PACKAGE LEAFLET:
INFORMATION FOR THE PATIENT

Ceptava 360 mg Gastro-resistant Tablets

SANDOZ

mycophenolic acid

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

SZ07204LT04B

1. What Ceptava is and what it is used for

Ceptava contains a substance called mycophenolic acid. This belongs to a group of medicines called immunosuppressants.

Ceptava is used to stop the body's immune system from rejecting a kidney transplant. It is used together with other medicines containing ciclosporin and corticosteroids.

2. What you need to know before you take Ceptava

WARNING
Mycophenolate causes birth defects and miscarriage. If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor.

Your doctor will speak to you and give you written information, particularly on the effects of mycophenolate on unborn babies. Read the information carefully and follow the instructions.
If you do not fully understand these instructions, please ask your doctor to explain them again before you take mycophenolate. See also further information in this section under "Warnings and precautions" and "Pregnancy and breast-feeding".

Do not take Ceptava:
- if you are allergic (hypersensitive) to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman who could be pregnant and you have not provided a negative pregnancy test before your first prescription, as mycophenolate causes birth defects and miscarriage
- if you are pregnant or planning to become pregnant or think you may be pregnant
- if you are not using effective contraception (see Contraception in women and men).
- if you are breast-feeding (see also "Pregnancy and breast-feeding").

If any of the above apply to you, tell your doctor without taking Ceptava.

Warnings and precautions
Talk to your doctor or pharmacist before taking Ceptava:
- if you have or have ever had serious digestive problems, such as stomach ulcer.
- if you have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan or Kelley-Seegmiller syndrome.

You should also be aware that:
- Ceptava lowers the skin´s level of protection from the sun. This increases the risk of skin cancer. You should limit your exposure to sunlight and ultraviolet (UV) light by covering exposed skin areas as much as possible and regularly applying sunscreen with a high protective factor. Ask your doctor for advice on protection from the sun.
- if you already had hepatitis B or C, Ceptava may increase the risk of these diseases re-appearing. Your doctor may perform blood analysis and check for symptoms of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine) you should tell your doctor immediately.
- if you get a persistent cough or become breathless, especially when taking other immunosuppressants, you should tell your doctor straight away.
- your doctor may want to check your blood level of antibodies during treatment with Ceptava particularly when the infections recur, especially if you are also taking other immunosuppressants, and will tell you whether you can continue taking Ceptava.
- if you get any signs of infection (such as fever or a sore throat) or unexpected bruising or bleeding you should tell your doctor straight away.
- your doctor may want to check your white blood cell count during treatment with Ceptava, and will tell you whether you can continue taking Ceptava.
- the active substance, mycophenolic acid, is not the same as other similar-sounding medicines such as mycophenolate mofetil. You should not switch between medicines unless your doctor tells you to.
- use of Ceptava in pregnancy may harm the foetus (see also "Pregnancy and breast-feeding") and increase the risk of pregnancy loss (spontaneous abortion).

Other medicines and Ceptava
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

In particular, you should talk to your doctor if you are taking any of the following:
- other immunosuppressant medicines such as azathioprine or tacrolimus.
- medicines used to treat high blood cholesterol levels such as cholestyramine.
- activated charcoal used to treat digestive problems such as diarrhoea, upset stomach, and gas.
- antacids that contain magnesium and aluminium.
- medicines used to treat viral infections such as aciclovir or ganciclovir.

You should also tell your doctor if you plan to have any **vaccinations**.

You must not donate blood during treatment with Ceptava and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with Ceptava and for at least 90 days after stopping treatment.

Ceptava with food and drink
Ceptava can be taken with or without food. You need to choose whether to take your tablets with or without food and then take them in the same way each day. This is to make sure that the same amount of your medication is absorbed into your body each day.

Elderly
Elderly people (age 65 years or older) can take Ceptava without any need to adjust the usual recommended dose.

Paediatric population and adolescents
The use of Ceptava in children and adolescents is not recommended due to lack of data.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternatives you can take to prevent rejection of your transplant organ if:
- You plan to become pregnant.
- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have sex without using an effective method of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking mycophenolate until you see him or her.

Pregnancy
Mycophenolate causes a very high frequency of miscarriage (50%) and of severe birth defects (23 - 27%) in the unborn baby. Birth defects which have been reported include anomalies of ears, of eyes, of face (cleft lip/palate), of development of fingers, of heart, oesophagus (tube that connects the throat with the stomach), kidneys and nervous system (for example spina bifida (where the bones of the spine are not properly developed)).
Your baby may be affected by one or more of these.

If you are a woman who could become pregnant, you must provide a negative pregnancy test, before starting treatment and must follow the contraception advice given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

Breast-feeding
Do not take Ceptava if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

Contraception in women taking Ceptava
If you are a woman who could become pregnant you must use an effective method of contraception with Ceptava. This includes:
- Before you start taking Ceptava
- During your entire treatment with Ceptava
- For 6 weeks after you stop taking Ceptava.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. Two forms of contraception are preferable as this will reduce the risk of unintended pregnancy. **Contact your doctor as soon as possible, if you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill.**

You are a woman who is not capable of becoming pregnant if any of the following applies to you:
- You are post-menopausal, i.e. at least 50 years old and your last period was more than a year ago (if your periods have stopped because you have had treatment for cancer, then there is still a chance you could become pregnant)
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy)
- Your womb (uterus) has been removed by surgery (hysterectomy)
- Your ovaries no longer work (premature ovarian failure, which has been confirmed by a specialist gynaecologist)
- You were born with one of the following rare conditions that make pregnancy impossible: the XY genotype, Turner's syndrome or uterine agenesis
- You are a child or teenager who has not started having periods.

Contraception in men taking Ceptava
The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes mycophenolate. However, a risk cannot be completely excluded. As a precaution you or your female partner are recommended to use reliable contraception during treatment and for 90 days after you stop taking Ceptava.

If you are planning to have a child, talk to your doctor about the potential risks.

Driving and using machines
Ceptava has not been shown to affect your ability to drive or use machines.

Ceptava contains sodium and lactose
This medicine contains 25.9 mg sodium (main component of cooking/table salt) in each gastro-resistant tablet. This is equivalent to 1.3% of the recommended maximum daily dietary intake of sodium for an adult.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Ceptava

Always take this medicine exactly as your doctor has told you. Ceptava will only be prescribed for you by a doctor with experience in treating transplant patients. Check with your doctor or pharmacist if you are not sure.

How much to take
The recommended daily dose of Ceptava is 1440 mg (4 tablets of Ceptava 360 mg). This is taken as 2 separate doses of 720 mg each (2 tablets of Ceptava. Take your tablets in the morning and in the evening.

The first dose of 720 mg will be given within 72 hours after transplantation.

If you have severe kidney problems
Your daily dose should not be more than 1440 mg (4 tablets of Ceptava 360 mg).

Taking Ceptava
Swallow the tablets whole with a glass of water.
Do not break or crush the tablets.
Do not take any tablets that are broken or split.
Avoid inhalation of the powder or direct contact of the powder with skin or mucous membrane. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water. Treatment will continue for as long as you need immunosuppression to stop your body rejecting your transplant.

If you take more Ceptava than you should
If you take more Ceptava than you should, or if someone else has taken your tablets, talk to a doctor or go to a hospital straight away. Medical attention may be necessary. Take the tablets with you and show them to your doctor or to the hospital staff. If you have run out of tablets, take the empty packaging with you.

If you forget to take Ceptava
If you forget to take Ceptava, take it as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ceptava
Do not stop taking Ceptava unless your doctor tells you to. Stopping Ceptava may increase the chance of your body rejecting your kidney transplant.

Continued on next page >>

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Elderly patients may experience more side effects due to a reduced immune defence.

Immunosuppressants, including Ceptava, reduces your body´s own defence mechanisms to stop you rejecting your transplanted organ. Consequently your body will not be as good as normal at fighting infections. So if you are taking Ceptava, you may therefore catch more infections than usual such as infections of the brain, skin, mouth, stomach and intestines, lungs and urinary tract.

Your doctor will perform regular blood tests to monitor any changes in the number of your blood cells or in the levels of substances carried in your blood, such as sugar, fat and cholesterol.

Some effects could be serious:
- Rash, itching, hives, breathlessness or difficult breathing, wheezing or coughing, light headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild, generalised itching, skin reddening and facial/ throat swelling (symptoms of severe allergic reaction)
- signs of infection including fever, chills, sweating, feeling tired, drowsy, or lack of energy. If you are taking Ceptava you may be more likely to get viral, bacterial and fungal infections than usual. Such infections could affect various parts of your body, but the parts most commonly affected are the kidneys, bladder, upper and/or lower airways.
- vomiting blood, black or bloody stools, stomach or intestinal ulcer.
- swelling of your glands, development of a new skin growth or enlargement of an existing skin growth, or changes in an existing mole. As can happen in patients taking immunosuppressants, a very small number of Ceptava patients have developed cancer of the skin or lymph nodes.

If you experience any of the above after taking Ceptava, talk to your doctor straight away.

Other side effects may include:
Very common (*may affect more than 1 in 10 people*)
- low level of white blood cells
- low level of calcium in the blood (hypocalcaemia)
- low level of potassium in the blood (hypokalemia)
- high level of uric acid in the blood (hyperuricemia)
- high blood pressure (hypertension)
- anxiety
- diarrhoea
- pain in joints (arthralgia)

Common (*may affect up to 1 in 10 people*)
- low level of red blood cells which can result in tiredness, breathlessness and looking pale (anaemia)
- low level of blood platelets which can result in unexpected bleeding and bruising (thrombocytopenia)
- high level of potassium in the blood (hyperkalemia)
- low level of magnesium in the blood (hypomagnesemia)
- dizziness
- headache
- cough
- low blood pressure (hypotension)
- shortness of breath (dyspnoea)
- abdominal or stomach pain, inflammation of the lining of the stomach, abdominal bloating, constipation, indigestion, wind (flatulence), loose stools, feeling sick (nausea), being sick (vomiting)
- tiredness, fever
- abnormal results of liver or kidney function tests
- respiratory infections
- acne
- weakness (asthenia)
- muscle pain (myalgia)
- swollen hands, ankles or feet (oedema peripheral)
- itching

Uncommon (*may affect up to 1 in 100 people*)
- fast heart beat (tachycardia) or irregular heart beat (ventricular extrasystoles), fluid in the lungs (pulmonary oedema)
- a growth that looks like a sac (*cyst*) containing fluid (*lymph*) (lymphocele)
- trembling, difficulty in sleeping
- redness and swelling of eyes (conjunctivitis), blurred vision
- wheezing
- belching, bad breath, bowel blockage (ileus), lip ulcers, heartburn, tongue discolouration, dry mouth, inflammation of the gums, inflammation of the pancreas leading to severe upper stomach pain (pancreatitis), blockage of the salivary glands, inflammation of the inner lining of the abdomen (peritonitis)
- infection of the bones, blood and the skin
- blood in urine, damage to the kidney, pain and difficulty passing urine
- hair loss, skin bruising
- inflammation of the joints (arthritis), back pain, muscle cramps
- loss of appetite, increased level of lipids (hyperlipidemia), sugar (diabetes), cholesterol (hypercholesterolemia), or decreased level of phosphate in the blood (hypophosphatemia)
- signs of flu (such as tiredness, chills, sore throat, aching joints or muscles), swelling of ankles and feet, pain, rigors, feeling thirsty or weak
- strange dreams, believing things that aren´t true (*delusions*)
- inability to get or keep an erection
- cough, difficulty breathing, painful breathing (possible symptoms of interstitial lung disease)

Not known *(frequency cannot be estimated from the available data)*
- rash
- fever, sore throat, frequent infections (possible symptoms of lack of white cells in the blood) (agranulocytosis)

Other side effects reported with medicines similar to Ceptava
Additional side effects have been reported with the group of medicines that Ceptava belongs to: inflammation of the colon (large intestine), inflammation of the stomach lining caused by cytomegalovirus, development of a hole in the intestinal wall, resulting in severe abdominal pain with possible bleeding, stomach or duodenal ulcers, a low level of specific white blood cells or of all blood cells, serious infections such as inflammation of the heart and its valves and of the membrane that covers the brain and spinal cord, shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) and other less common bacterial infections usually resulting in a serious lung disorder (*tuberculosis and atypical mycobacterial infection*). Talk to your doctor if you develop a persistent cough or breathlessness.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ceptava

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from moisture

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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 Ceptava contains

The active substance is mycophenolic acid (as mycophenolate sodium).
Each gastro-resistant tablet contains 360 mg of mycophenolic acid.

The other excipients are:
Core
Lactose anhydrous, crospovidone (type A), povidone K30, maize starch/corn starch, colloidal anhydrous silica/colloidal silicon dioxide, magnesium stearate

Coating
Hypromellose phthalate HP 50, titanium dioxide (E 171), iron oxide yellow (E 172)/ferric oxide, iron oxide red (E 172)/ferric oxide

What Ceptava looks like and contents of the pack

Pale orange-red film-coated ovaloid tablets with imprint (debossing) 'CT' on one side.
Dimensions: approximately 17.6 x 7.2 x 6.3 mm

PA/AL/PVC-aluminium blister packs.

Pack sizes: 50, 100, 120, 250 gastro-resistant tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

Manufacturer
Novartis Pharmaceutical Manufacturing LLC
Verovškova ulica 57.
1000 Ljubljana
Slovenia

Or

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
Sachsen-Anhalt, 39179 Barleben
Germany

Or

Novartis Pharma GmbH
Roonstrasse 25, 90429 Nuernberg
Germany

Or

Lek d.d., PE PROIZVODNJA
LENDAVA
Trimlini 2D, Lendava, 9220
Slovenia

This leaflet was last revised in 10/2025.

SZ07204LT04B

Artwork Proof Box:

Variation:	V025: Brand alignment
Proof no:	009.1
Date prepared:	03/12/2025
Font size:	9 pt
Fonts:	Helvetica
Dimension:	165 x 620 mm
Technical data:	
SKUs:	00000000
SZ codes:	SZ07204LT04B
Item codes:	00000000
Pharma codes:	00000000

Technical Colours:	
	Legend:
	Cutting:
Colours:	
	Black

SANDOZ