OXAZEPAM- oxazepam capsule, gelatin coated
Actavis Pharma, Inc.

Oxazepam Capsules, USP

CIV

40-9188

Revised — September 2016

Rx only

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death [*see **Warnings, Drug Interactions***].

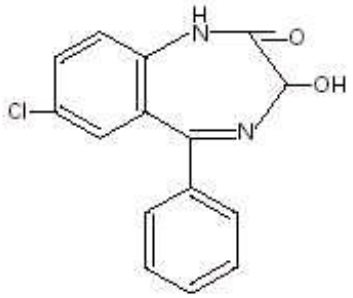
- Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

DESCRIPTION

Oxazepam, USP is the first of a chemical series of compounds known as the 3-hydroxybenzodiazepinones. A therapeutic agent providing versatility and flexibility in control of common emotional disturbances, this product exerts prompt action in a wide variety of disorders associated with anxiety, tension, agitation, and irritability, and anxiety associated with depression. In tolerance and toxicity studies on several animal species, this product reveals significantly greater safety factors than related compounds (chlordiazepoxide and diazepam) and manifests a wide separation of effective doses and doses inducing side effects.

Oxazepam capsules, USP contain 10 mg, 15 mg or 30 mg oxazepam, USP. The following inactive ingredients are contained in these capsules: corn starch, croscarmellose sodium, FD&C Red #40, gelatin, hypromellose, lactose (monohydrate), magnesium stearate, methylparaben, propylparaben, sodium lauryl sulfate, titanium dioxide, and other inert ingredients. The 10 mg capsule also contains D&C Red #28. The 15 mg capsule also contains D&C Yellow #10. The 30 mg capsule also contains D&C Red #28 and FD&C Blue #1.

Oxazepam, USP is 7-chloro-1,3-dihydro-3-hydroxy-5-phenyl-2*H*-1,4-benzodiazepin-2-one. A white crystalline powder with a molecular weight of 286.72, its structural formula is as follows:



$C_{15}H_{11}ClN_2O_2$

CLINICAL PHARMACOLOGY

Pharmacokinetic testing in healthy adult subjects has demonstrated that a single 30 mg dose of a capsule or tablet will result in equivalent extent of absorption. Peak plasma levels were observed to occur about 3 hours after dosing. The mean elimination half-life for oxazepam was approximately 8.2 hours (range 5.7 to 10.9 hours).

This product has a single, major inactive metabolite in man, a glucuronide excreted in the urine.

Age (less than 80 years old) does not appear to have a clinically significant effect on oxazepam kinetics. A statistically significant increase in elimination half-life in the very elderly (greater than 80 years of age) as compared to younger subjects has been reported, due to a 30% increase in volume of distribution, as well as a 50% reduction in unbound clearance of oxazepam in the very elderly *[see PRECAUTIONS, Geriatric Use]*.

INDICATIONS AND USAGE

Oxazepam capsules, USP are indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

Anxiety associated with depression is also responsive to oxazepam therapy.

This product has been found particularly useful in the management of anxiety, tension, agitation, and irritability in older patients.

Alcoholics with acute tremulousness, inebriation, or with anxiety, associated with alcohol withdrawal are responsive to therapy.

The effectiveness of oxazepam in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

CONTRAINDICATIONS

History of previous hypersensitivity reaction to oxazepam. Oxazepam is not indicated in psychoses.

WARNINGS

Risks from Concomitant Use with Opioids: Concomitant use of benzodiazepines, including oxazepam, and opioids may result in profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe oxazepam concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use, and follow patients closely for signs and symptoms of respiratory depression and sedation. In patients already receiving an opioid analgesic, prescribe a lower initial dose of oxazepam than indicated in the absence of an opioid and titrate based on clinical response. If an opioid is initiated in a patient already taking oxazepam, prescribe a lower initial dose of the opioid and titrate based upon clinical response.

Advise both patients and caregivers about the risks of respiratory depression and sedation when oxazepam is used with opioids. Advise patients not to drive or operate heavy machinery until the effects of concomitant use with the opioid have been determined *[see **Drug Interactions**]*.

As with other CNS-acting drugs, patients should be cautioned against driving automobiles or operating

dangerous machinery until it is known that they do not become drowsy or dizzy on oxazepam therapy.

Patients should be warned that the effects of alcohol or other CNS-depressant drugs may be additive to those of Oxazepam, possibly requiring adjustment of dosage or elimination of such agents.

Withdrawal symptoms of the barbiturate type have occurred after the discontinuation of benzodiazepines *[see DRUG ABUSE AND DEPENDENCE section]*.

Use in Pregnancy:

An increased risk of congenital malformations associated with the use of minor tranquilizers (chlordiazepoxide, diazepam, and meprobamate) during the first trimester of pregnancy has been suggested in several studies. Oxazepam, a benzodiazepine derivative, has not been studied adequately to determine whether it, too, may be associated with an increased risk of fetal abnormality. Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided. The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered. Patients should be advised that if they become pregnant during therapy or intend to become pregnant they should communicate with their physician about the desirability of discontinuing the drug.

PRECAUTIONS

General:

Although hypotension has occurred only rarely, oxazepam should be administered with caution to patients in whom a drop in blood pressure might lead to cardiac complications. This is particularly true in the elderly patient.

Information for Patients:

To assure the safe and effective use of oxazepam, patients should be informed that, since benzodiazepines may produce psychological and physical dependence, it is advisable that they consult with their physician before either increasing the dose or abruptly discontinuing this drug.

Drug Interactions:

The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. Benzodiazepines interact at GABAA sites and opioids interact primarily at mu receptors. When benzodiazepines and opioids are combined, the potential for benzodiazepines to significantly worsen opioid-related respiratory depression exists. Limit dosage and duration of concomitant use of benzodiazepines and opioids, and monitor patients closely for respiratory depression and sedation.

Pediatric Use:

Safety and effectiveness in pediatric patients under 6 years of age have not been established. Absolute dosage for pediatric patients 6 to 12 years of age is not established.

Geriatric Use:

Clinical studies of oxazepam were not adequate to determine whether subjects aged 65 and over respond differently than younger subjects. Age (less than 80 years old) does not appear to have a clinically significant effect on oxazepam kinetics *[see CLINICAL PHARMACOLOGY]*.

Clinical circumstances, some of which may be more common in the elderly, such as hepatic or renal impairment, should be considered. Greater sensitivity of some older individuals to the effects of oxazepam (e.g., sedation, hypotension, paradoxical excitation) cannot be ruled out *[see PRECAUTIONS, General; see ADVERSE REACTIONS]*. In general, dose selection for oxazepam for elderly patients

should be cautious, usually starting at the lower end of the dosing range *[see DOSAGE AND ADMINISTRATION]*.

ADVERSE REACTIONS

The necessity for discontinuation of therapy due to undesirable effects has been rare. Transient, mild drowsiness is commonly seen in the first few days of therapy. If it persists, the dosage should be reduced. In few instances, dizziness, vertigo, headache, and rarely syncope have occurred either alone or together with drowsiness. Mild paradoxical reactions, i.e., excitement, stimulation of affect, have been reported in psychiatric patients; these reactions may be secondary to relief of anxiety and usually appear in the first two weeks of therapy.

Other side effects occurring during oxazepam therapy include rare instances of nausea, lethargy, edema, slurred speech, tremor, altered libido, and minor diffuse skin rashes — morbilliform, urticarial, and maculopapular. Such side effects have been infrequent and are generally controlled with reduction of dosage. A case of an extensive fixed drug eruption also has been reported.

Although rare, leukopenia and hepatic dysfunction including jaundice have been reported during therapy. Periodic blood counts and liver-function tests are advisable.

Ataxia with oxazepam has been reported in rare instances and does not appear to be specifically related to dose or age.

Although the following side reactions have not as yet been reported with oxazepam, they have occurred with related compounds (chlordiazepoxide and diazepam): paradoxical excitation with severe rage reactions, hallucinations, menstrual irregularities, change in EEG pattern, blood dyscrasias including agranulocytosis, blurred vision, diplopia, incontinence, stupor, disorientation, fever, and euphoria.

Transient amnesia or memory impairment has been reported in association with the use of benzodiazepines.

To report SUSPECTED ADVERSE EVENTS, contact Actavis at 1-800-432-8534 or FDA at 1-800-FDA-1088 or http://www.fda.gov/ for voluntary reporting of adverse reactions.

DRUG ABUSE AND DEPENDENCE

Oxazepam Capsules are classified by the Drug Enforcement Administration as a schedule IV controlled substance.

Withdrawal symptoms, similar in character to those noted with barbiturates and alcohol (convulsions, tremor, abdominal and muscle cramps, vomiting, and sweating), have occurred following abrupt discontinuance of oxazepam. The more severe withdrawal symptoms have usually been limited to those patients who received excessive doses over an extended period of time. Generally milder withdrawal symptoms (e.g., dysphoria and insomnia) have been reported following abrupt discontinuance of benzodiazepines taken continuously at therapeutic levels for several months. Consequently, after extended therapy, abrupt discontinuation should generally be avoided and a gradual dosage-tapering schedule followed. Addiction-prone individuals (such as drug addicts or alcoholics) should be under careful surveillance when receiving oxazepam or other psychotropic agents because of the predisposition of such patients to habituation and dependence.

OVERDOSAGE

In the management of overdosage with any drug, it should be borne in mind that multiple agents may have been taken.

Symptoms:

Overdosage of benzodiazepines is usually manifested by varying degrees of central nervous system depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion and lethargy. In more serious cases, and especially when other drugs or alcohol were ingested, symptoms may include ataxia, hypotonia, hypotension, hypnotic state, stage one (1) to three (3) coma, and very rarely, death.

Management:

Induced vomiting and/or gastric lavage should be undertaken, followed by general supportive care, monitoring of vital signs, and close observation of the patient. Hypotension, though unlikely, usually may be controlled with norepinephrine bitartrate injection. The value of dialysis has not been adequately determined for oxazepam.

The benzodiazepine antagonist flumazenil may be used in hospitalized patients as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. **The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users and in cyclic antidepressant overdose.** The complete flumazenil package insert including **CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS** should be consulted prior to use.

DOSAGE AND ADMINISTRATION

Because of the flexibility of this product and the range of emotional disturbances responsive to it, dosage should be individualized for maximum beneficial effects.

USUAL DOSE

Mild-to-moderate anxiety, with associated tension, irritability, agitation, or related symptoms of functional origin or secondary to organic disease.	10 to 15 mg, 3 or 4 times daily
Severe anxiety syndromes, agitation, or anxiety associated with depression.	15 to 30 mg, 3 or 4 times daily
Older patients with anxiety, tension, irritability, and agitation.	Initial dosage: 10 mg, 3 times daily. If necessary, increase cautiously to 15 mg, 3 or 4 times daily.
Alcoholics with acute inebriation, tremulousness, or anxiety on withdrawal.	15 to 30 mg, 3 or 4 times daily

This product is not indicated in pediatric patients under 6 years of age. Absolute dosage for pediatric patients 6 to 12 years of age is not established.

HOW SUPPLIED

Oxazepam capsules, USP are available as follows:

10 mg — Each pink opaque gelatin #4 capsule printed with ℞ and 067 in black ink on both cap and body contains 10 mg of Oxazepam, USP. Capsules are supplied in bottles of 100 (NDC 0228-2067-10) and 500 (NDC 0228-2067-50).

15 mg — Each red opaque gelatin #4 capsule printed with ℞ and 069 in black ink on both cap and body contains 15 mg of Oxazepam, USP. Capsules are supplied in bottles of 100 (NDC 0228-2069-10) and 500 (NDC 0228-2069-50).

30 mg — Each maroon opaque gelatin #4 capsule printed with ℞ and 073 in blue ink on both cap and body contains 30 mg of Oxazepam, USP. Capsules are supplied in bottles of 100 (NDC 0228-2073-10).

Keep tightly closed.

Dispense in a tight, light-resistant container as defined in the USP.

Store at 25ºC (77ºF); excursions permitted to 15ºC to 30ºC (59ºF to 86ºF).

ANIMAL PHARMACOLOGY AND TOXICOLOGY

In mice, oxazepam exerts an anticonvulsant (anti-Metrazol) activity at 50-percent-effective doses of about 0.6 mg/kg orally. (Such anticonvulsant activity of benzodiazepines correlates with their tranquilizing properties.) To produce ataxia (rotabar test) and sedation (abolition of spontaneous motor activity), the 50-percent-effective doses of this product are greater than 5 mg/kg orally. Thus, about ten times the therapeutic (anticonvulsant) dose must be given before ataxia ensues, indicating a wide separation of effective doses and doses inducing side effects.

In evaluation of antianxiety of compounds, conflict behavioral tests in rats differentiate continuous response for food in the presence of anxiety-provoking stress (shock) from drug-induced motor incoordination. This product shows significant separation of doses required to relieve anxiety and doses producing sedation or ataxia. Ataxia-producing doses exceed those of related CNS-acting drugs.

Acute oral LD_{50} in mice is greater than 5000 mg/kg, compared to 800 mg/kg for a related compound (chlordiazepoxide).

Subacute toxicity studies in dogs for four weeks at 480 mg/kg daily showed no specific changes; at 960 mg/kg two out of eight died with evidence of circulatory collapse. This wide margin of safety is significant compared to chlordiazepoxide HCl, which showed nonspecific changes in six dogs at 80 mg/kg. On chlordiazepoxide, two out of six died with evidence of circulatory collapse at 127 mg/kg, and six out of six died at 200 mg/kg daily. Chronic toxicity studies of oxazepam in dogs at 120 mg/kg/day for 52 weeks produced no toxic manifestation.

Fatty metamorphosis of the liver has been noted in six-week toxicity studies in rats given this product at 0.5% of the diet. Such accumulations of fat are considered reversible, as there is no liver necrosis or fibrosis.

Breeding studies in rats through two successive litters did not produce fetal abnormality.

Oxazepam has not been adequately evaluated for mutagenic activity.

In a carcinogenicity study, oxazepam was administered with diet to rats for two years. Male rats receiving 30 times the maximum human dose showed a statistical increase, when compared to controls, in benign thyroid follicular cell tumors, testicular interstitial cell adenomas, and prostatic adenomas. An earlier published study reported that mice fed dietary dosages of 35 or 100 times the human daily dose of oxazepam for 9 months developed a dose-related increase in liver adenomas.[1] In an independent analysis of some of the microscopic slides from this mouse study, several of these tumors were classified as liver carcinomas. At this time, there is no evidence that clinical use of oxazepam is associated with tumors.

REFERENCE

1. FOX, K.A, LAHCEN, R.B.: Liver-cell Adenomas and Peliosis Hepatis in Mice Associated with Oxazepam. Res. Commun. Chem. Pathol. Pharmacol. *8*:481-488, 1974.

Manufactured by:
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Elizabeth, NJ 07207 USA

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Parsippany, NJ 07054 USA

40-9188

Revised — September 2016

MEDICATION GUIDE

Oxazepam (ox-AZE-e-pam) Capsules, USP C-IV

What is the most important information I should know about oxazepam?

- **Oxazepam is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**
- **Oxazepam can make you sleepy or dizzy, and can slow your thinking and motor skill.**

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how oxazepam affects you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking oxazepam without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, oxazepam may make your sleepiness or dizziness much worse.

- Do not take more oxazepam than prescribed.

What is oxazepam?

- Oxazepam is a prescription medicine used:

- to treat anxiety disorders
- for the short-term relief of the symptoms of anxiety or anxiety that can happen with depression
- to treat anxiety, tension, agitation and irritability in elderly people
- to relieve the symptoms of alcohol withdrawal including agitation, shakiness (tremor), anxiety associated with acute alcohol withdrawal.

- **Oxazepam is a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep oxazepam capsules in a safe place to prevent misuse and abuse. Selling or giving away oxazepam capsules may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if oxazepam is safe and effective in children under 6 years of age.
- It is known if oxazepam is safe and effective for use longer than 4 months.

Do not take oxazepam capsules if you:

- are allergic to oxazepam or any of the ingredients in oxazepam capsules. See the end of this Medication Guide for a complete list of ingredients in oxazepam capsules.

Before you take oxazepam capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had depression, mood problems, or suicidal thoughts or behavior
- have liver or kidney problems
- have or have had problems with fainting or low blood pressure
- are pregnant or plan to become pregnant. Oxazepam may harm your unborn baby. You and your healthcare provider should decide if you should take oxazepam while you are pregnant.
- are breastfeeding or plan to breastfeed. Oxazepam may pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take oxazepam.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking oxazepam with certain other medicines can cause side effects or affect how well oxazepam or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I take oxazepam capsules?

- See **"What is the most important information I should know about oxazepam?"**
- Take oxazepam capsules exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how many oxazepam capsules to take and when to take them.
- If you take too many oxazepam capsules, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking oxazepam?

- Oxazepam can cause you to be drowsy. Do not drive a car, operate heavy machinery, or do other dangerous activity until you know how oxazepam affects you.
- You should not drink alcohol while taking oxazepam. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of oxazepam?

Oxazepam may cause serious side effects, including:

- **See "What is the most important information I should know about oxazepam?"**
- **Low blood pressure**. Oxazepam can cause low blood pressure especially in elderly people.
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking oxazepam capsules suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping oxazepam capsules to avoid withdrawal symptoms.
- **Abuse and dependence.** Taking oxazepam can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

The most common side effects of oxazepam include:

• drowsiness	• dizziness
• vertigo (sensation of loss of balance)	• headache

These are not all the possible side effects of oxazepam. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store oxazepam capsules?

- Store oxazepam capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep oxazepam capsules in a tightly closed container and out of the light.
- **Keep oxazepam capsules and all medicines out of the reach of children.**

General information about the safe and effective use of oxazepam capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use oxazepam for a condition for which it was not prescribed. Do not give oxazepam capsules to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about oxazepam that is written for health professionals.

What are the ingredients in oxazepam capsules, USP?

Active ingredient: Oxazepam, USP

Inactive ingredients: Corn starch, croscarmellose sodium, FD&C Red #40, gelatin, hypromellose, lactose (monohydrate), magnesium stearate, methylparaben, propylparaben, sodium lauryl sulfate, titanium dioxide, and other inert ingredients. The 10 mg capsule also contains D&C Red #28. The 15 mg capsule also contains D&C Yellow #10. The 30 mg capsule also contains D&C Red #28 and FD&C Blue #1.

For more information, call Actavis at 1-800-432-8534.

This Medication Guide has been approved by the U.S. Food and Drug Administration
Issued: September 2016

Manufactured by:
Actavis Elizabeth LLC
Elizabeth, NJ 07207 USA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

40-9188
MG (41-1227/0916)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0228-**2067**-10

Oxazepam Capsules, USP 10 mg CIV

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

100 Capsules

Rx only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0228-**2069**-10

Oxazepam Capsules, USP 15 mg CIV

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

100 Capsules

Rx only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0228-**2073**-10

Oxazepam Capsules, USP 30 mg CIV

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

100 Capsules

Rx only

OXAZEPAM

oxazepam capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0228-2067
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXAZEPAM (UNII: 6GOW6DWN2A) (OXAZEPAM - UNII:6GOW6DWN2A)	OXAZEPAM	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

Product Characteristics			
Color	PINK	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	R;067
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0228-2067-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2007	
2	NDC:0228-2067-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2007	07/31/2016

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072253	01/02/2007	

OXAZEPAM

oxazepam capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0228-2069
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXAZEPAM (UNII: 6GOW6DWN2A) (OXAZEPAM - UNII:6GOW6DWN2A)	OXAZEPAM	15 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	RED	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	R;069
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0228-2069-10	100 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/02/2007	
2	NDC:0228-2069-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2007	10/31/2015

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072253	01/02/2007	

OXAZEPAM

oxazepam capsule, gelatin coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0228-2073
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OXAZEPAM (UNII: 6GOW6DWN2A) (OXAZEPAM - UNII:6GOW6DWN2A)	OXAZEPAM	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	R;073
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0228-2073-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072253	01/02/2007	

Labeler - Actavis Pharma, Inc. (119723554)