

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Estracyt® Capsules

Estramustine phosphate 140mg
(as estramustine sodium phosphate)



Read all of this leaflet carefully before you start taking 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Estracyt is and what it is used for
2. What you need to know before you take Estracyt
3. How to take Estracyt
4. Possible side effects
5. How to store Estracyt
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1. What Estracyt is and what it is used for

Estracyt contains estramustine phosphate and is one of a group of medicines called cytotoxics; these medicines are used in the treatment of cancer.

Estracyt is used to treat cancer of the prostate gland. You should consult your doctor if you are unsure why you have been given Estracyt.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Estracyt

Do not take Estracyt if you:

- are allergic to estramustine phosphate or any of the other ingredients of this medicine (listed in section 6) or oestradiol or nitrogen mustard
- have an ulcer in the stomach or intestines
- have a serious heart disease
- have a serious liver disease
- are having problems related to blood clots
- are suffering from problems caused by fluid retention.

Estracyt is not suitable for use in children. Since Estracyt is used to treat prostate cancer in males, Estracyt is not indicated for women.

If you are unsure what this means, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Estracyt if you suffer from or have suffered in the past from any of the following conditions:

- your bone marrow is not working well, or you have been told that you have low blood cell counts
- you have had problems with blood clots or sore veins
- you have been diagnosed with cerebral vascular disease (a condition which can sometimes lead to a 'stroke')
- you have diabetes
- you have or have had high blood pressure
- you have heart problems which can cause shortness of breath or ankle swelling
- you are an epileptic.
- you have or have had a high level of calcium in your blood
- you have or have had kidney disease

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Reasons for contacting your doctor immediately

Some side effects occur rarely but can potentially be very serious.

Tell your doctor immediately if you experience:

- an allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- increasing swelling, discomfort or discolouration of one or both legs
- chest pain or breathlessness.

Very common: may affect more than 1 in 10 people

- nausea (feeling sick) and vomiting (being sick), mostly in the first 2 weeks of treatment
- diarrhoea
- abnormal liver function
- reduction in red blood cells (anaemia)
- reduction in white blood cells
- enlargement of male breasts tissue
- fluid build-up in the body, causing swollen ankles and legs.

Common: may affect up to 1 in 10 people

- reduction in number of platelets that help your blood to clot
- headache
- tiredness
- heart attack
- blood clots in your blood vessels

- you have fluid retention
- you have heart problems which can cause shortness of breath or ankle swelling
- you suffer from migraines
- you have had or you are due to have any vaccination including a live or live-attenuated vaccination.

Regular Check-ups

Your doctor may need to test your blood, liver function and the level of calcium in your blood. He/she will tell you how often this should be done.

Other medicines and Estracyt

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way Estracyt works, or Estracyt itself can reduce the effectiveness of other medicines if taken at the same time. You should tell your doctor if you are taking any of the following medicines:

- Certain medicines used for the treatment of depression (tricyclic anti-depressants).
- Medicines containing calcium, magnesium or aluminium such as some indigestion remedies.
- Medicines known as ACE Inhibitors used to treat high blood pressure or heart disease.

Estracyt with food and drink and alcohol

Your capsules will work less well if you have calcium in your stomach. Calcium is found in milk, dairy products such as cheese and some indigestion remedies, make sure that you check the ingredients listed on the label. (Please refer to section 3).

Pregnancy, breast-feeding and fertility

Since Estracyt is used to treat prostate cancer in males, it is not intended for use in women.

Not known: frequency cannot be estimated from the available data

- increased blood pressure
- decrease in sexual function
- clot formed at the site of injection administration
- muscular weakness
- depression and confusion
- skin rash which may be itchy or have a burning sensation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Estracyt

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Estracyt contains

The active substance is estramustine phosphate. Each capsule contains 140mg of estramustine phosphate (as estramustine sodium phosphate).

If your partner is pregnant or breast-feeding, think they may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy should be avoided while you are being treated with Estracyt. If, during treatment, you are sexually active, both you and your partner are advised to use effective birth control to prevent pregnancy. Estracyt may cause birth defects, so it is important to tell your doctor if you think your partner is pregnant.

If your partner is breast-feeding during your treatment use a reliable form of barrier contraception while on this medication. Consult your doctor if you have any questions about this medication.

Driving and using machines

There is currently no evidence which suggests that Estracyt is likely to affect your ability to drive or use machines. Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Estracyt

Always take Estracyt exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the Elderly

The recommend dose is usually four to six capsules a day, taken at separate times, are used to start treatment. Depending on how your illness responds and how well you tolerate the medicine, your doctor may change the dose to anywhere between one and ten capsules a day. You may also find this information on the label. It is best to take Estracyt at the same time each day.

You will find more about ESTRACYT on the back of this leaflet

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The capsules should be taken on an empty stomach. The capsules should be taken at least one hour before a meal, or more than two hours after a meal. The capsules should be swallowed whole with a glass of water. Do not attempt to split open the capsules.

Do not take your medicine with milk or other drinks containing milk such as tea or coffee (see 'Estracyt with food and drink and alcohol'). Furthermore, do not take Estracyt at the same time as other medicines which contain calcium, magnesium or aluminium e.g. antacids (see 'Other medicines and Estracyt').

Use in Children

Estracyt is not suitable for use in children.

If you take more Estracyt than you should

If you accidentally take too much Estracyt contact your doctor at once or go to the nearest hospital casualty department (since the stomach may need to be emptied and any symptoms of the overdose treated). Always take the labelled medicine package with you, whether there is any Estracyt left or not.

If you forget to take Estracyt

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Estracyt

Do not stop taking Estracyt unless your doctor tells you to. Your doctor will tell you how long you should take Estracyt for. Should you need to stop taking Estracyt, your doctor will decide which is the best method for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

The other ingredients are: talc, sodium lauryl sulfate, colloidal silicon dioxide, magnesium stearate, gelatin, titanium dioxide (E171), black ink (containing shellac, black iron oxide (E172), ammonium hydroxide (E527) and propylene glycol (E1520)).

What Estracyt looks like and contents of the pack

Estracyt are white, hard gelatin capsules with the product name "ESTRACYT" and "K Ph 750" printed in black ink and are available in bottles containing 100 capsules.

Marketing Authorisation Holder

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
UK

Manufacturer

Pfizer Italia S.r.l.
Marino del Tronto
63100 Ascoli Piceno
Italy

Company contact address:
For any information about this medicine contact Medical Information at the following address:
Pfizer Limited, Walton Oaks, Dorking Road, Surrey, KT 20 7NS.

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