

ONCAZIL[®] (strodocazil)

This summary contains important information about Oncazil.

It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking Oncazil. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about Oncazil.

Oncazil is:

Oncazil is a drug used, along with diet and exercise, for the medical management of excess weight, including weight loss and the maintenance of weight loss, in adults and children 12 years and older. Oncazil is approved for use in overweight people with an initial body mass index (BMI) of 25 or higher. BMI varies by height and weight. For example, a person whose height is 5 feet 10 inches and weighs 175 has a BMI of 25. Your doctor can determine your BMI and will decide if you meet this level.

Who Should Not Use Oncazil

Oncazil should not be used if:

- you have liver damage
- you have experienced a heart attack or stroke
- you have had the flu within the last three weeks
- you are pregnant

If you have any concerns or questions about whether you should take Oncazil, talk to your doctor.

IMPORTANT: Make sure that your primary care doctor and all your other healthcare providers know what medicines you take and what medical conditions and allergies you have.

Medicine Interactions

Tell your doctor if you are taking:

- antibiotics (Oncazil may lose its effectiveness).
- NSAIDs (non-steroidal anti-inflammatories) such as Advil, Aleve, Motrin. Taking Oncazil with NSAIDs may create high levels of Oncazil in your bloodstream.
- over-the-counter cough and cold medicines, allergy products, and decongestants. Some contain medicines such as phenylpropanolamine, ephedrine, or pseudo ephedrine that may raise blood pressure or heart rate while taking Oncazil.

Warnings & Precautions

• Using over-the-counter or prescription antifungal medicines (for example, Lamisil) at the same time as Oncazil may cause a dangerous increase in blood pressure. Patients considering the use of antifungal medicines should talk to their doctor before starting such therapy.

• Patients with a history of kidney disease should be monitored carefully and placed on the lowest starting dose of Oncazil (see also **Monitoring Requirements**).

Side Effects

The following are the most common side effects reported in people taking Oncazil in clinical trials: fainting, mood swings, diarrhea, rash, nausea, vomiting, weakness, and difficulty swallowing.

Special Populations

Children

Oncazil has been studied in children as young as twelve years. Children should be given the lowest dosage possible and this dosage should never exceed 100 mg. Patients should be monitored for kidney functioning, as developing kidneys may be more sensitive to the effects of Oncazil.

Elderly

Oncazil has not been studied in adults over the age of 65.

Pregnancy

Oncazil should not be used during pregnancy. Animal studies showed that Oncazil may cause abnormal heart rates in infants before and after birth. It is not clear what consequences this may have for the developing fetus. Therefore, Oncazil is not recommended for use in pregnancy. Tell your doctor if you are pregnant or plan to get pregnant.

Clinical Trial Information

What tests were conducted

Oncazil was studied in three large trials with over 10,000 men and women. Oncazil was compared to placebo (pill with no medicine in it) to see if people lost more weight than without the drug.

How long clinical trials lasted

In two studies, patients took Oncazil for 12 weeks. In the third study, patients were followed for 18 months.

How Long It Takes to Work

Once you take your first pill, Oncazil will begin working immediately. As long as you remember to take a pill at the same time every week, you will not experience any changes in its effectiveness.

Different Dosage Forms

Oncazil is available in a once-a-week formulation.

Dosing

Your prescription for Oncazil will include up to twelve pills. Choose a time that you can remember each week. At that time, take one tablet with a full glass of water. Take one pill at the same time once a week.

What to do if a Dose is Missed

If you forget to take a pill during the first two days, take it as soon as you remember, record the date, and tell your doctor at your next visit. If you remember after the first two days, do not take it until your normally scheduled time and tell your doctor at your next visit.

Monitoring requirements

Your doctor will give you a simple kidney monitoring test every 4 months while you are taking Oncazil to check for heartbeat changes.

Ingredients

Strodocazil, lactose monohydrate, stearic acid, titanium dioxide, red ferric oxide, yellow ferric oxide, carnauba wax.

What to do in the Case of an Overdose

If you take more than the prescribed amount of Oncazil AND experience sharp pains in your chest, call 911 or go to the nearest emergency room.

Abuse Potential

Oncazil has not been shown to be habit-forming or cause withdrawal symptoms.

How Oncazil Works

It is not clear how Oncazil works. It is believed that it changes the function of one of the neurons in the brain that controls metabolic and endocrine function.

Lifestyle Factors to Think About When Taking Oncazil

Oncazil will not take the place of adequate nutrition and exercise. In order to benefit the most from taking Oncazil, talk to your doctor about establishing a good meal plan and exercise routine.

Other Things to Tell the Doctor

- If you are using an antifungal medicine (for example, Lamisil) to treat an infection.
- If you are having trouble remembering to take a pill weekly.
- If you experience any lightheadedness and/or weakness.

Storage

Store Oncazil at room temperature (65-80 degrees F).

General Information about Prescription Drugs

- Only take for what it is prescribed
- Only take as the doctor instructed
- Do not share this prescription with others

Reporting Side Effects

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How to Get More Information

- Talk to your doctor or pharmacist
- Visit www.oncazil.com
- Call 1-800-ONCAZIL

Oncazil
(strodocazil)

10 mg tablets

KAJ  **Pharmaceutica**

St. Louis, MO

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not have all the information needed to use Oncazil safely and effectively. See full prescribing information for Oncazil.

ONCAZIL® (strodocazil) Tablets

Initial U.S. Approval: 2006

-----INDICATIONS AND USAGE-----

Along with diet and exercise, for medical management of excess weight, including weight loss, and weight maintenance in adults and children 12 years and older, with an initial body mass index (BMI) of 25 or higher. Your doctor can determine your BMI and will decide if you meet this level.

-----DOSAGE AND ADMINISTRATION-----

10mg once-weekly by mouth

-----DOSAGE FORMS AND STRENGTHS-----

Tablets: 10mg

-----CONTRAINDICATIONS-----

Do not use Oncazil if

- you have liver damage
- you have experienced a heart attack or stroke
- you have had the flu within the last three weeks
- you are pregnant

If you have any concerns or questions about whether you should take Oncazil, talk to your doctor.

IMPORTANT: Make sure that your primary care doctor and all your other healthcare providers know what medicines you take and what medical conditions and allergies you have.

-----WARNINGS AND PRECAUTIONS-----

- **Antifungal medicines:** Using over-the-counter or prescription antifungal medicines (for example, Lamisil) at the same time as Oncazil may cause a dangerous increase in blood pressure. Patients considering the use of antifungal medicines should talk to their doctor before starting such therapy.
- **Kidney Disease:** Patients with a history of kidney disease should be monitored carefully and placed on the lowest starting dose of Oncazil. Your doctor will give you a simple kidney monitoring test every 4 months while you are taking Oncazil to check for kidney function changes.

-----ADVERSE REACTIONS-----

The following are the most common side effects reported in people taking Oncazil in clinical trials: fainting, mood swings, diarrhea, rash, nausea, vomiting, weakness, difficulty swallowing.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----DRUG INTERACTIONS-----

Tell your doctor before starting or if you are taking:

- antifungals (see Warnings and Precautions, above)
- antibiotics (Oncazil may lose its effectiveness)
- NSAIDs (non-steroidal anti-inflammatories) such as Advil, Aleve, Motrin. Taking Oncazil with NSAIDs may create high levels of Oncazil in your bloodstream.
- Over-the-counter cough and cold medicines, allergy products and decongestants. Some contain medicines such as phenylpropanolamine, ephedrine, or pseudo ephedrine that may raise blood pressure or heart rate while taking Oncazil.

-----USE IN SPECIFIC POPULATIONS-----

- **Children:** Children should be given the lowest dosage possible and this dosage should never exceed 100 mg. Patients should be monitored for kidney functioning, as developing kidneys may be more sensitive to the effects of Oncazil.
- **Elderly:** Oncazil has not been studied in adults over the age of 65.
- **Pregnancy:** Oncazil should never be used during pregnancy. Oncazil may cause abnormal heart rates in infants before and after birth.

Revised: 11/2006

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ONCAZIL[®] (strodacazil) Tablets

This summary contains important information about ONCAZIL ("ON-kah-zeel"). It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking ONCAZIL. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ONCAZIL.

What is ONCAZIL?

Oncazil is a drug used, along with diet and exercise, for the medical management of excess weight, including weight loss and the maintenance of weight loss, in adults and children 12 years and older. Oncazil is approved for use in overweight people with an initial body mass index (BMI) of 25 or higher. Your doctor can determine your BMI and will decide if you meet this level.

Who Should Not Use ONCAZIL?

Oncazil should not be used if:

- you have liver damage
- you have experienced a heart attack or stroke
- you have had the flu within the last three weeks
- you are pregnant

If you have any concerns or questions about whether you should take Oncazil, talk to your doctor.

IMPORTANT: Make sure that your primary care doctor and all your other healthcare providers know what medicines you take and what medical conditions and allergies you have.

What Warnings and Precautions Should I Know About ONCAZIL?

- Using over-the-counter or prescription antifungal medicines (for example, Lamisil) at the same time as Oncazil may cause a dangerous increase in blood pressure. Patients considering the use of antifungal medicines should talk to their doctor before starting such therapy.
- Patients with a history of kidney disease should be monitored carefully and placed on the lowest starting dose of Oncazil. Your doctor will give you a simple kidney monitoring test every 4 months while you are taking Oncazil to check for kidney function changes.

What Other Medicines May Interact with ONCAZIL?

Tell your doctor if you are taking:

- antifungals (see Warnings and Precautions, above)
- antibiotics (Oncazil may lose its effectiveness)
- NSAIDs (non-steroidal anti-inflammatories) such as Advil, Aleve, Motrin. Taking Oncazil with NSAIDs may create high levels of Oncazil in your bloodstream.
- over-the-counter cough and cold medicines, allergy products and decongestants. Some contain medicines such as phenylpropanolamine, ephedrine, or pseudoephedrine that may raise blood pressure or heart rate while taking Oncazil.

What Should I Know About Use in Children?

Children

Oncazil has been studied in children as young as twelve years. Children should be given the lowest dosage possible and this dosage should never exceed 100 mg. Patients should be monitored for kidney functioning, as developing kidneys may be more sensitive to the effects of Oncazil.

What Should I Know About Use in the Elderly?

Elderly

Oncazil has not been studied in adults over the age of 65.

What Should I Know About Use in Pregnant or Nursing Women?

Pregnancy

Oncazil should not be used during pregnancy. Animal studies showed that Oncazil may cause abnormal heart rates in infants before and after birth. It is not clear what consequences this may have for the developing fetus. Therefore, Oncazil is not recommended for use in pregnancy. Tell your doctor if you are pregnant or plan to get pregnant.

What are the Side Effects of ONCAZIL?

The following are the most common side effects reported in people taking Oncazil in clinical studies:

- fainting
- mood swings
- diarrhea
- rash
- nausea
- vomiting
- weakness
- difficulty swallowing

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Rx only

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10mg tablets

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Prescription Drug Facts

Indication Along with diet and exercise, for medical management of excess weight, including weight loss and maintenance of weight loss in adults and children 12 years and older with an initial body mass index (BMI) of 25 or higher. Your doctor can determine your BMI and will decide if you meet this level.

Warnings

Do not use with antifungal drugs such as Lamisil. This may cause a dangerous increase in blood pressure.

Do not use if you

- have liver damage
- had a prior heart attack or stroke
- had the flu within the last three weeks
- are pregnant

Ask a doctor before use if you have kidney disease. Patients with a history of kidney disease should be monitored carefully and placed on the lowest starting dose of ONCAZIL. Your doctor will give you a simple kidney monitoring test every 4 months while you are taking ONCAZIL to test for kidney function changes.

Ask a doctor before use if you are taking

- antifungal drugs. Taking ONCAZIL with antifungal drugs can cause your blood pressure to go up to dangerous levels.
- antibiotics. ONCAZIL may lose its effectiveness.
- NSAIDs (non-steroidal anti-inflammatory drugs) such as Advil, Aleve, Motrin. Taking ONCAZIL with NSAIDs may create high levels of ONCAZIL in your bloodstream.
- over-the-counter cough and cold medicines, allergy products and decongestants. Some contain medicines such as phenylpropanolamine, ephedrine, or pseudo ephedrine that may raise blood pressure or heart rate while taking Oncazil.

When using this product you may have

- fainting
- mood swings
- diarrhea
- rash
- nausea
- vomiting
- weakness
- difficulty swallowing

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

If pregnant or breast feeding, do not use this product.

Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.

Other information ■ Rx only ■ 10mg tablets ■ Last updated 11/2006

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