ESZOPICLONE- eszopiclone tablet, film coated
DirectRX

ESZOPICLONE

Indications and Usage

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Dosage and Administration

Use the lowest effective dose for the patient.

2.1 Dosage in Adults

The recommended starting dose is 1 mg. Dosing can be raised to 2 mg or 3 mg if clinically indicated. In some patients, the higher morning blood levels of eszopiclone following use of the 2 mg or 3 mg dose increase the risk of next day impairment of driving and other activities that require full alertness [see Warnings and Precautions (5.1)]. The total dose of eszopiclone should not exceed 3 mg, once daily immediately before bedtime [see Warnings and Precautions (5.6)].

2.2 Geriatric or Debilitated Patients

The total dose of eszopiclone should not exceed 2 mg in elderly or debilitated patients.

2.3 Patients with Severe Hepatic Impairment, or Taking Potent CYP3A4 Inhibitors

In patients with severe hepatic impairment, or in patients coadministered eszopiclone tablets with potent CYP3A4 inhibitors, the total dose of eszopiclone should not exceed 2 mg [see Warnings and Precautions (5.7)].

2.4 Use with CNS Depressants

Dosage adjustments may be necessary when eszopiclone tablets are combined with other CNS depressant drugs because of the potentially additive effects [see Warnings and Precautions (5.1)].

2.5 Administration with Food

Taking eszopiclone tablets with or immediately after a heavy, high-fat meal results in slower absorption and would be expected to reduce the effect of eszopiclone tablets on sleep latency [see Clinical Pharmacology (12.3)].

Dosage forms and strengths

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Contraindications

Eszopiclone is contraindicated in patients with known hypersensitivity to eszopiclone. Hypersensitivity reactions include anaphylaxis and angioedema [see Warnings and Precautions (5.3)].

Warnings and Precautions

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Adverse Reactions

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Drug Interactions

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Use in Specific Populations

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Drug abuse and Dependence

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Overdosage

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Description

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Clinical Pharmacology

-

Nonclinical Toxicology

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Clinical Studies

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Information for Patients

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Medication Guide

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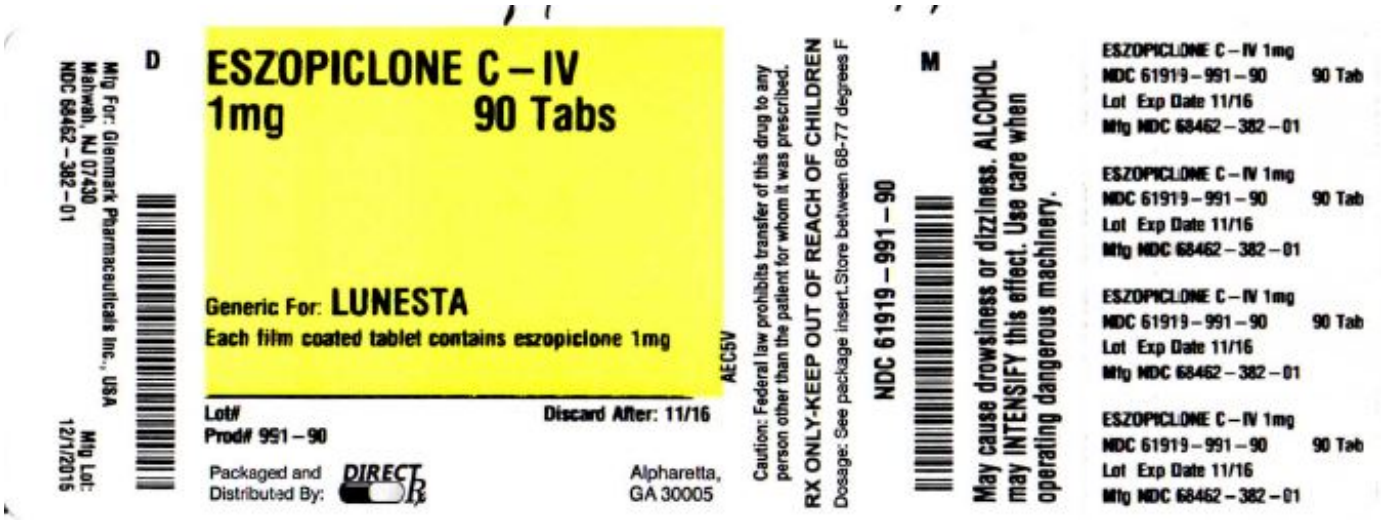
Package Label



ESZOPICLONE

eszopiclone tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-991(NDC:68462-382)
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ESZOPICLONE (UNII: UZX80K71OE) (ESZOPICLONE - UNII:UZX80K71OE)	ESZOPICLONE	1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	blue (light blue)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	382;G
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-991-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091166	12/01/2015	

Labeler - DirectRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DirectRX		079254320	repack(61919-991)

Revised: 12/2015 DirectRX