

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved
PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

Estracyt® Capsules



Each capsule contains:

Estramustine Phosphate 140 mg

A list of inactive and allergenic ingredients in the preparation is in section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine has been prescribed for you. Do not pass it on to others, it may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for women and children.

1. WHAT IS THE MEDICINE INTENDED FOR?

Second-line therapy of advanced prostate cancer, when standard therapies are no longer effective.

Therapeutic group:

Estracyt® belongs to a group of medicines called cytotoxics; these medicines are used to treat cancer.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- X Do not use if you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- X Do not use if you are hypersensitive (allergic) to estradiol or to nitrogen mustard.
- X Do not use if you have an ulcer in the stomach or intestine.
- X Do not use if you have a serious heart disease.
- X Do not use if you have a serious liver disease.
- X Do not use if you have problems related to blood clotting.
- X Do not use if you are suffering from complications related to fluid retention.
- X Do not use in women and children.

Special warnings regarding use of the medicine

Do not use this medicine without consulting a doctor before starting the treatment if you are suffering, or have suffered in the past, from one or more of the following conditions:

- Low blood cell count or bone marrow function problems.
- Hypercoagulation or vein-related problems (including sore veins).
- Cerebrovascular disease (a condition which can sometimes lead to a stroke).
- Diabetes, hypertension, or liver function problems (you must be under medical surveillance during the course of treatment with this medicine).
- Epilepsy.
- High blood calcium levels (you must monitor blood calcium levels).
- Kidney function problems or fluid retention.
- Heart problems which can cause shortness of breath or ankle swelling.
- Migraines.
- If you have had or you are due to have a vaccination of any kind, **consult with the doctor** (vaccination with a live vaccine should be avoided during the course of treatment).
- If you are hypersensitive to any type of food or medicine, inform the doctor before taking this medicine.
- If you are due to undergo laboratory tests, inform the doctor, since treatment with this medicine may affect the results.

Do not use the medicine if you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- medicines which affect the central nervous system (e.g., tricyclic antidepressants), since Estracyt® may increase their levels in the blood.
- preparations containing calcium, magnesium or aluminum (e.g., medicines to relieve heartburn), since the combination may impair Estracyt® absorption (do not take the preparations simultaneously).
- medicines from the angiotensin converting enzyme inhibitors (ACE inhibitors) group for treatment of hypertension, for fear of side effects such as edema.

Use of Estracyt®, food and alcohol

The effectiveness of the medicine is impaired when taken simultaneously with foods containing calcium; therefore, do not take the medicine with milk or its products or with food containing calcium, such as: sardines, salmon or broccoli.

Pregnancy and breastfeeding

Estracyt® may cause harm to the fetus, therefore, pregnancy should be avoided during the course of treatment. You and your partner must use effective contraceptives. Consult a doctor if your partner is pregnant or breastfeeding.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions! Check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined only by the doctor.

Do not exceed the recommended dose!

Do not open and disperse the contents of the capsule! The effect of this mode of administration has not been evaluated.

It is recommended to take the medicine at the same time each day.

Tests and follow-up:

You may have to perform blood tests, tests to measure blood calcium level as well as liver function tests during the course of treatment. The doctor will tell you how often these tests should be performed.

If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the scheduled time, take a dose as soon as you remember, unless it is time for the next dose. **Never take a double dose!**

Persist with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue the treatment with the medicine without consulting a doctor.

Do not take medicines in the dark! Check the label and the dose **each time** you take your medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Estracyt® may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.

Discontinue use and refer to a doctor immediately in the event of:

A severe allergic reaction, such as: difficulty in breathing, swelling of the eyelids, face or lips, widespread rash or itching (on the whole body).

Chest pain or breathlessness.

Increasing swelling, discomfort or discoloration of one or both legs.

Very common side effects (occur in more than 1 in 10 users):

Nausea and vomiting (mostly in the first 1-2 weeks of treatment), diarrhea, liver function problems, reduced red blood cell count (anemia), reduced white blood cell count, breast enlargement in men, swelling of the legs and ankles (due to fluid build-up in the body, edema).

Common side effects (occur in up to 1 in 10 users):

Reduced platelet count (that help in blood coagulation), headaches, tiredness, heart attack, formation of blood clots.

Side effects whose frequency is not known:

Increased blood pressure, reduced sexual function, formation of blood clots at the injection sites, muscle weakness, depression, confusion, skin rash which may be accompanied by itch or burning sensation.

If any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of the indicated month.

Store the medicine at a temperature below 25°C.

After opening, the medicine can be used **within 25 days**.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Talc, sodium lauryl sulphate, silica colloidal anhydrous, magnesium stearate, gelatin, titanium dioxide, shellac, black iron oxide, ammonium hydroxide, propylene glycol.

What the medicine looks like and the contents of the pack:

Estracyt®: white, hard gelatin capsules, with the word "ESTRACYT" imprinted on the upper part and "K Ph 750" on the lower part. The capsule contains an off-white powder. The package contains 100 capsules.

Manufacturer: Pfizer Italia S.r.l., Ascoli Piceno, Italy.

License holder: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

This leaflet was checked and approved by the Ministry of Health in May 2016.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Estracyt®: 112.29.29412.00