RAVIMED TABLET

Medroxyprogesterone Acetate (5mg)

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What RAVIMED TABLET is used for

RAVIMED TABLET is used to treat the following conditions:

- Endometriosis (abnormal growth of tissue layer outside uterus)
- Secondary amenorrhoea (absence of menstrual bleeding for three months in the absence of pregnancy).
- Abnormal uterine bleeding
- Adjunct to hormone estrogen therapy

How RAVIMED TABLET works

RAVIMED contains a progestogen that comes from progesterone, a natural sex hormone.

Medroxyprogesterone acetate helps to re-establish a regular menstrual cycle.

Before you use RAVIMED TABLET

- When you must not use it
Do not take RAVIMED
TABLET if you have an
allergy to
medroxyprogesterone acetate
or to any of the ingredients
listed at the end of this leaflet.

Do not use RAVIMED TABLET if you have had any of the following medical conditions unless advised otherwise by your doctor:

- A blood clotting disorder
- Liver problems
- Unusual or irregular vaginal bleeding
- Any lumps in your breast
- Any bleeding or discharge from your nipples
- Severe uncontrolled high blood pressure
- Blood in your urine
- Missed abortion

- <u>Before you start to use it</u>
Before taking RAVIMED
TABLET, you must tell your
doctor or pharmacist if you
have, or have had, any of the
following conditions:

- Heart problems
- Kidney problems
- Migraine
- Epilepsy (fits)
- Asthma
- Diabetes
- Depression
- Allergic to any other medicines or any other substances, such as foods preservatives or dyes.

Pregnancy

RAVIMED TABLETS are not to be used as a test for pregnancy or where pregnancy is suspected.

Taking other medicines Inform your doctor pharmacist before taking RAVIMED TABLET. Before using RAVIMED TABLET, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

How to use RAVIMED TABLET

- How much to use

Follow the instructions carefully. If you do not understand the instructions on the label, ask your doctor, or pharmacist for help.

Endometriosis

For endometriosis, starting on the first day of the menstrual cycle the dosage is 10 mg three times daily for 90 consecutive days.

Cyclic oestrogen therapy
In the adjunct of cyclic oestrogen therapy, dosage is 10 – 20 mg daily for the last 7 – 10 days of each cycle of the therapy.

Abnormal uterine bleeding

For the case of heavy or irregular bleeding, the dosage is 2.5 to 10 mg daily for 5-10 days beginning on the assumed or calculated 16th - 21st day of the cycle.

Secondary amenorrhoea

For amenorrhoea (when you are not having periods) not due to pregnancy, conjunction treatment with RAVIMED TABLET, the dose is 5-10 mg daily for 10 days started anytime during cycle or 2.5-10 mg for 5-10 days beginning on the assumed or calculated 16th to 21st day of the cycle.

Treatment should be repeated for three consecutive cycles.

- When to use it
 Take RAVIMED TABLET as
 your doctor has prescribed.
- <u>How long to use it</u>
 Continue taking RAVIMED
 TABLET as your doctor has prescribed. If symptoms persist, consult your doctor.
- If you forget to use it
 Consult your doctor or
 pharmacist on what you should
 do 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.

- <u>If you use too much</u> (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.

Some of the symptoms of overdose are as following:

- Nervousness
- Sleeping difficulty
- Fatigue
- Depression
- Dizziness
- Headache

While you are using RAVIMED TABLET

- Things you must do
- Tell all doctors and pharmacists who are treating you that you are taking RAVIMED TABLET.
- Tell your doctor immediately if you become pregnant while taking RAVIMED TABLET.

- Tell your doctor if you have sudden onset of migraine or changes in your vision while you are taking RAVIMED TABLET.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking RAVIMED TABLET.
- If you feel that RAVIMED TABLET is not helping your condition, tell your doctor.
- Things you must not do
- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give RAVIMED TABLET to anyone else, even if they have the same symptoms or condition as you.
- Do not use RAVIMED TABLET to treat any other complaints unless your doctor tells you to.
- Things to be careful of
 Do not drive a car or operate
 machinery until you know how
 Ravimed Tablet affects you.

RAVIMED TABLET may cause dizziness, drowsiness or fatigue in some people.

Some laboratory tests may be affected by the use of Medoxyprogesterone Acetate.

Side effects

Like all medicines, RAVIMED TABLET can cause side effects, although not everybody gets them. If side effects persist, do not take the medicine and refer to the doctor.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

• Serious allergic reaction

- Nervousness, sleeping difficulty, drowsiness, fatigue, depression, dizziness, headache and shaking.
- Hives, rash, acne and sweating.
- Nausea
- Breast tenderness
- Unusual changes in vaginal secretions
- High fever, weight gain

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if experience any symptoms of stroke and blood clots listed below:

- painful swelling in the arms or legs
- swollen or tender veins
- chest pain or shortness of breath

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of RAVIMED TABLET

- Storage

Store below 30°C. Protect from light. Store in a cool place. Keep out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines. These measures will help to protect the environment.

Product description

- What it looks like
- 7 mm, pink round tablet, scored on one side with 'DUO 861' marking and marking 'duo' on the other side.
- <u>Ingredients</u>
- Active ingredient:
- Medroxyprogesterone acetate
- Inactive ingredients:
- Aerosil
- Carmoisine
- Cornstarch
- Promigel
- Lactose
- Magnesium stearate
- Quinoline Yellow
- <u>MAL number</u> MAL19950156AZ

Manufacturer and Product Registration Holder

Duopharma (M) Sdn. Bhd. Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia

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