

**PATIENT PACKAGE INSERT  
IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) - 1986**

The medicine is dispensed with  
a doctor's prescription only

## Cinacalcet Teva 30 mg Tablets

### Composition:

Each tablet contains:

Cinacalcet (as hydrochloride) 30 mg

## Cinacalcet Teva 60 mg Tablets

### Composition:

Each tablet contains:

Cinacalcet (as hydrochloride) 60 mg

## Cinacalcet Teva 90 mg Tablets

### Composition:

Each tablet contains:

Cinacalcet (as hydrochloride) 90 mg

For information about inactive ingredients,  
please see section 6 - "Further  
information".

**Read the 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.

This medicine has been prescribed for  
your treatment. 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  
children under 18 years of age.**

### 1. WHAT IS THE MEDICINE INTENDED FOR?

- This medicine is intended to treat  
secondary hyperparathyroidism in  
patients with serious kidney disease  
who need dialysis to clear their blood  
of waste products.
- To reduce hypercalcemia (high levels  
of calcium in the blood) in patients with  
parathyroid cancer.
- To reduce high levels of calcium in the  
blood (hypercalcemia) in patients with  
primary hyperparathyroidism when  
removal of the gland is not possible.

### Therapeutic group:

The medicine controls the levels of  
calcium and has anti-parathyroid activity.  
It is used to treat ailments caused by  
impaired function of organs called the  
parathyroid glands.

### 2. BEFORE USING THE MEDICINE

#### Do not use this medicine if:

you are sensitive (allergic) to the active  
ingredient – cinacalcet or to any of the  
additional ingredients contained in the  
medicine (listed in section 6).

### Special warnings regarding use of the medicine:

Consult your doctor or pharmacist or  
nurse before taking Cinacalcet Teva.

### Before treatment with Cinacalcet Teva, tell the doctor if:

You have, or have had:

- **epileptic attacks** (seizures or  
convulsions). There is an increased  
risk of such attacks in patients who have  
already had them in the past.
- **liver problems.**
- **heart failure.**

Life-threatening events and deaths  
associated with low blood calcium levels  
(hypocalcemia) have been reported in  
patients taking cinacalcet.

Low calcium levels can affect your  
heart rhythm. Inform your doctor if you  
experience a particularly rapid heart beat,  
if you have heart rhythm problems, or if  
you are taking medicines known to cause  
heart rhythm problems, during treatment  
with Cinacalcet Teva.

For further information, see section 4 -  
"Side effects".

### Smoking:

During treatment with Cinacalcet Teva,  
tell the doctor:

- if you start or stop smoking, as this may  
affect the way the medicine works.

### Children and adolescents:

This medicine is not intended for children  
under the age of 18 years.

### Tests and follow-up:

The doctor will refer you for regular blood  
tests during the course of treatment with  
the medicine to check your response to  
this medicine and will adjust the dosage  
as necessary, to regulate the calcium  
levels.

### Drug interactions:

**If you are taking, or have recently  
taken, other medicines, including  
non-prescription medicines and  
nutritional supplements, tell the  
doctor or pharmacist.** In particular, if  
you are taking:

Medicines such as these that may affect  
the activity of Cinacalcet Teva:

- medicines for treatment of **skin** and  
**fungal infections** (e.g., ketoconazole,  
itraconazole and voriconazole)
- medicines for treatment of **bacterial  
infections** (e.g., telithromycin,  
rifampicin and ciprofloxacin)
- medicines for treatment of **HIV** infection  
and **AIDS** (e.g., ritonavir)
- medicines for treatment of **depression**  
(fluvoxamine)

Cinacalcet Teva may affect the activity of  
the following medicines:

- medicines for treatment of **depression**  
(e.g., amitriptyline, desipramine,  
nortriptyline and clomipramine)
- medicines for treatment of **heart  
rhythm disturbances** (e.g., flecainide  
and propafenone)
- medicines for treatment of **hypertension**  
(e.g., metoprolol)

### Use of the medicine and food:

This medicine should be taken during or  
immediately after a meal.

### Pregnancy and breastfeeding:

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

Cinacalcet Teva has not been tested in  
pregnant women. In case of pregnancy,  
your doctor may decide to modify your  
treatment, as the medicine might harm  
the unborn baby.

It is not known whether Cinacalcet Teva is  
secreted into breastmilk. Your doctor will  
discuss with you if you should discontinue  
either breastfeeding or treatment with  
Cinacalcet Teva.

### Driving and using machines:

The effect of the medicine on the ability  
to drive and use machines has not been  
tested. Dizziness and seizures have  
been reported by patients treated with  
this medicine. If you experience any of  
these side effects of the medicine, your  
ability to drive or operate machinery may  
be affected.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to  
the doctor's instructions. Check with the  
doctor or pharmacist if you are uncertain  
about the dosage and treatment regimen  
of the preparation.

**The dosage and treatment regimen will  
be determined by the doctor only. The  
usual dosage is generally:**

If you are being treated for secondary  
hyperparathyroidism:

The usual starting dosage for Cinacalcet  
Teva is 30 mg (one tablet) once per day.

If you are being treated for parathyroid  
cancer or primary hyperparathyroidism:

The usual starting dosage for Cinacalcet  
Teva is 30 mg (one tablet) twice per day.

**Do not exceed the recommended  
dose.**

### Instructions for use

- Swallow the medicine with water.
- Take the medicine during or immediately  
after a meal.

### Crushing/halving/chewing

- Swallow the tablet whole and do not  
halve it.
- There is no information regarding  
crushing and pulverizing the tablet.

**If you accidentally took a higher  
dosage,** you may experience: numbness  
or tingling around the mouth, muscle  
aches or cramps, and convulsions. If you  
took an overdose or if a child 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 this medicine** at  
the designated time, do not take a double  
dose; take the next dose at the regular  
time.

Adhere to the treatment as recommended  
by the doctor.

Even if there is an improvement in your  
health, do not stop treatment with the  
medicine without consulting the doctor.

**If you stop taking the medicine:** If you  
want to stop using the medicine, consult  
a doctor or pharmacist.

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

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

### 4. SIDE EFFECTS

As with any medicine, use of Cinacalcet  
Teva may cause side effects in some  
users. Do not be alarmed when reading  
the list of side effects. You may not suffer  
from any of them.

**Refer to a doctor immediately if you  
experience any of the following side  
effects:**

- numbness or tingling around the mouth
- muscle aches
- muscle cramps
- convulsions

These may be signs that your calcium  
levels are too low (hypocalcemia).

### Additional side effects:

**Very common side effects (effects  
that may occur in more than one in  
ten patients):**

- nausea and vomiting. These side effects  
are normally quite mild and do not last a  
long time

**Common side effects (effects that may  
occur in one out of ten patients):**

- dizziness
- numbness or tingling sensation of the  
skin (paresthesia)
- lack of or decreased appetite
- muscle pains
- weakness
- rash
- reduced testosterone levels
- high potassium levels in the blood  
(hyperkalemia)
- allergic reaction (hypersensitivity)
- headache
- convulsions/seizures
- low blood pressure
- upper respiratory tract infection
- breathing difficulties (dyspnea)
- cough
- indigestion (dyspepsia)
- diarrhea
- abdominal pain, pain in the upper  
abdomen
- constipation
- muscle cramps
- back pains
- low calcium levels in the blood  
(hypocalcemia)

**Possible side effects of unknown  
frequency:**

- hives/itching (urticaria)
- swelling of the face, lips, mouth, tongue  
or throat, which may cause difficulty in  
swallowing or breathing (angioedema)
- unusually fast heart rhythm or unusual  
heartbeat, which may be associated with  
low levels of calcium in the blood (QT  
prolongation and ventricular arrhythmia  
secondary to low blood calcium levels)

In a small number of patients with heart  
failure who took cinacalcet, their condition  
worsened and/or they suffered from low  
blood pressure.

### Children and adolescents

The use of cinacalcet in children and  
adolescents has not been established.  
A death of a patient with very low blood  
calcium levels (hypocalcemia) was  
reported in a clinical trial in adolescents.

**If a side effect occurs, if one of the  
side effects worsens or if you suffer  
from a side effect not mentioned in the  
leaflet, consult the doctor.**

### Reporting side effects

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](http://www.health.gov.il)) that directs you to the  
online form for reporting side effects, or  
by entering the link:  
<https://sideeffects.health.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 and sight of  
children and/or infants in order 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/blister. The expiry date refers  
to the last day of that month.
- **Store below 25°C. Store in the  
original 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.

### 6. FURTHER INFORMATION

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

Microcrystalline cellulose, Starch  
pregelatinised, Crospovidone, Polyvinyl  
alcohol, Titanium dioxide, Macrogol 3350  
(Polyethylene glycol), Silica colloidal  
anhydrous, Magnesium stearate, Talc,  
Yellow iron oxide, FD&C blue #2 (Indigo  
carmine aluminium lake).

**What the medicine looks like and the  
contents of the package:**

Cinacalcet Teva 30 mg:

An oval, coated, light green to green  
tablet, with "C 30" debossed on one side  
and no debossing on the other side of  
the tablet.

Cinacalcet Teva 60 mg:

An oval, coated, light green to green  
tablet, with "C 60" debossed on one side  
and no debossing on the other side of  
the tablet.

Cinacalcet Teva 90 mg:

An oval, coated, light green to green  
tablet, with "C 90" debossed on one side  
and no debossing on the other side of  
the tablet.

Cinacalcet Teva is packaged in trays  
(blisters) or in bottles. The blister package  
contains 14, 28, 30 or 84 tablets. The  
bottle package contains 30 tablets.

Not all package sizes may be marketed.

**Name of License Holder and  
Manufacturer and its Address:**

Teva Pharmaceutical Industries Ltd.,  
P.O.B. 3190, Petah-Tikva.

The leaflet was revised in August 2020

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

30 mg: 154.47.34190

60 mg: 154.48.34191

90 mg: 154.49.34186