 81200
Johor Bahru, Johor, Malaysia.

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