

# Drug Safety Labeling Changes (SLC) Quick Reference

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The Drug Safety Labeling Changes (SLC) database provides approved safety labeling changes from January 2016 forward. Data prior to January 2016 will continue to be available on the MedWatch website.

## How to Search by Drug Name (brand or generic) or Active Ingredient

Enter at least three characters. Searches use predictive text.

### Drug Name Search

Drug Name or Active Ingredient:

## How to Search by Date

Enter date range (January 2016 forward). All labeling sections will be searched unless unchecked.

### Date Search

For Safety Labeling Changes before January 1, 2016 see the [MedWatch Safety Labeling Page](#)

Date Range:

Labeling Section:

<input checked="" type="checkbox"/> Boxed Warning	<input checked="" type="checkbox"/> Adverse Reactions	<input checked="" type="checkbox"/> Drug Interactions
<input checked="" type="checkbox"/> Contraindications	<input checked="" type="checkbox"/> Warnings and Precautions	<input checked="" type="checkbox"/> Use in Specific Populations
<input checked="" type="checkbox"/> PCI/PI/MG (Patient Counseling Information/Patient Information/Medication Guide)		

## How to Search Within Results / Choose Result

Search within multiple results, filter results, sort by column, or select drug name.

visited on 1/19/2018

Filter results:

Drug Name	Active Ingredient	Application Number	Supplement Date	Database Updated
<a href="#">DRUG PRODUCT</a>	DRUG PRODUCT	000000	01/15/2016	08/22/2016
<a href="#">DRUG PRODUCT</a>	DRUG PRODUCT	000000	01/15/2016	05/08/2016
<a href="#">DRUG PRODUCT</a>	DRUG PRODUCT	000000	01/15/2016	05/08/2016
<a href="#">DRUG PRODUCT #2</a>	DRUG PROD #2	000000	01/15/2016	07/11/2016

### How to Download Data Files

Search results can be downloaded and saved in CSV format.

## Drug Safety Labeling Changes (SLC)

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**DRUG PRODUCT** (#000000)  
**(GENERIC NAME)**  
 Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER)

[Download Data](#)

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01/15/2016 (SUPPL-40)

[Approved Drug Label \(PDF\)](#)

**Boxed Warnings**

**WARNINGS: DRUG PRODUCT CAN INCREASE THE RISK OF CARDIOVASCULAR EVENTS**

**Contraindications**  
 Concurrent use of DRUG PRODUCT with other nephrotoxic drugs should be avoided

**Warnings and Precautions**  
 Hepatic impairment can potentiate the response to DRUG PRODUCT and decrease its metabolism. Use DRUG PRODUCT with caution in these patients

**Adverse Reactions**  
 DRUG PRODUCT can cause nausea, vomiting and/or gastrointestinal distress

**Drug Interactions**  
 Alcohol is known to potentiate the effect of DRUG PRODUCT. Patients, therefore, should be warned against excessive alcohol intake while receiving DRUG PRODUCT

**Use in Specific Populations**  
 DRUG PRODUCT should be used with caution in pediatric patients

**PCI/PI/MG (Patient Counseling Information/Patient Information/Medication Guide)**

**Patient Counseling Information**  
 Instruct patients to take DRUG PRODUCT only as prescribed. If a dose is missed, it should be taken as soon as the patient remembers

**Patient Information**  
 What are the possible side effects of DRUG PRODUCT?  
 Dry mouth, cough, headache, nausea, vomiting

**Medication Guide**  
 Eye Disorders  
 Patients taking DRUG PRODUCT should seek immediate medical attention if they experience blurred vision or visual disturbance

Click here to download the approved drug labeling.

Click here to download data in a CSV file.

### How to Access Multiple Supplements

Multiple Supplements within search results can be collapsed or expanded for viewing purposes.

[Expand all](#)

03/17/2016 (SUPPL-5330)

03/16/2016 (SUPPL-13)

visited on 1/19/2018

[Collapse All](#)

03/17/2016 (SUPPL-5330)
<p><a href="#">Approved Drug Label (PDF)</a></p> <p><b>Drug Interactions</b> Alcohol is known to potentiate the effect of DRUG PRODUCT. Patients, therefore, should be warned against excessive alcohol intake while receiving DRUG PRODUCT</p>
03/16/2016 (SUPPL-13)
<p><a href="#">Approved Drug Label (PDF)</a></p> <p><b>Warnings and Precautions</b> Hepatic impairment can potentiate the response to DRUG PRODUCT and decrease its metabolism. Use DRUG PRODUCT with caution in these patients</p>

<b><a href="/Drugs/DrugSafety/default.htm">More in Drug Safety and Availability (/Drugs/DrugSafety/default.htm)</a></b>	
<b><a href="/Drugs/DrugSafety/ucm215175.htm">Drug Alerts and Statements (/Drugs/DrugSafety/ucm215175.htm)</a></b>	
<b><a href="/Drugs/DrugSafety/ucm085729.htm">Medication Guides (/Drugs/DrugSafety/ucm085729.htm)</a></b>	
<b><a href="/Drugs/DrugSafety/ucm199082.htm">Drug Safety Communications (/Drugs/DrugSafety/ucm199082.htm)</a></b>	
<a href="/Drugs/DrugSafety/DrugShortages/default.htm">Drug Shortages (/Drugs/DrugSafety/DrugShortages/default.htm)</a>	▼
<a href="/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm">Postmarket Drug Safety Information for Patients and Providers (/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)</a>	▼
<b><a href="/Drugs/DrugSafety/InformationbyDrugClass/default.htm">Information by Drug Class (/Drugs/DrugSafety/InformationbyDrugClass/default.htm)</a></b>	
<b><a href="/Drugs/DrugSafety/MedicationErrors/default.htm">Medication Errors (/Drugs/DrugSafety/MedicationErrors/default.htm)</a></b>	
<b><a href="/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm">Drug Safety Podcasts (/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm)</a></b>	
<a href="/Drugs/DrugSafety/SafeUseInitiative/default.htm">Safe Use Initiative (/Drugs/DrugSafety/SafeUseInitiative/default.htm)</a>	▼
<b><a href="/Drugs/DrugSafety/DrugRecalls/default.htm">Drug Recalls (/Drugs/DrugSafety/DrugRecalls/default.htm)</a></b>	
<a href="/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm">Drug Supply Chain Integrity (/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm)</a>	▼