MEDICATION GUIDE Eszopicione Tablets, Coated 67 (ES-zoe-PIK-lone)

Read the Medication Guide that comes with eszopiclone tablets before you start taking it and each time you get a refill. There may be

new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. What is the most important information I

should know about eszopiclone tablets?

- Do not take more eszopiclone tablets than prescribed.
 - Do not take eszopiclone tablets unless you are able to stay in bed a full night (7 to 8 hours) before you must be
- active again. Take eszopiclone tablets right before you get in bed, not sooner.

Eszopiclone tablets may cause serious side effects, including:

Complex sleep behaviors that have caused serious injury and death. After taking eszopiclone tablets, you may get up out

of bed while not being fully awake and do an activity that you do not know you are doing (complex sleep behaviors). The next morning, you may not remember that you did anything during the night. These activities may occur with eszopiclone tablets whether or not you

drink alcohol or take other medicines that

Reported activities and behaviors include:

- doing activities when you are asleep like: o making and eating food
 - o talking on the phone o having sex o driving a car ("sleep-driving")

make you sleepy.

o sleep walking Stop taking eszopiclone tablets and call your healthcare provider right away if you

The morning after you take eszopiclone tablets your ability to drive safely and think clearly may be decreased. You also may

find out that you have done any of the above

activities after taking eszopiclone tablets.

experience sleepiness during the day. Do not take eszopiclone tablets if you:

- have ever experienced a complex sleep behavior (such as driving a car, making and eating food, talking on the phone or having sex while not fully awake) after taking eszopiclone tablets.
 - drank alcohol that evening or before bed

sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take eszopiclone tablets with your other medicines. cannot get a full night's sleep

take other medicines that can make you

What are eszopiclone tablets? Eszopiclone tablets are a sedative-hypnotic

(sleep) medicine. Eszopiclone tablets are

used in adults for the treatment of a sleep problem called insomnia. Symptoms of insomnia include:

waking up often during the night

trouble falling asleep

Eszopiclone tablets are not for children.

Eszopiclone tablets are a federally controlled substance (C-IV) because it can be abused or

lead to dependence. Keep eszopiclone tablets in a safe place to prevent misuse and

abuse. Selling or giving away eszopiclone

tablets may harm others, and is against the law. Tell your doctor if you have ever abused

medicines or street drugs. Who should not take eszopiclone tablets?

or been dependent on alcohol, prescription

Do not take eszopiclone tablets if you have

ever had a complex sleep behavior happen after taking eszopiclone tablets. Do not take eszopiclone tablets if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in eszopiclone tablets.

Eszopiclone tablets may not be right for you. Before starting eszopiclone tablets, tell your doctor about all of your health conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts have a history of drug or alcohol abuse or
- addiction have liver disease
- are pregnant, planning to become pregnant, or breastfeeding

Tell your doctor about all of the medicines you

take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact with each other, sometimes causing serious side effects. Do not take eszopiclone tablets with other medicines that can make you sleepy.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take eszopicione tablets? Take eszopiclone tablets exactly as prescribed. Do not take more eszopiclone tablets than prescribed for you. Take eszopiclone tablets right before you get into bed. Do not take eszopiclone tablets with or right after a meal. Do not take eszopiclone tablets unless you are able to get a full night's sleep before you must be active again. Call your doctor if your insomnia worsens or is not better within 7 to 10

days. This may mean that there is another condition causing your sleep problems. If you take too much eszopiclone tablets or overdose, call your doctor or poison control center right away, or get

emergency treatment. What are the possible side effects of eszopiclone tablets? Possible serious side effects of eszopiclone tablets include: getting out of bed while not being fully

awake and doing an activity that you do

not know you are doing. (See "What is

the most important information I should

abnormal thoughts and behavior.

Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, acting strangely, hallucinations, worsening of depression, and suicidal thoughts or actions. memory loss anxiety

know about eszopicione tablets?)

severe allergic reactions. Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking eszopiclone tablets. Call your doctor right away if you have any

of the above side effects or any other side effects that worry you while using eszopiclone tablets. The most common side effects of

eszopiclone tablets are: unpleasant taste in mouth, dry mouth

drowsiness dizziness

headache

symptoms of the common cold You may still feel drowsy the next day after

taking eszopiclone tablets. Do not drive or do other dangerous activities after taking eszopiclone tablets until you feel fully awake. These are not all the side effects of

How should I store eszopiclone tablets? Store eszopiclone tablets at room temperature, between 59°F to 86°F (15°C) to 30°C).

doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-

Do not use eszopiclone tablets after the expiration date. Keep eszopiclone tablets and all medicines out of reach of children.

General Information about eszopiclone tablets. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

Do not use eszopiclone tablets for a condition for which it was not prescribed. Do not share eszopiclone tablets with other people, even if you think they have

FDA-1088.

the same symptoms that you have. It may harm them and is against the law. This Medication Guide summarizes the most important information about eszopiclone tablets. If you would like more information, talk

with your doctor. You can ask your doctor or pharmacist for information about eszopiclone tablets that is written for healthcare professionals. For customer service, call 1-888-943-3210

or 1-855-926-3384. To report side effects, call 1-888-943-3210 or 1-855-926-3384. What are the ingredients in eszopiclone

tablets? Active Ingredient: eszopiclone Inactive Ingredients: dibasic calcium phosphate dihydrate, colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose,

magnesium stearate, microcrystalline

cellulose, polyethylene glycol, titanium dioxide,

and triacetin. In addition, both the 1 mg and 3

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mg tablets contain FD&C Blue #2

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