



PACKAGE LEAFLET

TARLUSAL 5 mg Tablets

Taken by mouth.

Active substance: Each tablet contains 5 mg medroxyprogesterone acetate.

Excipient(s): Lactose monohydrate (from cow's milk), talc, corn starch, sucrose, calcium stearate, mineral oil (paraffin liquid)

Read all of this PACKAGE LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet:

- 1. What TARLUSAL is and what it is used for***
- 2. What you need to know before you use TARLUSAL***
- 3. How to use TARLUSAL***
- 4. Possible side effects***
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1. WHAT TARLUSAL IS AND WHAT IT IS USED FOR

- TARLUSAL contains 5 mg medroxyprogesterone acetate in each tablet as the active substance.
- TARLUSAL is a white-colored, odorless, round-shaped tablet, smooth on both sides, and with the letter "T" written on one side. It is available in blisters containing 12 tablets.
- TARLUSAL contains medroxyprogesterone acetate, which belongs to a group of medicines called 'progestogens'. Progestogens are similar to the natural female hormone, progesterone.
- TARLUSAL is used to treat excessive secretion of estrogen (a group of hormones that play an important role in the female menstrual cycle) and, as a result, heavy or irregular menstrual bleeding and other menstrual problems, amenorrhea and endometriosis (the condition where the endometrial tissue in the womb is found outside the womb).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TARLUSAL

DO NOT TAKE TARLUSAL:

- If you are allergic to medroxyprogesterone acetate or to any of the excipients in the composition of TARLUSAL (see the list of excipients),
- If you have or had a vaginal bleeding for which your doctor cannot find the cause (except menstrual bleeding),
- If you have vascular occlusion or inflammation,
- If you have had bleeding in your brain,
- If you have severe liver problems,



- If you had been or are currently being treated for breast cancer,
- If you have genital cancer,
- If you are pregnant or might be pregnant.

Your doctor may perform a pregnancy test before or during treatment if you do not have bleeding during your menstrual period.

TAKE SPECIAL CARE WITH TARLUSAL:

- If you have an unexpected vaginal bleeding during your treatment,
- If you have migraine pain,
- If you are depressed or have a history of depression,
- If you have diabetes,
- If you have epilepsy,
- If you have asthma,
- If you have heart-related problems,
- If you have kidney failure,
- If you have sudden partial or complete vision loss or sudden onset of proptosis (protruding eyeball), double vision or migraine,
- If you or your family have a history of blood clots.

All women are at risk of developing blood clots in the veins of the legs, in the lungs or other parts of the body. The chances of getting a clot are very slightly higher if you are taking a hormone medicine like TARLUSAL. You are more likely to get a clot whether or not you are taking TARLUSAL if:

- You are very overweight
- You have had a blood clot in the veins or lungs before
- You have relatives who have had blood clots
- You are unable to move for long periods of time (for example after an operation)
- You have a serious injury or have major surgery
- You have a history of repeated miscarriage

Tell your doctor if you have just had an operation or if you are going to have an operation while taking TARLUSAL.

Please consult your doctor if these warnings apply to you, even at any time in the past.

Taking TARLUSAL with food and drink

TARLUSAL does not interact with any food or drinks.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Do not use TARLUSAL if you are pregnant or planning to become pregnant. Otherwise, TARLUSAL is expected to harm your unborn baby. Since it is not a reliable birth control method, it is important to use another birth control method (e.g. condom) while you are using TARLUSAL.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.



Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

TARLUSAL should not be used during breastfeeding. If you are breast-feeding, speak to your doctor who will advise whether you should use an alternative method of feeding your baby.

Driving and using machines

TARLUSAL has no known effect on your ability to drive and use machines.

Important information about some of the ingredients of TARLUSAL

TARLUSAL contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines

While taking TARLUSAL, tell your doctor or pharmacist, especially if you are using the following medications:

- “Aminogluthemide” used in the treatment of Cushing’s syndrome (a disorder characterized by weight gain, obesity, increased blood pressure and skin weakening resulting in stretch marks on the skin),
- Medicines for thinning the blood (e.g. warfarin).

TARLUSAL may interfere with certain tests that measure blood and hormone levels.

If you are taking or have recently taken any other medicines, including medicines obtained without prescription, please tell your doctor or pharmacist.

3. HOW TO TAKE TARLUSAL

Instructions for proper use and dose/frequency of administration

Please follow your doctor's instructions carefully. The number of tablets will depend on the condition you are being treated for. The following information will help you see what the usual dose is for a particular problem.

In endometriosis:

You will take 10 mg 3 times a day (30 mg) for 3 months (90 days) starting on the first day of your menstrual period. If you experience any irregular spotting or normal bleeding during your treatment, this is normal and nothing to worry about.

In cases of heavy or irregular menstrual bleeding and other menstrual problems:

You will usually take 2.5 mg - 10 mg for 8-10 days, after 16 days have passed since the beginning of your last menstrual period. A few days after you stop taking the tablets, you may have menstrual-like bleeding.

In the treatment of amenorrhea:

You will take 2.5 mg - 10 mg daily for 5-10 days, repeated for three periods. A few days after you stop using the tablets, you will usually have menstrual-like bleeding. In some cases, your doctor may prescribe estrogen hormone at a dose of 5-10 mg for 10 days simultaneously with TARLUSAL.

If you do not have a menstrual period after finishing a course of TARLUSAL, consult your doctor in case you are pregnant.



Method and route of administration

Tablets are taken orally.

You can use TARLUSAL before or after meals.

Swallow TARLUSAL tablets with sufficient amount of water (e.g. 1 glass of water) without chewing or crushing.

Different age groups

Use in children

It is not used in this age group.

Use in the elderly

It is not used in this age group.

Special conditions

Kidney failure

No dose adjustment is required in patients with kidney failure.

Liver failure

Your doctor will tell you how many tablets and what dosage you should take. Do not use TARLUSAL in severe liver failure.

If you have the impression that the effect of TARLUSAL is too strong or too weak, talk to your doctor or pharmacist.

If you take more TARLUSAL than you should

If you have taken more TARLUSAL than you should, consult your doctor or pharmacist.

If you forget to take TARLUSAL

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times. *Do not take a double dose to make up for a forgotten dose.*

If you stop taking TARLUSAL

Do not stop using TARLUSAL without consulting your doctor.

A few days after you stop using TARLUSAL, you will have a menstrual-like bleeding.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TARLUSAL may cause side effects in people sensitive to its ingredients.

Side effects in this package leaflet are listed in the following categories:

Very common : may affect at least 1 in 10 patients.

Common : may affect less than 1 in 10 patients but more than 1 in 100 patients.

Uncommon : may affect less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare : may affect less than 1 in 1,000 patients.

Very rare : may affect less than 1 in 10,000 patients.

Not known : may affect too few patients to be determined with the available data.

Rare

- Hypersensitivity reactions (wheezing; shortness of breath; feeling faint; swelling of the face or tongue, hands and feet; skin rash with severe itching)
- Vascular occlusion
- Deep-vein thrombosis (blood clot in the vein) (severe pain and bruising in your leg)
- Weight change, edema/fluid retention, swelling in the hands and wrists



- Depression, insomnia, irritability, headache, drowsiness, dizziness
- Nausea
- Acne, hair loss, excessive hair growth on the face or body, itching, rash, hives
- Milky discharge from the breast (galactorrhea) even though you are not pregnant, pain and tenderness in the breast
- Tiredness, fever
- Decreased glucose tolerance

Not known

- Prolonged loss of egg production in the female ovary
- Abnormal bleeding in the uterus (irregular, increasing, decreasing), absence of menstrual bleeding, erosion of the cervix and discharge from the vagina
- Blood clot in the brain (abnormal, long-lasting headache, blurred vision, difficulty speaking, or fainting)
- Blood clot in the lungs (sudden, severe pain in your chest, bloody cough)
- Jaundice

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TARLUSAL

Keep TARLUSAL out of the reach and sight of children and in its original package.

Store at room temperature below 25°C, in a dry place. Protect from light.

Use in line with the expiry date.

Do not use TARLUSAL after the expiry date, which is stated on the package.

Do not use TARLUSAL if you notice any defects in the product and/or its package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:

DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site:

DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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