



U.S. Food and Drug Administration

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# DTC Research Update

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# Outline

- Overview of research in progress
- *Brief* preliminary results from Brief summary study 1 (*purpose*)
- Preliminary results from Brief summary study 3 (*format*)



# Selected Research in Progress 1

- Improvement of the **Brief Summary** in DTC Print Ads
- Visual **Distraction** During Risk in DTC Television Ads
- Presentation of **Efficacy** Information in DTC Print Ads



# Selected Research in Progress 2

- Toll-Free Number for Reporting Side Effects in DTC Television Ads
- Presentation of Quantitative Information in DTC Print and Television Ads
- Impact of Incentives in DTC Print Ads



# Brief Summary

How to Improve the Presentation of  
Brief Summary Information in DTC  
Print Advertisements





# Brief Summary Studies Overview

- Study I
  - Investigate the current brief summary format
- Study II
  - Test different ways of presenting side effect information
- Study III
  - Test different formats



# Brief Summary Study 1 Purpose

- How do people use the brief summary *in its current form*?
- Does risk information on promotion page affect use of brief summary?



# Brief Summary Study 1

## Specific Questions

- Does risk info or medical condition affect:
  - ✦ time spent reading the ad
  - ✦ comprehension
  - ✦ selection of topics
  - ✦ intent to ask doctor for info
- What brief summary topics are most useful?



# Brief Summary Study 1 Design

		Medical Condition		
		Asthma	High Cholesterol	Excess Weight
Low Risk Ad				
High Risk Ad				





Introducing

**Oncazol**  
(strodocazol)

A New Option for Asthma



### A New Option for YOU

Are you looking for a new way to help control your asthma? Ask your doctor if prescription Oncazol is right for you!

Oncazol is a new treatment for asthma problems that you take only once a week.

Now you don't have to think about taking a pill every day. Leave that nagging feeling behind for the entire week!

Oncazol is generally safe and effective. Clinical trials have shown that it helps provide safe and effective asthma symptom control. Individual results may vary.

**Important Information:**

Oncazol will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.

In rare cases, Oncazol may cause serious heart valve problems that begin with a noticeable change in heart rhythm. Also, in rare cases, Oncazol may cause a mild and temporary skin sensitivity to heat. If it does not go away in two days, call your doctor. Other side effects include dry mouth, upset stomach and headache.

Please see important information on the next page.

To learn more about a once-a-week treatment, talk to your doctor about Oncazol or go online at [www.oncazil.com](http://www.oncazil.com) or call 1-800-ONCAZIL.

**Oncazol**  
(strodocazol)  
10 mg tablets

KAJ-Pharmaceutica

AH 5



## ONCAZIL (strodocazil)

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 Oncazel. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about Oncazel.

### Oncazel is:

Oncazel is a drug used to treat asthma in adults and children as young as 12 years.

Oncazel will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.

### Who Should Not Use Oncazel

Oncazel should not be used if:

- you have liver damage
- you have experienced a heart attack or stroke
- you have recently had the flu
- you are pregnant

### Medicine Interactions

Tell your doctor if you are taking:

- antibiotics (Oncazel may lose its effectiveness).
- NSAIDs (non-steroidal anti-inflammatories; Advil, Aleve, Motrin) (Can increase the amount of Oncazel in your bloodstream).

### Warnings

**Heart Valve Damage:** Rare but serious heart valve problems have been reported with the use of Oncazel. Generally, these problems begin with a noticeable change in heart rhythm. Notify your doctor immediately if you experience a strange heartbeat pattern, or pain in your chest or down your left arm.

### Precautions

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

### Side Effects

#### Serious but Rare

Heart valve damage has been noted in rare cases (see also Warnings). Other rare but serious side effects include severe cough and chest pain.

#### Common Side Effects

Other side effects have been reported in those taking Oncazel. These side effects are generally mild or moderate and go away within a few days. These side effects include a temporary skin sensitivity to heat, dry mouth, headache, and upset stomach.

### Special Populations

#### Children

Oncazel 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 young kidneys may be more sensitive to the effects

of Oncazel.

#### Elderly

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

#### Pregnancy

Oncazel should not be used during pregnancy. Animal studies showed that Oncazel 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, Oncazel 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

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

#### How long clinical trials lasted

In two studies, patients took Oncazel 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, Oncazel 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

Oncazel is available in a once-a-week and a once-a-day formulation. Talk to your doctor about the best dosing form for you.

### Dosing

Your prescription for Oncazel 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 Oncazel to check for kidney function 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 Oncazel AND experience sharp pains in your chest, call 911 or go to the nearest emergency room.

### Abuse Potential

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

### How Oncazel Works

It is believed that Oncazel changes the function of one of the neurons in the brain that controls respiratory functions.

### Lifestyle Factors to Think About When Taking Oncazel

Oncazel will not take the place of fast-acting inhalers for sudden symptoms. In order to benefit the most from taking Oncazel, talk to your doctor about identifying specific asthma triggers that affect you and how to avoid them.

### Other Food and Medicines You May Be Taking

**Caffeine.** Oncazel does not interact with caffeine.

**Alcohol.** Use caution when drinking alcohol and taking Oncazel. Oncazel may speed up the effects of alcohol.

**Herbal supplements.** Oncazel is not known to interact with any herbal substances, but tell your doctor if you take any.

**Over-the-Counter Drugs.** NSAIDs (Advil, Aleve, Motrin) may cause more of Oncazel to build up in your bloodstream, causing an upset stomach.

### Other Things to Tell the Doctor

- If you develop a temporary skin sensitivity to heat.
- If you are having trouble remembering to take a pill weekly.
- If you experience any lightheadedness and/or weakness.

### Storage

Store Oncazel 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](http://www.oncazil.com)
- Call 1-800-ONCAZIL

Rx only

10 mg tablets

**Oncazel**  
(strodocazil) **KAJ** Pharmaceuticals  
St. Louis, MO  
AH 5



© 2009  
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# Brief Summary Study 1

## Sample Characteristics

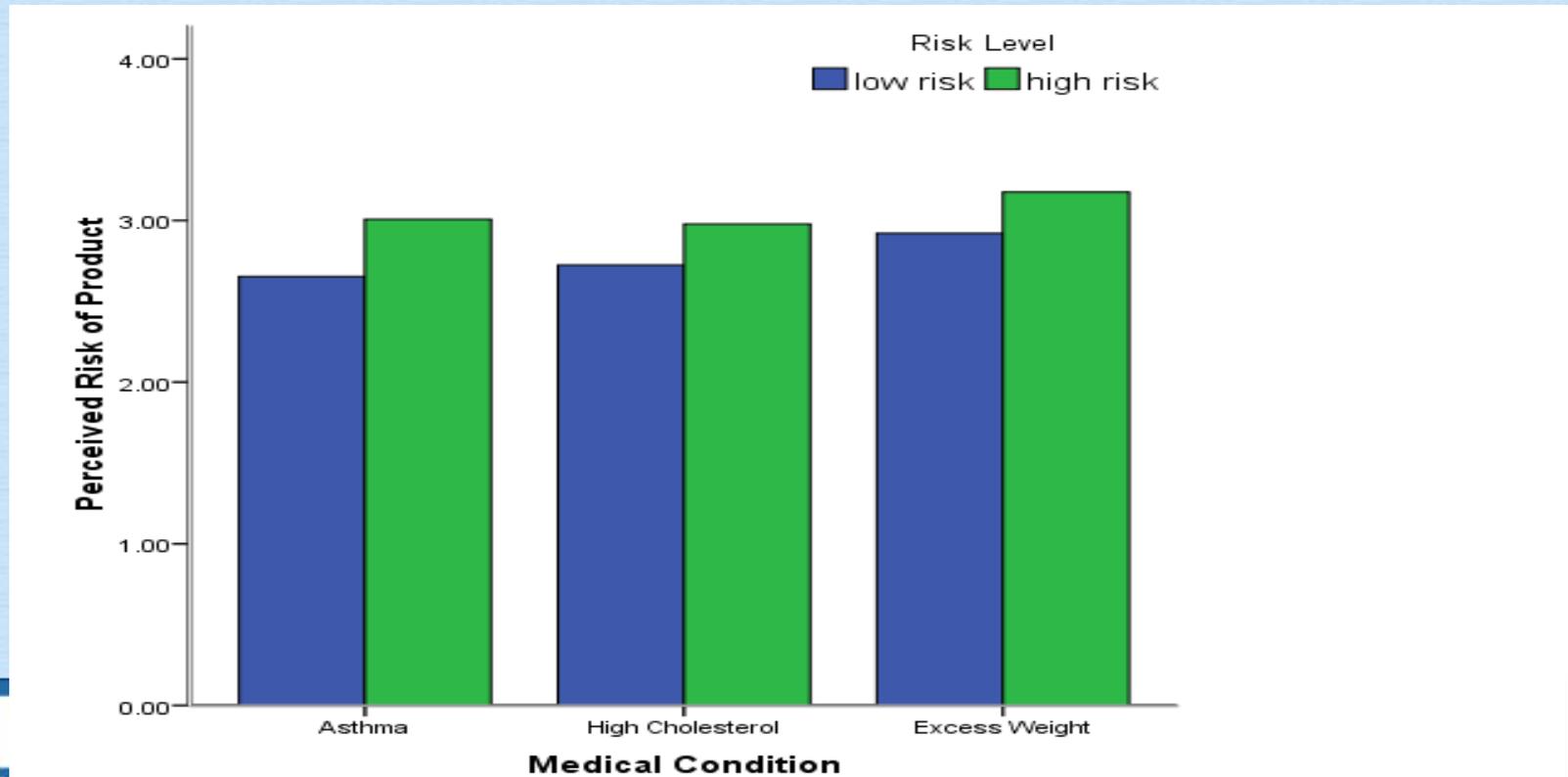
- 52% female
- 55% white
- 85% non-Hispanic
- 32% high school graduate or less
- Mean Age: 36 years (*range 18-81*)
  
- 79% sufferers (*N = 629*)
- 21% caregivers (*N = 171*)

*N* = 800



# Brief Summary Study 1 Manipulation Check

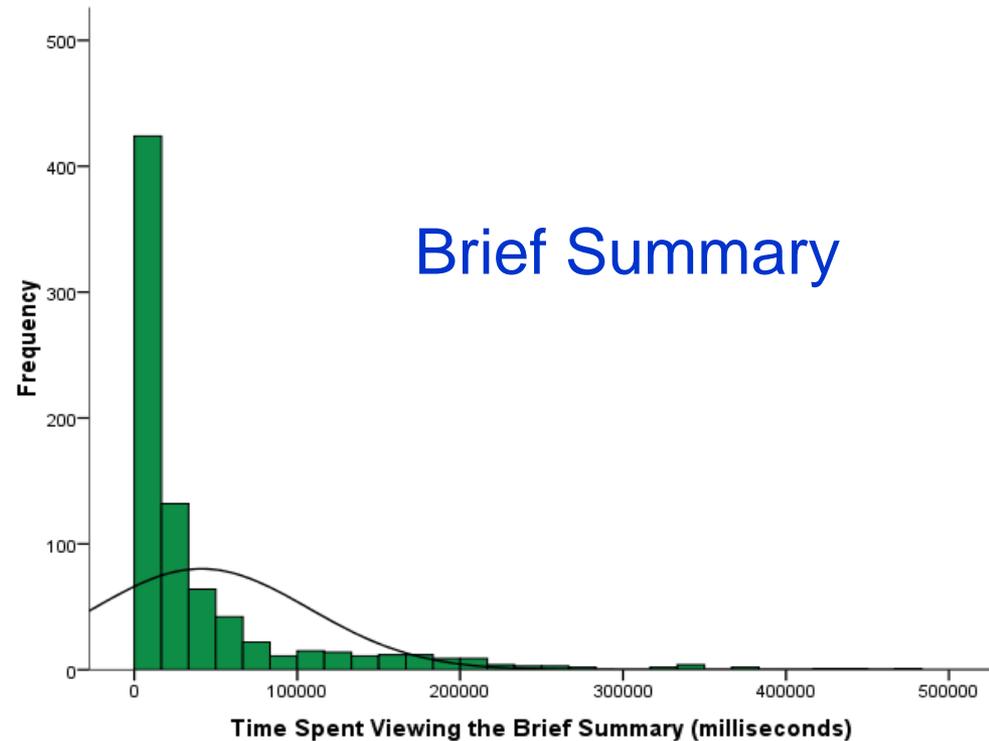
Participants in all three medical conditions rated the product in the high risk ad as more risky than the product in the low risk ad.



# How much time did participants spend reading the promotion page and the brief summary?



Average time = 26.12 seconds  
(Range = 0.52 to 183.38 seconds)  
**median = 18.47 seconds**



Average time = 41.08 seconds  
(Range = 0.34 to 478.60 seconds)  
**median = 13.87 seconds**

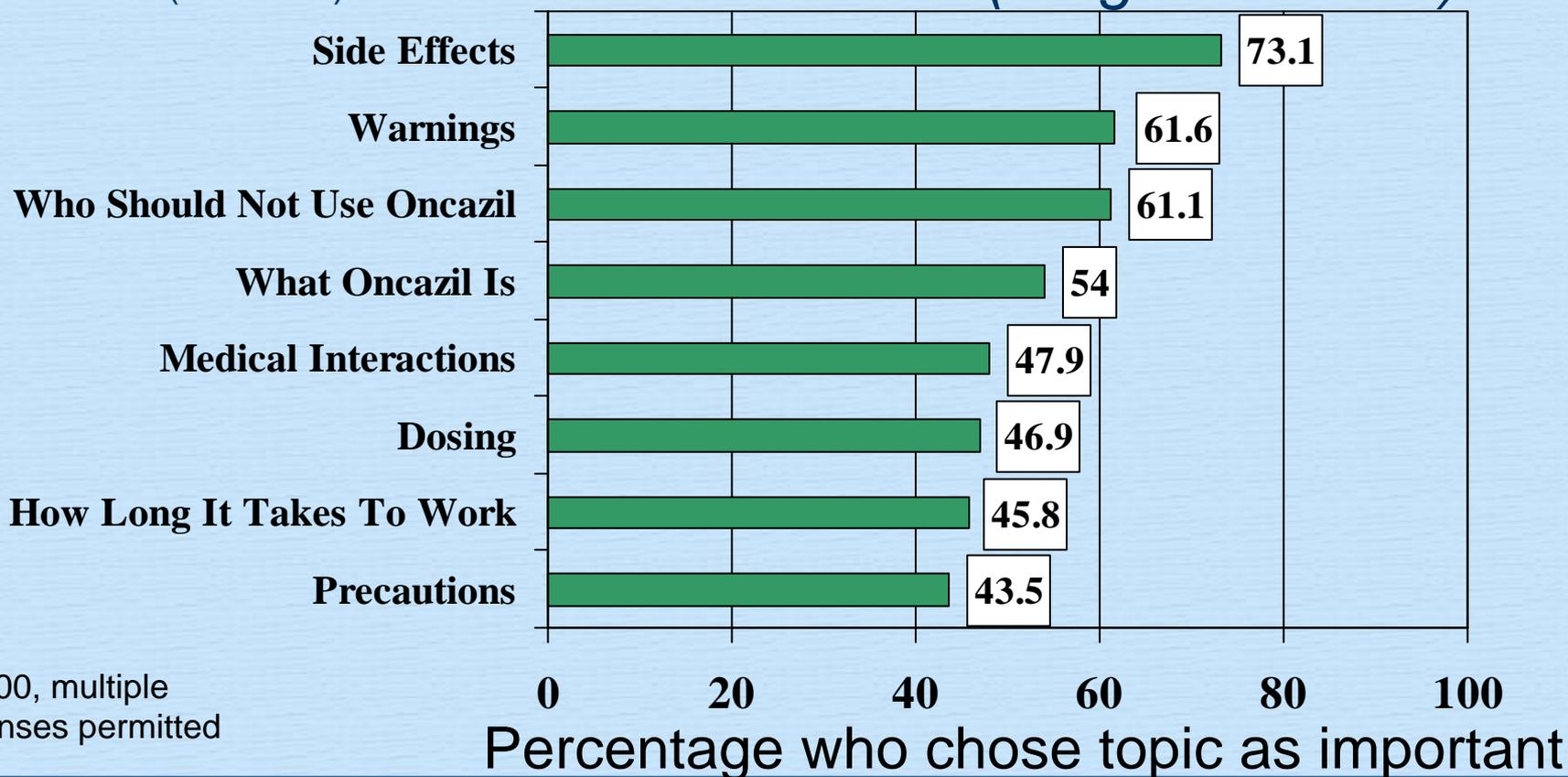


# What brief summary topics were selected as useful?

Average number of topics selected = 8.37

(SD=6.17)

(range = 0 to 24)



N = 800, multiple responses permitted



# Brief Summary Study 1

## Preliminary Conclusions

- The presence of a serious risk did not change time spent, comprehension, number of topics selected, or intent to ask doctor about Oncazil
- In general, results were consistent across medical conditions
- Time spent on the ad predicted comprehension, number of topics selected and intent to ask doctor
- Health literacy and age were consistent factors



Introducing

**Oncazil**  
(strodocazil)

A New Option for Asthma



## A New Option for YOU

Are you looking for a new way to help control your asthma? Ask your doctor if prescription Oncazil is right for you!

Oncazil is a new treatment for asthma problems that you take only once a week.

Now you don't have to think about taking a pill every day. Leave that nagging feeling behind for the entire week!

Oncazil is generally safe and effective. Clinical trials have shown that it helps provide safe and effective asthma symptom control. Individual results may vary.

**Important Information:** Oncazil will not replace fast-acting inhalers for sudden symptoms. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks. In rare cases, Oncazil may cause serious heart valve problems that begin with a noticeable change in heart rhythm. Also, in rare cases Oncazil may cause a mild and temporary skin sensitivity to heat. If it does not go away in two days, call your doctor. Other side effects include dry mouth, upset stomach, and headache.

Please see important information on the next page.

To learn more about a once-a-week treatment, talk to your doctor about Oncazil or go online at [www.oncazil.com](http://www.oncazil.com) or 1-800-ONCAZIL.

**Oncazil**  
(strodocazil)  
10 mg tablets

KAJ-Pharmaceutica

AH 5



## 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](http://www.oncazil.com)
- Call 1-800-ONCAZIL

**Oncazil**  
(strodocazil)

10 mg tablets

KAJ-Pharmaceutica

St. Louis, MO

# Brief Summary Format

- Which format or formats present risk information in the most useful manner?
- Traditional
- Question & Answer
- Highlights
- Prescription Drug Facts Box



## ONCAZIL<sup>®</sup> (strodamazil)

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

Strodamazil, 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](http://www.oncazil.com)
- Call 1-800-ONCAZIL

**Oncazil**  
(strodamazil)

10 mg tablets

**KAJ** ♦ **Pharmaceutica**

St. Louis, MO



# Q&A

## ONCAZIL<sup>®</sup> (strodocazil) 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?

Oncazol 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. Oncazol 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?

Oncazol 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 Oncazol, 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 Oncazol 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 Oncazol. Your doctor will give you a simple kidney monitoring test every 4 months while you are taking Oncazol 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 (Oncazol may lose its effectiveness)
- NSAIDs (non-steroidal anti-inflammatories) such as Advil, Aleve, Motrin. Taking Oncazol with NSAIDs may create high levels of Oncazol 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 Oncazol.

### What Should I Know About Use in Children?

#### Children

Oncazol 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 Oncazol.

### What Should I Know About Use in the Elderly?

#### Elderly

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

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

#### Pregnancy

Oncazol should not be used during pregnancy. Animal studies showed that Oncazol 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, Oncazol 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 Oncazol 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](http://www.fda.gov/medwatch).

### Rx only

**Oncazol**  
(strodocazil) 10mg tablets  
KAJ  Pharmaceutica  
St. Louis, MO



# Highlights

## 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® (strodacazil) 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](http://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

**Oncazil**  
(strodacazil) 10mg tablets  
**KAJ** ♦ **Pharmaceutica**  
St. Louis, MO



## ONCAZIL<sup>®</sup> (strodocazil) Tablets

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.

### 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 phenylpropranolamine, 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](http://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



# Brief Summary Format

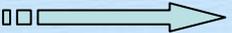
How did format affect:

- Reported intention to ask a doctor?
- Risk/benefit tradeoff?
- Participants' beliefs that they could understand the information?
- Participants' preference?
- Comprehension of risk information?



# Format Methodology

## Mall-intercept

- View an ad for a drug to treat excess weight
- Computer-administered
- Viewed 1 of 4 formats  Questions
- Viewed all 4 formats  Questions



# Format Sample

N = 300

<b>Gender</b>	<b>50% male; 50% female</b>	
Ethnicity	72% Caucasian; 19% African-American; < 1% Asian; 7% Other	
	Mean ( <i>SD</i> )	Range
<b>Age (in years)</b>	<b>34 (12.93)</b>	<b>18-77</b>
BMI	33 (6.95)	19.20-55.09



# Format Analyses

- Analysis of Variance (ANOVA)
- Covariates included:
  - Age
  - Gender
  - Race
  - Educational level
  - Body Mass Index (BMI)
  - Time spent viewing the brief summary



# Format Preliminary Results

- No differences in reported intention to ask a doctor about Oncazil
  - »  $F(3, 278) = 0.47, p > .05$
- No differences in risk/benefit tradeoff
  - »  $F(3, 278) = 0.57, p > .05$



# Format Preliminary Results

- Self-efficacy: A person's belief in ability to succeed in a particular situation (*confidence*)
- We tailored Albert Bandura's original scale to ask participants specifically about their ability to use the brief summary

*e.g. "[How confident are you that you could] identify who should not take this drug?"*



# Format Self-Efficacy

	Traditional	Q&A	Highlights	Drug Facts	Total
	7.19 (1.87)	7.46 (1.84)	7.58 (1.80)	8.03 (1.63)	7.57 (1.80)
N	71	78	75	76	300

Scale ranged from 0 (*not at all confident*) to 10 (*completely confident*)

$F(3, 278) = 2.57, p = .05$





# Format Preferences

## Attitude toward the ad

- Measured two ways:
  - 10-item Likert scale from 1 (*strongly disagree*) to 5 (*strongly agree*)
    - Cronbach's  $\alpha = .83$
    - Between subjects
  - 6-item scale from 1 (*not at all*) to 10 (*very/extremely*)
    - Cronbach's  $\alpha$ s = .80-.92
    - Within subjects



# Format Preferences

## Attitude toward the ad

- *Between Subjects*: each person saw and rated only one ad

	Traditional	Q&A	Highlights	Drug Facts	Total
	3.49 (0.58)	3.78 (0.58)	3.71 (0.54)	4.03 (0.64)	3.76 (0.61)
N	71	78	75	76	300

Scale ranged from 1 (*strongly disagree*) to 5 (*strongly agree*)

$$F(3, 278) = 10.36, p < .001$$



# Format Preferences

Attitude toward the ad

- *Within Subjects*: each person saw and rated all four ads

Traditional	Q&A	Highlights	Drug Facts
6.14 (2.36)	6.99 (1.74)	7.04 (1.65)	8.22 (1.74)

Scale ranged from 1 (*not at all*) to 10 (*very/extremely*)

$F(3, 297) = 2.90, p < .05$



# Format Preferences

## Ranking of Ads

	Traditional	Q&A	Highlights	Rx Drug Facts
1 <sup>st</sup>	60 (20%)	40 (13%)	38 (13%)	162 (54%)
2 <sup>nd</sup>	65 (22%)	96 (32%)	74 (25%)	65 (22%)
3 <sup>rd</sup>	54 (18%)	120 (40%)	89 (30%)	37 (12%)
4 <sup>th</sup>	121 (40%)	44 (15%)	99 (33%)	36 (12%)



# Format Comprehension

Measured two ways:

- 12-item recall scale
  - True/False: scores range from 0-12
  - “You must be at least 18 years old to take Oncazil”
- 4-item application scale
  - Yes/No: scores range from 0-4
  - “You have been taking medicine for kidney disease. Can you take Oncazil?”



# Format Comprehension

	Traditional	Q&A	Highlights	Drug Facts
Recall	6.89 (1.98)	7.13 (1.75)	7.24 (2.30)	7.60 (1.70)
Application	2.41 (0.95)	2.49 (1.09)	2.51 (1.09)	2.51 (1.09)
N	71	78	75	76

Recall:

*Range: 0-12*

$F(3, 278) = 2.69, p < .05$

Application:

*Range: 0-4*

$F(3, 278) = 0.42, p > .05$



# Format Summary

- No differences in behavioral intention or risk/benefit tradeoff
- Rx Drug Facts format scored highest in:
  - Self-efficacy
  - Rated preference for ad
  - Recall comprehension



# Format Summary

## Participant rankings

1. Rx Drug Facts Box
2. Question & Answer
3. Traditional
4. Highlights



# Format Implications

- Preliminary data: no forms are dismissed at this point
- Support for altering format of brief summary
- Additional studies to determine content of brief summary forthcoming



# Brief Summary Next Steps

- Analyses of Study 2 are ongoing
- Content manipulations:
  - Addition of efficacy information
  - Addition of side effect frequency information
  - Addition of framing of side effects
- Additional format variation exploration



# Online FDA Resources

- General FDA information:
  - [www.fda.gov](http://www.fda.gov) **NEW!**
- DDMAC home page:
  - <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm> **NEW!**
- Interested in a DDMAC job?:
  - [DDMACJOBS@fda.hhs.gov](mailto:DDMACJOBS@fda.hhs.gov)
  - Contact info: [amie.odonoghue@fda.hhs.gov](mailto:amie.odonoghue@fda.hhs.gov)

