

## **Rasagiline (marketed as Azilect)**

This is a summary of the most important information about Azilect. For details, talk to your healthcare professional.

### What Is Azilect?

Azilect is a prescription medicine used to treat the signs and symptoms of Parkinson's disease in adults. Azilect is used alone or with the medicine levodopa

Azilect has not been studied in children.

### Who Should Not Be Treated With Azilect?

#### Do not take Azilect if you:

- have an adrenal gland tumor called a pheochromocytoma
- are schedule for surgery. Azilect should be stopped 14 days before surgery.

### What Are The Risks?

The following are the major potential risks and side effects of Azilect therapy. However, this list is not complete.

# Azilect may cause serious and life-threatening side effects when taken:

- with many other medicines
- with foods or drinks that contain tyramine. Ask your healthcare professional for a list of tyramine-containing foods and drinks that should be avoided with Azilect.

Call your health care professional right away if you have any of these serious side effects:

- severe headache
- blurred vision, large pupils, vision changes, sudden sensitivity to light
- trouble thinking
- fainting or loss of consciousness
- seizure
- signs or symptoms of a stroke
- irregular heartbeat
- chest pain
- neck stiffness or soreness

- unexplained nausea or vomiting
- sweating or clammy skin (sometimes with fever)

# Azilect may also cause the following serious side effects:

- A skin cancer called melanoma: People with Parkinson's disease may have a higher chance of developing melanoma. It is not known if this higher chance is related to Parkinson's disease or to the medicines used to treat the disease. You should have regular check-ups to monitor for melanoma.
- **difficulty with movements:** You may have more involuntary movement or difficulty in performing voluntary movements if you take Azilect with levodopa.
- low blood pressure: Azilect may cause a sudden fall in blood pressure when standing up too fast. This can lead to dizziness or lightheadedness. This may happen more often during the first 2 months of treatment. Low blood pressure is also more likely to happen if you are also taking levodopa.
- **hallucinations**: Hearing or seeing things that are not there. Hallucinations are more likely to happen if you are also taking levodopa.
- **other common side effects** that may happen with Azilect include:
  - o dizziness
  - o joint pain
  - o heartburn
  - o nausea and vomiting
  - o fever
  - o muscle pain
  - o dry mouth
  - o stomach area pain
  - o falls or accidental injury
  - o headache
  - o weight loss
  - o loss of appetite
  - o sleepiness
  - o constipation



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570 Druginfo@cder.fda.gov



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#### This is NOT a complete list of side effects reported

with Azilect. Your health care professional can discuss with you a more complete list of side effects.

### What Should I Tell My Healthcare Professional?

**Before you start taking Azilect**, tell your healthcare professional if you:

- have an adrenal gland tumor called a pheochromocytoma
- have heart problems or had a stroke
- have high blood pressure
- have severe headaches or have headaches often
- have or had liver problems
- are trying to become pregnant, are already pregnant, or are breast-feeding
- are scheduled to have surgery

### **Can other Medicines or Food affect Azilect?**

Azilect and certain other medicines may interact with each other. Tell your healthcare professional about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional. Especially tell your healthcare professional if you take:

- antidepressants
- appetite suppressants
- bronchodilators
- cough/cold medicines
- drugs for Attention Deficit Hyperactivity Disorder
- certain drugs for glaucoma
- certain herbal products
- certain drugs for high blood pressure
- certain pain medicines
- certain migraine medicines
- certain muscle relaxants

- levodopa/carbidopa
- ciprofloxacin
- theophylline

Azilect may cause **serious and life-threatening side effects** when taken **with foods or drinks that contain tyramine.** 

Foods, drinks, and dietary supplements which have tyramine are:

- Air dried, aged and fermented meats, sausages and salamis (including cacciatore, hard salami and mortadella); pickled herring; any spoiled or improperly stored meat (such as beef, chicken or fish) or animal livers, (e.g., foods that have undergone changes in coloration, odor, or become moldy)
- Broad bean pods (fava bean pods)
- Aged cheeses
- All varieties of tap beer and beers that have not been pasteurized so as to allow for ongoing fermentation
- red wines
- Concentrated yeast extract (e.g. Marmite), sauerkraut, most soybean products (including soy sauce and tofu)
- OTC supplements containing tyramine

This list is NOT complete. You may obtain a list of tyramine-rich products from the Azilect product labeling and also from your healthcare provider.

### How Should I take Azilect?

- Take Azilect by mouth exactly as prescribed. Azilect is usually taken once a day
- Azilect can be taken with or without food .

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