

INSTRUCTIONS FOR USE

CELPTU 250 mg film-coated tablet

For oral use.

- **Active ingredient:** Mycophenolate mofetil. Each film-coated tablet contains 250 mg mycophenolate mofetil.
- **Excipients:** Microcrystalline cellulose, croscarmellose sodium, povidone K-90-F, magnesium stearate, Opadry purple*.

*Opadry purple contains hypromellose, titanium dioxide (E171), polyethylene glycol/macrogol, black iron oxide, red iron oxide colorants.

Read these INSTRUCTIONS FOR USE carefully before you start using this medicine, because they contain important information for you.

- **Keep these instructions for use. You may need to read them again later.**
- **If you have any further questions, please ask your doctor or pharmacist.**
- **This medicine has been prescribed for you personally, do not give it to others.**
- **When you visit a doctor or hospital while using this medicine, tell your doctor that you are using this medicine.**
- **Follow the instructions in this leaflet exactly. Do not use high or low doses other than the dose recommended for you regarding this medicine.**

In these Instructions for Use:

1. What is CELPTU and what is it used for?

2. Things to consider before using CELPTU

3. How to use CELPTU?

4. What are the possible side effects?

5. How to store CELPTU?

are included.

1. What is CELPTU and what is it used for?

CELPTU is in the form of film-coated tablets containing 250 mg mycophenolate mofetil.

CELPTU acts by inhibiting the activity of an enzyme called inosine monophosphate dehydrogenase (IMPDH) in the body, suppressing the immune system (it is an immunosuppressant).

CELPTU is available in packages containing 100 and 300 film-coated tablets, in blisters of 10 tablets.

CELPTU is used to prevent your body from rejecting a transplanted kidney, liver, or heart. CELPTU can be used concurrently with a calcineurin inhibitor (immunosuppressive drugs like CELPTU, which prevent the body's rejection after organ transplantation) or a corticosteroid (drugs with a similar structure to cortisol, a hormone secreted by the adrenal glands in the body).

2. Things to consider before using CELPTU

Mycophenolate can cause birth defects and miscarriage. If you are a woman of childbearing potential, you must have had a negative pregnancy test result before starting treatment and you must follow the birth control instructions given to you by your doctor.

Your doctor will discuss with you specifically the effects of mycophenolate on unborn babies and will provide you with written information. Read this information carefully and follow the instructions.

If you do not fully understand these instructions, please speak to your doctor to explain them again before you start treatment with mycophenolate. Also, refer to the detailed information under the sections "USE CELPTU CAREFULLY in the following situations", "Pregnancy" and "Breastfeeding".

DO NOT USE CELPTU in the following situations

If;

- You are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid, or any of the excipients contained in CELPTU.
- If you are a woman of childbearing potential and have not given a negative pregnancy test result before your first administration, mycophenolate can cause birth defects and miscarriage.
- You are pregnant or planning to become pregnant or think you might be pregnant.
- If you are not using an effective method of birth control (see Pregnancy, birth control and breastfeeding).
- You are breastfeeding.

USE CELPTU CAREFULLY in the following situations

Before starting treatment with CELPTU, talk to your doctor if you have any of the following conditions:

If;

- You show signs of infection such as fever or sore throat,
- Unexpected bruising occurs on your body and bleeding occurs,
- You have previously experienced digestive system problems such as stomach ulcers,
- You are planning to become pregnant or you or your partner become pregnant while using CELPTU.

Your doctor should perform a complete blood count to monitor the risk of decreased neutrophil count (neutropenia).

Effects of sunlight

CELPTU lowers your body's defense system. As a result, the risk of skin cancer increases.

Therefore, the amount of sunlight and UV light you receive should be reduced.

- Wearing protective clothing for your head, neck, arms, and legs
- Using high SPF sunscreen

You should not donate blood during CELPTU treatment and for at least 6 weeks after treatment is discontinued. Men should not donate sperm during CELPTU treatment and for at least 90 days after treatment is discontinued.

If these warnings apply to you at any time in the past, please consult your doctor.

Using CELPTU with food and drink

Eating or drinking has no effect on your treatment with CELPTU.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

Birth control in women using CELPTU:

If you are a woman of childbearing potential, you should always use two effective methods of birth control during CELPTU use. This includes:

- Before starting CELPTU
- Throughout your entire treatment with CELPTU
- For 6 weeks after stopping CELPTU.

Consult your doctor for the most suitable birth control method for you. This will vary depending on your individual situation. **If you think your birth control method is not effective for you or if you forgot to take your birth control pill, contact your doctor as soon as possible.**

If any of the following apply to you, it means you are a woman not of childbearing potential:

- You are post-menopausal, e.g., at least 50 years old and your last period was more than a year ago (if your period stopped due to cancer treatment, you may still be able to become pregnant)
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy)
- Your uterus has been removed by surgery (hysterectomy)
- Your ovaries are no longer functioning (premature ovarian failure confirmed by a gynecologist)

- You were born with one of these rare conditions that make pregnancy impossible: XY genotype, Turner syndrome, or uterine agenesis.
- You are a child or adolescent who has not yet reached puberty.

Birth control in men using CELPTU:

Available data do not indicate an increased risk of birth defects or miscarriage in fathers using CELPTU. However, the risk cannot be entirely ruled out. As a precaution, it is recommended that you and your female partner use reliable birth control methods during treatment and for 90 days after treatment.

If you are considering having children, contact your doctor to discuss the potential risks and alternative treatments that can be taken to prevent rejection of the transplanted organ.

Pregnancy in women using CELPTU:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If:

- You are planning to become pregnant,
- Your period is late or you think it is late, you have unusual menstrual bleeding or you suspect you are pregnant,
- You have had sexual intercourse without using an effective method of birth control,

your doctor will discuss the risks and alternative treatments that can be taken to prevent rejection of the transplanted organ. If you become pregnant during mycophenolate treatment, you should tell your doctor immediately. However, you should continue to use CELPTU until you speak with your doctor.

Mycophenolate causes miscarriage in a very high frequency (50%) and serious birth defects (23-27%) in unborn babies. Birth defects reported so far include abnormalities in the ears, eyes, face (cleft lip/palate), formation of fingers, heart, esophagus (the tube connecting the throat to the stomach), kidneys, and nervous system (e.g., spina bifida (conditions where the bones of the spine do not develop correctly)). Your baby may be affected by one or more of these conditions.

If you are a woman of childbearing potential, your pregnancy test result must be negative before starting treatment and you must follow the birth control instructions given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

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

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

Since the drug can pass into breast milk, even in small amounts, you should not use CELPTU if you are breastfeeding.

Driving and using machines

CELPTU has a moderate effect on the ability to drive and use machines. If you feel sleepy, drowsy, or dizzy, consult your doctor or pharmacist and do not drive or use any machines until you feel better.

Important information about some of the excipients in CELPTU

CELPTU contains 16.25 mg croscarmellose sodium. This should be considered for patients on a controlled sodium (salt) diet.

Using with other medicines

If you are currently using or have recently used any other medicines, including herbal medicines and medicines obtained without a prescription, tell your doctor or pharmacist. This is because CELPTU can affect the way some other medicines work. Also, other medicines can affect the way CELPTU works.

Especially tell your doctor before starting CELPTU treatment if you are using any of the following medicines:

- If you are using azathioprine, cyclosporine A, tacrolimus, or other immunosuppressive drugs (sometimes given to patients after transplant surgery),
- If you are using cholestyramine (used in the treatment of patients with high blood cholesterol),
- If you are using rifampicin (a type of antibiotic used to treat infections such as tuberculosis),
- If you are using phosphate binders (sevelamer) (used to reduce phosphate absorption in patients with

chronic kidney failure),

- If you are using antibiotics (used for bacterial infections),
- If you are using isavuconazole (used for fungal infections),
- If you are using telmisartan (used to treat high blood pressure).
- If you are using antacids and proton pump inhibitors for discomfort in your stomach such as indigestion,
- If you are using an antiviral drug such as acyclovir and ganciclovir,
- If you are using a medicine like probenecid, used to treat gout or increased uric acid levels in the blood (hyperuricemia) due to other causes,

Vaccines

If you need to use a vaccine (live vaccine) while using CELPTU, consult your doctor or pharmacist first. Your doctor will tell you which vaccine you should use.

If you are currently using or have recently used any prescribed or non-prescribed medicine, please inform your doctor or pharmacist about them.

3. How to use CELPTU?

Instructions for appropriate use and dose/frequency of administration:

You should always use CELPTU exactly as your doctor has advised. If you are not sure, check with your doctor or pharmacist.

The amount of dose you will use depends on the organ transplanted to you. Normal doses are stated below. Treatment will continue as long as you need it to prevent your body from rejecting the transplanted organ.

Use in case of kidney transplant:

In adults, the first dose is given within 72 hours after transplant surgery. The recommended daily dose is 8 tablets given as two separate doses (2 g of active substance). This dose should be taken as 4 tablets in the morning and 4 tablets in the evening.

Use in case of heart transplant:

In adults, the first dose is given within 5 days following the operation. The recommended daily dose is 12 tablets given as two separate doses (3 g of active substance). This dose should be taken as 6 tablets in the morning and 6 tablets in the evening.

Use in case of liver transplant:

In adults, the first oral dose of CELPTU is given at least four days after transplant surgery and when you can swallow oral medication. The recommended daily dose is 12 tablets given as two separate doses (3 g of active substance). This dose should be taken as 6 tablets in the morning and 6 tablets in the evening.

Route and method of administration:

Swallow your CELPTU tablets with a glass of water. Do not break or crush the tablets.

Different age groups:

Use in children (2-18 years):

Use in case of kidney transplant:

The dose to be given varies depending on the child's body size. Your doctor will determine the most appropriate dose based on your child's height and weight (body surface area – measured in square meters (m²)). The recommended dose is 600 mg/m² taken twice daily.

Use in children under 2 years of age is not recommended.

Use in case of heart transplant:

There are no data on the use of CELPTU in children who have undergone heart transplantation.

Use in children under 2 years of age is not recommended.

Use in case of liver transplant:

There are no data on the use of CELPTU in children who have undergone liver transplantation.

Use in children under 2 years of age is not recommended.

Use in the elderly:

The recommended dose of 1 g twice daily for kidney transplant patients and 1.5 g twice daily for heart and liver transplant patients is also suitable for elderly patients.

Special use cases:

Kidney failure:

In kidney transplant patients with severe chronic kidney failure, doses greater than 1 g twice daily should be avoided outside the immediate post-kidney transplant period. If you have kidney failure problems, your doctor may tell you to take a lower daily dose of CELPTU.

There are no data regarding patients with kidney failure who have received heart or liver transplants.

Liver failure:

No special dose adjustment is required in kidney transplant patients with liver failure. There is no information regarding the use of CELPTU in heart transplant patients with liver failure.

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

If you use more CELPTU than you should:

If you have used more CELPTU than you should, talk to a doctor or go to a hospital immediately. Do the same if someone else has accidentally used your medicine. Carry your medicine with you.

Medicines used for cholesterol treatment, such as cholestyramine, can remove mycophenolic acid, the active metabolite of this drug (chemical compound resulting from metabolism of the drug), by increasing its excretion.

If you have used more CELPTU than you should, talk to a doctor or pharmacist.

If you forget to use CELPTU:

If you forget to take CELPTU, take this dose as soon as you remember and continue to take the next dose at your usual time.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with CELPTU is discontinued

- Discontinuing CELPTU treatment increases the likelihood of your body rejecting your transplanted organ.
- Do not stop taking your medicine unless your doctor tells you to.
- If you have any additional questions about the use of this medicine, please ask your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, CELPTU can cause side effects in people who are sensitive to the substances contained in it.

Some of the very common side effects include diarrhea, decreased red and/or white blood cells, infection, and vomiting. Your doctor may ask you to have regular blood tests to monitor changes in your blood cell counts or signs of infection.

Children are more prone to side effects such as diarrhea, infection, and decreased red and/or white blood cells compared to adults.

CELPTU weakens the body's defense mechanism to prevent the rejection of transplanted kidney, heart, or liver by your body. Therefore, your body's ability to fight infections will not be as good as normal. This means that if you are using CELPTU, you are more likely to get infections such as brain, skin, mouth, stomach and intestines, lung and urinary tract infections than usual.

As can happen in patients using this type of immunosuppressive drugs, skin and lymph node cancers have occurred in a very small number of patients.

You may experience common side effects affecting your whole body, these are general undesirable side effects. These side effects include; severe allergic reactions (such as anaphylaxis, angioedema), fever,

feeling very tired, difficulty sleeping, pain (stomach, chest, muscle or joint pain), headache, flu symptoms, and swelling.

If any of the following occur, stop using CELPTU and IMMEDIATELY inform your doctor or go to the emergency department of your nearest hospital:

- *If you show signs of infection such as fever or sore throat,*
- *If unexpected bruising occurs on your body and bleeding occurs,*
- *If you experience rash, swelling in the face, lips, tongue or throat with difficulty breathing, you may be having a serious allergic reaction to this medicine (such as anaphylaxis, angioedema).*

These are all very serious side effects. If you have any of these, it means you have a serious allergy to CELPTU. You may need urgent medical attention or hospitalization.

All of these very serious side effects are quite rare.

Very common: May be seen in at least 1 in 10 patients.

Common: May be seen in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: May be seen in less than 1 in 100 patients, but more than 1 in 1000 patients.

Rare: May be seen in less than 1 in 1000 patients.

Very rare: May be seen in less than 1 in 10000 patients.

Unknown: May be seen in too few patients to be determined from available data.

Very common:

In kidney transplant patients;

- Bacterial and viral infections
- Decrease in red blood cells (anemia), decrease in white blood cells (leukopenia),
- Increase in blood cholesterol level (hypercholesterolemia), decrease in blood phosphate level (hypophosphatemia)
- Headache
- Increase in blood pressure (hypertension)
- Cough, shortness of breath (dyspnea)
- Abdominal pain, constipation, diarrhea, indigestion (dyspepsia), nausea, vomiting
- Blood in urine (hematuria)
- Feeling of muscle weakness (asthenia), edema, fever

In liver transplant patients;

- Bacterial infections, fungal infections, and viral infections
- Decrease in red blood cells (anemia), increase in white blood cells (leukocytosis), decrease in white blood cells (leukopenia), decrease in platelet count (thrombocytopenia)
- Increase in blood sugar level (hyperglycemia), increase in blood potassium level (hyperkalemia), decrease in blood calcium level (hypocalcemia), decrease in blood potassium level (hypokalemia), decrease in blood magnesium level (hypomagnesemia), decrease in blood phosphate level (hypophosphatemia)
- Confusion, depression, insomnia, anxiety (behavioral and psychological agitation)
- Dizziness, headache, numbness (paresthesia), tremor
- Increase in heart rate (tachycardia)
- Increase in blood pressure (hypertension), decrease in blood pressure (hypotension)
- Cough, shortness of breath (dyspnea), pleural effusion (fluid accumulation in the sac surrounding the heart)
- Abdominal distension (tension in the abdominal area), abdominal pain, constipation, decreased appetite, diarrhea, indigestion (dyspepsia), bloating, nausea, vomiting
- Increase in liver enzymes, liver inflammation (hepatitis), increase in blood bilirubin level (hyperbilirubinemia)
- Rash
- Increase in blood creatinine, increase in blood urea, kidney failure

- Feeling of muscle weakness (asthenia), tremor, edema, hernia, pain, fever

In heart transplant patients;

- Bacterial infections, fungal infections, and viral infections
- Decrease in red blood cells (anemia), ecchymosis (skin bruising), increase in white blood cells (leukocytosis), decrease in white blood cells (leukopenia), decrease in platelet count (thrombocytopenia)
- Increase in blood acid ratio (acidosis), increase in blood cholesterol level (hypercholesterolemia), increase in blood sugar level (hyperglycemia), increase in blood potassium level (hyperkalemia), increase in blood fat amount (hyperlipidemia), decrease in blood potassium level (hypokalemia), decrease in blood magnesium level (hypomagnesemia), increase in blood uric acid level (hyperuricemia), gout (joint inflammation)
- Confusion, depression, insomnia, agitation (restlessness), anxiety (behavioral and psychological agitation)
- Dizziness, headache, muscle tension (hypertonia), numbness (paresthesia), drowsiness, tremor
- Increase in heart rate (tachycardia)
- Increase in blood pressure (hypertension), decrease in blood pressure (hypotension), widening of blood vessels (vasodilation)
- Cough, shortness of breath (dyspnea), pleural effusion (fluid accumulation in the sac surrounding the heart)
- Abdominal pain, constipation, decreased appetite, diarrhea, indigestion (dyspepsia), bloating, nausea, vomiting
- Increase in lactate dehydrogenase enzyme level in blood, increase in liver enzymes, increase in blood bilirubin level (hyperbilirubinemia)
- Acne, rash, thickening of the skin (skin hypertrophy)
- Joint pain, muscle weakness
- Increase in blood creatinine, increase in blood urea, kidney failure
- Feeling of muscle weakness (asthenia), tremor, edema, hernia, pain, fever

Common:

In kidney transplant patients;

- Fungal infections
- Benign skin tumor (benign skin neoplasm), tumor (neoplasm), skin cancer
- Ecchymosis (skin bruising), increase in white blood cells (leukocytosis), decrease in all blood cells (pancytopenia), decrease in platelet count (thrombocytopenia)
- Increase in blood acid ratio (acidosis), increase in blood sugar level (hyperglycemia), increase in blood potassium level (hyperkalemia), increase in blood fat amount (hyperlipidemia), decrease in blood calcium level (hypocalcemia), decrease in blood potassium level (hypokalemia), decrease in blood magnesium level (hypomagnesemia), increase in blood uric acid level (hyperuricemia), gout (joint inflammation), weight loss
- Confusion, depression, insomnia, anxiety (behavioral and psychological agitation)
- Dizziness, muscle tension (hypertonia), numbness (paresthesia), drowsiness, tremor, transient neurological dysfunction (convulsion)
- Increase in heart rate (tachycardia)
- Decrease in blood pressure (hypotension), venous thrombosis, widening of blood vessels (vasodilation)
- Pleural effusion (fluid accumulation in the sac surrounding the heart)
- Abdominal distension (tension in the abdominal area), bowel inflammation (colitis), decreased appetite, esophageal inflammation (esophagitis), bloating, stomach inflammation (gastritis), gastrointestinal bleeding, stomach ulcer (gastric ulcer), gum enlargement (gingival hyperplasia), bowel obstruction (ileus), mouth ulcer, mouth sores (stomatitis)
- Increase in blood alkaline phosphatase, increase in lactate dehydrogenase enzyme level in blood, increase in liver enzymes, liver inflammation (hepatitis), increase in blood bilirubin level (hyperbilirubinemia)

- Acne, hair loss (alopecia), rash, thickening of the skin (skin hypertrophy)
- Joint pain, muscle weakness
- Increase in blood creatinine, kidney failure
- Tremor, hernia, discomfort, pain

In liver transplant patients;

- Benign skin tumor (benign skin neoplasm), tumor (neoplasm)
- Ecchymosis (skin bruising), decrease in all blood cells (pancytopenia)
- Increase in blood acid ratio (acidosis), increase in blood cholesterol level (hypercholesterolemia), increase in blood fat amount (hyperlipidemia), increase in blood uric acid level (hyperuricemia), gout (joint inflammation), weight loss
- Agitation (restlessness), abnormal thinking
- Muscle tension (hypertonia), drowsiness, transient neurological dysfunction (convulsion)
- Venous thrombosis, widening of blood vessels (vasodilation)
- Bowel inflammation (colitis), esophageal inflammation (esophagitis), stomach inflammation (gastritis), gastrointestinal bleeding, stomach ulcer (gastric ulcer), gum enlargement (gingival hyperplasia), bowel obstruction (ileus), mouth ulcer, pancreatic inflammation (pancreatitis), mouth sores (stomatitis)
- Hypersensitivity
- Increase in blood alkaline phosphatase, jaundice (yellowing of the skin and whites of the eyes due to accumulation of a substance called bilirubin, which results from the breakdown of blood cells)
- Acne, hair loss (alopecia), thickening of the skin (skin hypertrophy)
- Joint pain, muscle weakness
- Blood in urine (hematuria)
- Discomfort

In heart transplant patients;

- Benign skin tumor (benign skin neoplasm), tumor (neoplasm), skin cancer
- Pseudolymphoma (lymphoma-like condition developing due to the drug)
- Decrease in blood calcium level (hypocalcemia), decrease in blood phosphate level (hypophosphatemia), weight loss
- Abnormal thinking
- Transient neurological dysfunction (convulsion), abnormal taste sensation in the mouth (dysgeusia)
- Venous thrombosis
- Abdominal distension (tension in the abdominal area), bowel inflammation (colitis), esophageal inflammation (esophagitis), belching, stomach inflammation (gastritis), gastrointestinal bleeding, stomach ulcer (gastric ulcer), gum enlargement (gingival hyperplasia), bowel obstruction (ileus), mouth ulcer, mouth sores (stomatitis)
- Hypersensitivity
- Increase in blood alkaline phosphatase, jaundice (yellowing of the skin and whites of the eyes due to accumulation of a substance called bilirubin, which results from the breakdown of blood cells)
- Hair loss (alopecia)
- Blood in urine (hematuria)
- Discomfort

Uncommon:

- Protozoal infections
- Lymphoma (lymphoma), lymphoproliferative disorder (a group of diseases caused by uncontrolled proliferation of lymphoid tissues)
- Pure red cell aplasia, bone marrow failure, pseudolymphoma (lymphoma-like condition developing due to the drug)
- Agitation (restlessness), abnormal thinking
- Abnormal taste sensation in the mouth (dysgeusia)
- Lymphocele (accumulation of lymph fluid in a sac)
- Bronchiectasis (a condition where the airways in the lungs are abnormally widened), interstitial lung

disease (a group of diseases that cause damage to lung tissue)

- Belching, pancreatic inflammation (pancreatitis)
- Hypersensitivity, hypogammaglobulinemia (immune system deficiency due to low levels of proteins called gamma globulins)
- Jaundice (yellowing of the skin and whites of the eyes due to accumulation of a substance called bilirubin, which results from the breakdown of blood cells)
- Increase in blood urea

In liver transplant patients;

- Protozoal infections
- Lymphoma (lymphoma), lymphoproliferative disorder (a group of diseases caused by uncontrolled proliferation of lymphoid tissues), skin cancer
- Pure red cell aplasia, bone marrow failure, pseudolymphoma (lymphoma-like condition developing due to the drug)
- Abnormal taste sensation in the mouth (dysgeusia)
- Lymphocele (accumulation of lymph fluid in a sac)
- Bronchiectasis (a condition where the airways in the lungs are abnormally widened), pulmonary fibrosis (thickening and hardening of the air sacs in the lungs)
- Belching
- Increase in lactate dehydrogenase enzyme level in blood

In heart transplant patients;

- Protozoal infections
- Lymphoma (lymphoma), lymphoproliferative disorder (a group of diseases caused by uncontrolled proliferation of lymphoid tissues)
- Pure red cell aplasia, bone marrow failure, decrease in all blood cells (pancytopenia)
- Lymphocele (accumulation of lymph fluid in a sac)
- Bronchiectasis (a condition where the airways in the lungs are abnormally widened), pulmonary fibrosis (thickening and hardening of the air sacs in the lungs)
- Pancreatic inflammation (pancreatitis)
- Liver inflammation (hepatitis)

Very rare:

In kidney transplant patients;

- Pulmonary fibrosis (thickening and hardening of the air sacs in the lungs)

In liver transplant patients;

- Interstitial lung disease (a group of diseases that cause damage to lung tissue)
- Hypogammaglobulinemia (immune system deficiency due to low levels of proteins called gamma globulins)

In heart transplant patients;

- Interstitial lung disease (a group of diseases that cause damage to lung tissue)
- Hypogammaglobulinemia (immune system deficiency due to low levels of proteins called gamma globulins)

If you encounter any side effects not mentioned in these instructions for use, inform your doctor or pharmacist.

Reporting of side effects

If you experience any side effects, whether or not listed in the Instructions for Use, talk to your doctor, pharmacist or nurse. You can also report side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on www.titck.gov.tr or by calling the side effect notification line at 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

5. How to store CELPTU?

Keep CELPTU out of the sight and reach of children and in its packaging.

Store at room temperature below 30° C. Store in the original packaging to protect from light.

Use in accordance with the expiry date.

Do not use CELPTU after the expiry date on the packaging.

Do not dispose of medicines with wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Do not throw away expired or unused medicines! Give them to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Marketing Authorisation Holder: Koçsel İlaç Sanayi ve Ticaret A.Ş Gebze OSB2 Mah. 1700. Sk. No: 1703/2 Çayırova/KOCAELİ Tel: 0850 250 66 56 e-mail: info@onkokocsel.com

Manufacturer: Onko İlaç Sanayi ve Ticaret A.Ş. Gebze Organize San. Bölgesi 1700 Sokak, No:1703 Çayırova/ Kocaeli

These instructions for use were approved on 28/11/2022.