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Azilect (rasagiline)



Medically reviewed by <u>Melissa Badowski, PharmD, MPH, FCCP</u> — By <u>Patricia Weiser, PharmD</u> on February 21, 2021

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What is Azilect?

Azilect is a brand-name prescription medication. It's approved by the Food and Drug Administration (FDA) to treat <u>Parkinson's disease</u>. This is a condition that affects the nervous system and causes muscle movements that you can't control. The most common symptom of Parkinson's disease is tremors (shaking movements), usually in the hands or feet.

Drug details

The active drug in Azilect is rasagiline. Azilect belongs to a drug class known as monoamine oxidase-B inhibitors, which are also known as MAOIs. A drug class is a group of medications that work in a similar way.

Azilect comes as a tablet that you swallow. You'll likely take this drug once daily. Azilect comes in two strengths: 0.5 milligram (mg) and 1 mg.

Effectiveness

For information about the effectiveness of Azilect, see the "<u>Azilect uses</u>" section below.

Azilect generic

Azilect is a brand-name drug that contains the active drug rasagiline. This active drug is also available as a generic medication. A generic drug is an exact copy of the active drug in a brand-name medication.

The generic is considered to be as safe and effective as the original drug. Generics tend to cost less than brand-name drugs.

If you're interested in using the generic form of Azilect, talk with your doctor. They can tell you whether it comes in forms and strengths that can be used for your condition.

Azilect side effects

Azilect can cause mild or serious side effects. The following lists contain some of the key side effects that may occur while taking Azilect. These lists do not include all possible side effects.

For more information about the possible side effects of Azilect, talk with your doctor or pharmacist. They can give you tips on how to deal with any side effects that may be concerning or bothersome.

Note: The Food and Drug Administration (FDA) tracks the side effects of drugs it has approved. If you would like to notify the FDA about a side effect you've had with Azilect, you can do so through MedWatch.

Mild side effects

Mild side effects of Azilect may differ depending on whether you take the drug alone or with other drugs for <u>Parkinson's disease</u>, such as levodopa (<u>Inbrija</u>).

Mild side effects of Azilect when taken alone

If you take Azilect alone for <u>Parkinson's disease</u>, mild side effects* can include:

- flu-like symptoms, such as chills or body aches
- joint pain
- indigestion
- headache
- conjunctivitis (pinkeye)
- fever
- gastroenteritis (inflammation of the lining of the stomach and intestines that's caused by an infection)
- runny nose
- joint inflammation (swelling and damage)
- skin bruising
- feelings of tingling or prickling
- vertigo (dizziness)

Mild side effects of Azilect when taken with other drugs for Parkinson's disease

If you take Azilect in addition to other drugs for Parkinson's disease, mild side effects* can include:

- peripheral edema (swelling in your hands, legs, or feet)
- cough
- insomnia (trouble falling asleep or staying asleep)
- · weight loss
- nausea or vomiting

- · reduced appetite
- stomach pain
- constipation
- dry mouth
- rash
- abnormal dreams

Most of these side effects may go away within a few days or a couple of weeks. But if they become more severe or don't go away, talk with your doctor or pharmacist.

Serious side effects

Serious side effects from Azilect aren't common, but they can occur. These side effects can occur whether you're taking the drug alone or with other medications for <u>Parkinson's disease</u>. Call your doctor right away if you have serious side effects. Call 911 or your local emergency number if your symptoms feel life threatening or if you think you're having a medical emergency.

Serious side effects and their symptoms can include:

- Hypertension (high blood pressure) usually doesn't cause any symptoms, but symptoms of very high blood pressure can include:
 - sweating
 - anxiety
 - trouble sleeping
 - blushing
 - headache
 - nosebleeds
- Depression. Symptoms can include:
 - feeling down
 - loss of interest in activities that you used to enjoy
 - lack of energy

^{*} These are partial lists of mild side effects from Azilect. To learn about other mild side effects, talk with your doctor or pharmacist, or view Azilect's <u>prescribing information</u>.

- reduced sexual desire
- weight changes
- sleeping too much or not enough
- Hallucinations. Symptoms can include:
 - seeing or hearing something or someone that isn't real
 - smelling or feeling something that isn't there
 - tasting something that you didn't eat
- Serotonin syndrome (high levels of a chemical called serotonin).
 Symptoms can include:
 - dilated pupils
 - confusion
 - excessive sweating
 - blood pressure changes
 - rapid heartbeat
 - diarrhea
 - muscle spasms or stiffness
 - very high body temperature
- Falling.
- Low blood pressure.*
- Dyskinesia (abnormal muscle movements that you can't control).**
- Sleepiness.*
- Allergic reaction.*

Side effect details

You may wonder how often certain side effects occur with this drug. Here's some detail on certain side effects this drug may cause.

Low blood pressure

^{*} For more information about this side effect, see "Side effect details" below.

[†] Dyskinesia may occur when taking Azilect in combination with levodopa (Inbrija), another drug commonly used to treat Parkinson's disease.

In <u>clinical trials</u>, some people had an increased risk of side effects related to <u>low blood pressure</u>, including <u>orthostatic hypotension</u>. This is a sudden drop in <u>blood pressure</u> caused by a change in posture.

Low blood pressure side effects occurred only in people who took Azilect in combination with other drugs, such as levodopa (Inbrija), to treat Parkinson's disease. People who used Azilect alone didn't note low blood pressure as a side effect.

Orthostatic hypotension

Researchers found that orthostatic hypotension was a common side effect in people who took Azilect in combination with other drugs to treat Parkinson's disease.

Here's how orthostatic hypotension occurs. When you're sitting or lying down, gravity causes your blood to pool in your legs. When you stand up, your body usually pushes blood upward to provide your brain with oxygen. Azilect and other drugs may prevent your body from pushing blood upward efficiently. This can cause your blood pressure to drop.

Symptoms of low blood pressure, including orthostatic hypotension, may include:

- dizziness
- blurred vision
- fainting

Orthostatic hypotension seems to occur most often in the first 2 months of adding Azilect to your Parkinson's disease treatment plan. After 2 months, this side effect tends to ease or go away over time. To find out how often orthostatic hypotension occurred in clinical studies, see the drug's <u>prescribing information</u>.

To help prevent or relieve orthostatic hypotension, it's best to change positions slowly. Try not to jump out of a chair or bed suddenly.

Managing low blood pressure side effects

Some people who took Azilect with other drugs, such as levodopa (Inbrija), in the clinical studies, had low blood pressure while lying down.

This side effect wasn't related to posture changes, and it was less common than orthostatic hypotension.

To help prevent or reduce side effects related to low blood pressure while taking Azilect, you can try the following:

- Drink plenty of fluids to stay hydrated.
- Wear compression socks or stockings to reduce blood pooling in your legs.
- Avoid or limit alcohol.
- Check with your doctor if you should add more salt to your diet.
 Adjusting your diet this way may help raise your blood pressure.

If these side effects become severe or don't go away after 2 months, talk with your doctor. They may suggest other ways to help ease this side effect.

If you have questions about your risk for low blood pressure while using Azilect, talk with your doctor.

Dyskinesia

New or worsened <u>dyskinesia</u> was a common side effect of people who took Azilect with levodopa (Inbrija) in <u>clinical trials</u>. Levodopa is another medication for Parkinson's disease.

Dyskinesia refers to abnormal muscle movements that you can't control. When Azilect to your levodopa treatment, dyskinesia symptoms may start or worsen if you've already developed them.

Common dyskinesia symptoms include:

- tremor or shaking of your hands or feet
- head bobbing
- fidgeting
- rocking or swaying
- sudden jerky movements of your limbs, head, or face

If you're concerned about dyskinesia with Azilect and levodopa, talk with your doctor. They may suggest changes to your treatment plan, such as reducing your levodopa dosage. It's important that you don't change your medication dosages without your doctor's approval.

Sleepiness

In a <u>clinical study</u> of people who took Azilect with other medications for Parkinson's disease, sleepiness occurred in a small percentage of people.

Some people who took these drugs reported falling asleep while performing daily activities. This included falling asleep while eating or having conversations. Rarely, people treated with Azilect and other medications for Parkinson's disease reported falling asleep while driving.

Sleepiness due to Azilect has been linked to driving accidents. In these situations, some people reported that they didn't have any warning signs, such as feeling drowsy, before falling asleep. Also, some people had been taking Azilect for more than 1 year when the accidents occurred.

Based on this, it may not be safe to drive while you're taking Azilect, or at least until you know how the drug affects you. Discuss the risks and benefits of Azilect treatment with your doctor.

Compulsive behaviors

After Azilect was approved, some people reported developing new or compulsive behaviors while taking the drug. These worsened impulses weren't seen in <u>clinical trials</u> of Azilect. Some people may feel that they can't stop themselves from engaging in certain behaviors while taking medications for Parkinson's disease, including Azilect. Examples of these behaviors can include:

- gambling
- binge eating
- spending money in an uncontrolled way
- intense sexual urges

For some people, these urges are intense. If you notice compulsive behavior while taking Azilect, talk with your doctor. They may lower your dosage or have you stop taking the drug. To learn more, see the "Azilect precautions" section below.

ALLERGIC REACTION

As with most drugs, some people can have an allergic reaction after taking Azilect. Symptoms of a mild allergic reaction can include:

- skin rash
- itchiness
- flushing (warmth, swelling, redness, or discoloration in your skin)

A more severe allergic reaction is rare but possible. Symptoms of a severe allergic reaction can include:

- swelling under your skin, typically in your eyelids, lips, hands, or feet
- swelling of your tongue, mouth, or throat
- trouble breathing

Call your doctor right away if you have an allergic reaction to Azilect, as the reaction could become severe. Call 911 or your local emergency number if your symptoms feel life threatening or if you think you're having a medical emergency.

As with all medications, the <u>cost</u> of Azilect can vary. The actual price you'll pay depends on your insurance plan, your location, and the pharmacy you use.

Keep in mind that you may be able to get a 90-day supply of Azilect. If approved by your insurance company, getting a 90-day supply of the drug could reduce your number of trips to the pharmacy and help lower the cost. If you're interested in this option, check with your doctor or your insurance company.

Before approving coverage for Azilect, your insurance company may require you to get prior authorization. This means that your doctor and insurance company will need to communicate about your prescription before the insurance company will cover the drug. The insurance company will review the prior authorization request and decide if the drug will be covered.

If you're not sure if you'll need to get prior authorization for Azilect, contact your insurance company.

Financial and insurance assistance

If you need financial support to pay for Azilect, help may be available.

The Medicine Assistance Tool website lists programs that may help lower the cost of Azilect. For more information and to find out if you're eligible for support, visit <u>this website</u>.

Mail-order pharmacies

Azilect may be available through a mail-order pharmacy. Using this service may help lower the drug's cost and allow you to get your medication without leaving home.

If recommended by your doctor, you may be able to receive a 90-day supply of Azilect, so there's less concern about running out of the medication. If you're interested in this option, check with your doctor and your insurance company. Some Medicare plans may help cover the cost of mail-order medications.

If you don't have insurance, you can ask your doctor or pharmacist about online pharmacy options.

Generic version

Azilect is available in a generic form called rasagiline. A generic drug is an exact copy of the active drug in a brand-name medication. The generic is considered to be as safe and effective as the original drug. And generics tend to cost less than brand-name drugs. To find out how the cost of rasagiline compares with the cost of Azilect, visit GoodRx.com.

If your doctor has prescribed Azilect and you're interested in using rasagiline instead, talk with them. Your doctor may have a preference for one version or the other. You'll also need to check your insurance plan, as it may only cover one or the other.

Azilect uses

The Food and Drug Administration (FDA) approves prescription drugs such as Azilect to treat certain conditions. Azilect may also be used <u>off-label</u> for other conditions. Off-label drug use means using a drug for a purpose other than what it's been approved for by the FDA.

Azilect for Parkinson's disease

Azilect is approved by the Food and Drug Administration (FDA) to treat <u>Parkinson's disease</u>. For this purpose, Azilect can be taken by itself or in combination with other drugs that also treat Parkinson's disease. (To learn more, see the "<u>Azilect use with other drugs</u>" section below.)

Parkinson's disease explained

Parkinson's disease is a condition that affects the nervous system. The most noticeable symptoms of Parkinson's disease are usually movement-related, such as tremors (shaking). People with this condition also usually have non-movement related symptoms, including:

- depression
- a difficulty chowing and cwallowing

- problems with urination
- constipation
- · trouble sleeping

The symptoms of Parkinson's disease develop gradually. In most people, symptoms appear at age 60 years or later. They often start on one side of the body, such as a tremor in one hand. Symptoms spread to both sides of the body and usually worsen over time. Some people with Parkinson's disease also develop <u>dementia</u>, which is a general decline in intellectual abilities, such as memory and communication.

Effectiveness for Parkinson's disease

Azilect contains the active drug rasagiline, which has been shown to be effective in <u>clinical trials</u> for treating Parkinson's disease symptoms. The trials measured how well people taking Azilect improved in mental and physical activity (fewer tremors).

If you'd like to read more about how this drug performed in studies, see the <u>prescribing information</u> for Azilect.

Azilect and children

Azilect isn't approved for use in children. The drug hasn't been tested in children because Parkinson's disease doesn't occur in them.

Azilect use with other drugs

Azilect is approved by the Food and Drug Administration (FDA) to treat <u>Parkinson's disease</u>. For this purpose, Azilect can be taken by itself or in combination with other drugs that also treat Parkinson's disease.

If Azilect isn't managing your symptoms well enough, your doctor may recommend that you take an additional drug. And if your current Parkinson's disease medication isn't managing your symptoms effectively, your doctor may prescribe Azilect.

Other medications that your doctor may prescribe for you in addition to Azilect may include:

- amantadine
- anticholinergics, such as benztropine (Cogentin) or trihexyphenidyl
- catechol-O-methyltransferase (COMT) inhibitors, such as entacapone (Comtan) or tolcapone (Tasmar)
- dopamine agonists, such as pramipexole (Mirapex), rotigotine (Neupro), ropinirole (Requip)
- istradefylline (Nourianz)
- carbidopa/levodopa/entacapone (Stalevo)
- levodopa/carbidopa (Sinemet)

Levodopa/carbidopa is one of the more commonly prescribed medications for Parkinson's disease. Your starting dosage of Azilect will depend on whether you're also taking a medication that contains levodopa.

Your doctor can help determine the best treatment plan for you and adjust it as needed based on how well the medications help your condition.

Azilect and alcohol

If you take Azilect, drinking alcohol is not recommended.

Some beers, wines, and foods contain a large amount of a substance called <u>tyramine</u>. When tyramine is combined with Azilect, a dangerous

interaction could cause a sudden and extreme rise in your <u>blood</u> <u>pressure</u>.

Even if an alcoholic beverage doesn't contain tyramine, alcohol could worsen certain side effects of Azilect, such as:

- sleepiness
- dizziness
- falling and related accidental injuries
- indigestion
- nausea or vomiting
- compulsive behaviors,* such as gambling or binge eating

If you have any questions about alcohol and tyramine, talk with your doctor or pharmacist.

* This side effect occurred after Azilect was approved. For more information, see "Side effect details" in the "Azliect side effects" section above.

Azilect interactions

Azilect can <u>interact</u> with several other medications. It can also interact with certain supplements, as well as certain foods.

Different interactions can cause different effects. For instance, some interactions can interfere with how well a drug works. Other interactions can increase the number of side effects or make them more severe.

Azilect and other medications

Below is a list of medications that can interact with Azilect. This list does not contain all drugs that may interact with Azilect.

Before taking Azilect, talk with your doctor and pharmacist. Tell them about all prescription, over-the-counter, and other drugs you take. Also, tell them about any vitamins, herbs, and supplements you use. Sharing this information can help you avoid potential interactions.

If you have questions about drug interactions that may affect you, ask your doctor or pharmacist.

Azilect and antidepressants

If you're taking certain <u>antidepressant</u> medications, you shouldn't use Azilect. Taking the drugs together could increase your risk for <u>serotonin syndrome</u> (high levels of a chemical called <u>serotonin</u>). Although rare, serotonin syndrome is a serious medical emergency that, in rare cases, could lead to death if untreated. For symptoms of serotonin syndrome, see the "<u>Azilect side effects</u>" section above.

Examples of antidepressants that you shouldn't take with Azilect include:

- monoamine oxidase inhibitors (MAOIs), such as phenelzine (Nardil) or tranylcypromine (Parnate)
- selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine (Prozac), escitalopram (Lexapro), or sertraline (Zoloft)
- serotonin and norepinephrine reuptake inhibitors (SNRIs), such as desvenlafaxine (Pristiq), duloxetine (Cymbalta), or venlafaxine (Effexor XR)
- tricyclic antidepressants, such as amitriptyline or nortriptyline (Pamelor)

If you're taking an antidepressant, talk with your doctor before you use Azilect. They can determine the right medications for you.

Azilect and certain cold medications

Certain over-the-counter (OTC) <u>cold</u> or <u>allergy medications</u> can cause potentially harmful interactions with Azilect. These include dextromethorphan and certain <u>nasal decongestants</u>.

While taking Azilect, you shouldn't take cold medications that contain dextromethorphan. You should wait at least 14 days after your last dose of Azilect before taking cold medications containing dextromethorphan. (After 14 days, Azilect should be out of your system.)

Dextromethorphan, which is sometimes abbreviated "DM," is a cough suppressant found in some OTC cold and cough medications. Examples include Delsym and Mucinex DM. The combination of Azilect and dextromethorphan has been reported to cause episodes of <u>hallucinations</u> or bizarre behavior.

When you take certain nasal decongestants in combination with Azilect, your <u>blood pressure</u> could become very high. This might be especially harmful if you already have <u>hypertension</u> (high blood pressure) or other heart problems. Examples of these nasal decongestants include ephedrine, phenylephrine, and pseudoephedrine. They come as oral tablets, nasal sprays, eye drops, and inhaled forms.

If you're taking an OTC cold or allergy medication, talk with your doctor before you start using Azilect. They can help determine whether the medication is safe to use and recommend other treatments if needed.

Azilect and certain pain medications

Azilect is a type of drug called a <u>monoamine oxidase inhibitor (MAOI)</u>. Life-threatening reactions have been reported in people who received certain anesthesia drugs or opioid drugs while taking MAOIs. Opioids are powerful pain medications. They're often used before, during, or after surgery as anesthesia or to relieve pain.

In addition, <u>serotonin syndrome</u> (high levels of a chemical called <u>serotonin</u>) has been reported in people who received these medications while using MAOIs. Although rare, serotonin syndrome is a serious medical emergency that, in rare cases, could lead to death if untreated. For symptoms of serotonin syndrome, see the "<u>Azilect side effects</u>" section above.

You shouldn't receive certain opioids until at least 14 days after stopping Azilect treatment. (After 14 days, Azilect should be out of your system.) These opioids include:

- methadone
- meperidine (Demerol)
- tramadol (Ultram)

Keep in mind that if you have a medical emergency and need surgery, you may not be able to tell the staff which drugs you're taking. For this reason, it's important to wear a medical alert bracelet or necklace that

shows you're using Azilect. To learn more, see the "Common questions about Azilect" section below.

If you have questions about pain medication and Azilect, talk with your doctor.

Azilect and drugs that can cause sleepiness

Azilect may make you feel sleepy during the day.* In fact, some people have fallen asleep during routine daily activities, such as driving. If you take sedation drugs to help you sleep, taking Azilect could increase your risk for sleepiness. Other drugs may have sleepiness as a side effect, so using Azilect with them could also raise your risk.

Examples of these medications include:

- alprazolam (Xanax, Xanax XR)
- Iorazepam (Ativan)
- eszopiclone (Lunesta)
- ciprofloxacin (Cipro)

If you're concerned with daytime sleepiness with Azilect, talk with your doctor. They can advise you on the risks and benefits of the medication.

Azilect and levodopa

If you're taking a medication that contains levodopa (Inbrija, Sinemet, Stalevo), you may have an increased risk for dyskinesia after you start using Azilect. Dyskinesia refers to abnormal muscle movements that you can't control. To learn more, see the "Azilect side effects" section above.

Before you start taking Azilect, talk with your doctor. They can determine whether any of your medications contain levodopa. If they do, your doctor may adjust your treatment plan. This can include reducing the dosage of Azilect or other medications.

Azilect and herbs and supplements

^{*} For more about this side effect, see the "Azilect side effects" section above.

St. John's wort is an herb that's thought to act similarly to an antidepressant, increasing the levels of certain chemicals in the brain.

If you take Azilect, you shouldn't use St. John's wort. This includes teas, tablets, and capsules that contain the herb.

Taking Azilect and St. John's wort could raise your risk for <u>serotonin</u> <u>syndrome</u> (high levels of a chemical called <u>serotonin</u>).* This interaction could also prevent Azilect from working effectively to treat your Parkinson's symptoms.

* For more information on serotonin syndrome, see the "<u>Azilect side effects</u>" section above.

Azilect and foods

You can take Azilect with or without food. But keep in mind that there are certain foods to avoid while you're being treated with the drug. There are also certain beverages to avoid.

The foods listed below are naturally rich in a substance called tyramine. If you take Azilect and consume a high level of tyramine, a dangerous interaction could cause a sudden, extreme rise in <u>blood pressure</u>.

Some examples of foods and beverages high in tyramine include:

- aged cheeses, such as Stilton
- smoked or cured meats, such as salami
- some beers and wines
- some fruits, especially when they get too ripe
- sourdough bread

You can find a more complete list <u>here</u>. If you accidentally consume foods or beverages high in tyramine while taking Azilect, talk with your doctor right away. They may want to monitor your blood pressure or advise you to seek emergency medical care.

Azilect dosage

The Azilect dosage your doctor prescribes will depend on several factors. These include:

- whether or not you're taking a prescription drug that contains levodopa, a medication that also treats Parkinson's disease
- other medications that you take
- other medical conditions you may have, including mild liver disease

The following information describes dosages that are commonly used or recommended. **However, be sure to take the dosage your doctor prescribes for you.** Your doctor will determine the best dosage to fit your needs.

Drug forms and strengths

Azilect comes as a tablet that you swallow. It's available in two different strengths: 0.5 milligrams (mg) and 1 mg.

Dosage for Parkinson's disease

If Azilect is the only Parkinson's disease medication that your doctor prescribes for you, you'll likely take one 1-mg tablet once daily.

If Azilect is prescribed for you along with a medication that contains levodopa (such as <u>Sinemet</u>), you'll likely take one 0.5-mg tablet daily to start. Your doctor will see whether you have any side effects and how well the drug is working for you. Based on these factors, they may increase your dosage of Azilect to one 1-mg tablet daily.

If you take certain medications that interact with Azilect, such as ciprofloxacin (<u>Cipro</u>), or if you have mild liver disease, your doctor may adjust your dosage.

Make sure to take the dosage your doctor prescribes for you. They can determine the best dosage to fit your needs.

What if I miss a dose?

If you miss a dose of Azilect, take it as soon as you remember. But if you don't remember until it's time to take your next dose, don't double up

side effects, such as <u>orthostatic hypotension</u> (a sudden drop in <u>blood</u> <u>pressure</u> caused by a change in posture).

To help make sure that you don't miss a dose, try using a <u>medication</u> reminder. This can include setting an alarm or timer on your phone or downloading a reminder app. A kitchen timer can work, too.

Will I need to use this drug long term?

Azilect is meant to be used as a long-term treatment. If you and your doctor determine that Azilect is safe and effective for you, you'll likely take it long term.

Azilect withdrawal and dependence

It's very important not to stop taking Azilect suddenly.

Some medications, including Azilect, cause your body to react when you suddenly stop using the drug. This reaction is known as withdrawal.

Serious withdrawal symptoms have been reported when people abruptly stopped taking Azilect. These symptoms can include:

- very high fever
- muscle stiffness
- confusion

In addition, <u>autonomic instability</u> may occur. This condition, which may also be called autonomic dysfunction, can be the result of nerve damage. Symptoms can include sweating too much or little and <u>orthostatic</u> <u>hypotension</u> (a sudden drop in <u>blood pressure</u> caused by a change in posture).

If you want to stop taking Azilect, you must talk with your doctor first. If your doctor agrees that it's necessary to end your treatment, they'll guide you on how to gradually decrease your dosage before you stop using the drug.

How to take Azilect

You should take Azilect according to your doctor's or healthcare provider's instructions.

When to take

Azilect comes as a tablet that you swallow once daily. Try to take your dose at the same time each day. There's no best time of day to take Azilect.

Consider taking your daily dose of Azilect at the time of day that you have the most consistent routine. For example, this could be every morning after you brush your teeth.

To help make sure that you don't miss a dose, try using a <u>medication</u> reminder. This can include setting an alarm or timer on your phone or downloading a reminder app. A kitchen timer can work, too.

Taking Azilect with food

You can take Azilect with or without food. However, there are certain foods that you shouldn't eat during your Azilect treatment. For more information, see the "Azilect interactions" section above.

Can Azilect be crushed, split, or chewed?

You should swallow Azilect tablets. It's not known whether they can be crushed, split, or chewed. If you have trouble swallowing tablets, talk with your doctor or pharmacist. They may be able to advise you on how to make medication easier to take.

Alternatives to Azilect

Other drugs are available that can treat <u>Parkinson's disease</u>. Some may be a better fit for you than others. If you're interested in finding an

alternative to Azilect, talk with your doctor. They can tell you about other medications that may work well for you.

Note: Some of the drugs listed here are used <u>off-label</u> to treat these specific conditions. Off-label drug use is when an FDA-approved drug is used for a purpose other than what it's been approved for by the FDA.

Some other drugs that may be used to treat Parkinson's disease include:

- amantadine
- anticholinergics, such as benztropine (Cogentin) or trihexyphenidyl (Artane)
- catechol-O-methyltransferase (COMT) inhibitors, such as entacapone (Comtan) or tolcapone (Tasmar)
- dopamine agonists, such as pramipexole (Mirapex), rotigotine (Neupro), ropinirole (Requip)
- istradefylline (Nourianz)
- levodopa/carbidopa (Sinemet)
- other monoamine oxidase inhibitors (MAOIs) such as selegiline and safinamide (Xadago)

How Azilect works

It's believed that <u>Parkinson's disease</u> is the result of damage to the brain cells that produce <u>dopamine</u>. (Dopamine is a neurotransmitter, which is a chemical that sends messages between your brain and body.) The levels of dopamine affect many vital brain functions, such as mood, sleep, memory, and muscle control. When the levels drop, Parkinson's symptoms can occur. These symptoms include problems with some vital brain functions, such as:

- uncontrolled muscle movements, such as tremors
- depression
- trouble falling asleep or staying asleep
- memory problems

Recent <u>research</u> suggests that an underlying <u>autoimmune disorder</u> may cause Parkinson's disease. With autoimmune disorders, your <u>immune</u> <u>system</u> mistakenly attacks your body's own healthy tissues as if they were bacteria or <u>viruses</u>.

Some of the studies have shown that people with Parkinson's often have early signs of damage to the brain cells that produce dopamine. This damage occurs years before they start having tremors or other movement-related symptoms. More research is needed, but this finding may lead to new and improved future therapies that could possibly prevent or delay Parkinson's disease symptoms.

What Azilect does

Azilect belongs to a drug class known as <u>monoamine oxidase inhibitors</u> (<u>MAOIs</u>). A drug class is a group of medications that have a similar mechanism of action. (A mechanism of action is how a drug works in the body.)

Azilect contains the active drug rasagiline, which blocks the action of an <u>enzyme</u> called MAO. This enzyme is in the brain, and it breaks down certain neurotransmitters, including dopamine. When MAO can't break down dopamine, the levels of dopamine increase. This eases or stops tremors.

How long does it take to work?

In a <u>clinical study</u>, people reported that their Parkinson's symptoms eased after 1 week of taking Azilect daily.

If you've been using Azilect for more than a couple of weeks and haven't noticed any symptoms relief, talk with your doctor. They may suggest making adjustments to your treatment plan.

Common questions about Azilect

Here are answers to some frequently asked questions about Azilect.

Are there any contraindications to using Azilect?

Yes. A contraindication is a condition or factor that would prevent you from taking a medication. There are some contraindications to using Azilect.

You shouldn't take certain medications with Azilect. If you're using one of the drugs mentioned below, your doctor will typically recommend an alternative. This may be an alternative to Azilect or an alternative to the medication that's contraindicated (should not be used in any circumstance).

Contraindications include taking any of the following drugs while using Azilect:

- meperidine (Demerol)
- tramadol (Ultram)
- methadone
- dextromethorphan (Delsym)
- cyclobenzaprine (Flexeril)
- other monoamine oxidase inhibitors (MAOIs), such as selegiline
- St. John's wort, an herb

If your doctor advises you to stop taking Azilect, you shouldn't use the above medications until at least 14 days after your last dose of Azilect. For more information, talk with your doctor.

Will I be able to have surgery if I'm taking Azilect?

Yes, but it's important to be aware that some medications used for surgery may interact with Azilect. These include:

 Certain anesthetics used for surgery. Some anesthetics used for surgery shouldn't be used with Azilect. This includes meperidine (Demerol). Harmful serious side effects, such as serotonin syndrome, could occur. This syndrome occurs when you have high levels of a chemical called serotonin. For more information, see the "Azilect side effects" section above.

- Certain medications that reduce nausea and vomiting after anesthesia. Some drugs that ease nausea and vomiting after anesthesia could interact with Azilect. This includes metoclopramide (Reglan), which could make Azilect less effective.
- Pain medications after surgery. Pain medications, including opioids, are often given after surgery to relieve pain. But certain opioids aren't safe to take with Azilect. These include tramadol (Ultram), and methadone.

It's crucial that the doctor and surgical team know you take Azilect. But if you have a medical emergency and need surgery, you may not be able to tell them which drugs you're taking. For this reason, it's important to wear a medical alert bracelet or necklace that shows you're using Azilect, which is a monoamine oxidase inhibitor (MAOI) drug. If the staff is aware that you're taking an MAOI, they'll typically select alternatives that are safe to use with Azilect. If this isn't possible, they'll monitor you very closely after surgery.

If you're taking Azilect and planning to have surgery, talk with your doctor. They can help make sure the medical staff is properly informed of the medications you're taking. For more information about drug interactions with Azilect, see the "Azilect interactions" section above.

Azilect and pregnancy

It's not known whether Azilect is safe to take during pregnancy. This is because there haven't been enough human <u>studies</u>. Animal studies showed harmful effects when Azilect was given during pregnancy. These effects include low birth weight and decreased rate of offspring survival. But animal studies don't always predict what would happen in humans.

If you're pregnant or plan to become pregnant, talk with your doctor before using Azilect. They can advise you on the risks and benefits of the drug. And if you become pregnant while taking Azilect, talk with your doctor right away. They can help determine whether you should keep using the medication.

Azilect and birth control

It's not known if Azilect is safe to take during pregnancy. If you're sexually active and you or your partner can become pregnant, talk with your doctor about your <u>birth control</u> needs while you're using Azilect.

For more information about taking Azilect during pregnancy, see the "Azilect and pregnancy" section above.

Azilect and breastfeeding

It isn't known if Azilect is safe to take while breastfeeding. The effects of Azilect on human breast milk haven't been studied.

If you're breastfeeding or plan to breastfeed, talk with your doctor. They can review the pros and cons of Azilect with you and recommend healthy ways to feed your child.

Azilect precautions

Before taking Azilect, talk with your doctor about your health history.

Azilect may not be right for you if you have certain medical conditions or other factors affecting your health. These include:

High blood pressure. If you have <u>high blood pressure</u>, it's possible that Azilect could raise your <u>blood pressure</u>. Consider using a home blood pressure monitor to <u>check your blood pressure</u> regularly while you take Azilect. In addition, your doctor may monitor your blood pressure more closely than usual. Or they may adjust the dosage of <u>blood pressure</u> <u>medication</u> you may be taking.

Orthostatic hypotension. If you have a history of <u>low blood pressure</u> or <u>fainting</u>, taking Azilect may increase your risk for <u>orthostatic hypotension</u>. This side effect usually goes away after the first 2 months of taking Azilect. If you're still concerned about your <u>blood pressure</u> becoming too low while taking this drug, talk with your doctor. They may be able to suggest ways to keep your blood pressure within a safe range.

Hallucinations. If you have a history of <u>hallucinations</u>, Azilect may worsen your condition. After the drug was approved, there were reports of delusions, confusion, and psychotic-like behavior in people taking Azilect. These reports didn't occur in <u>clinical trials</u> of the drug. If you're concerned about hallucinations with Azilect, talk with your doctor. They can advise you on the drug's risks and benefits and recommend a different treatment if needed.

Severe mental illness. If you have a history of severe <u>mental illness</u>, you shouldn't use Azilect. This is because the drug may worsen your condition. After Azilect was approved, there were reports of delusions, confusion, and psychotic-like behavior in people taking the drug. These reports didn't occur in <u>clinical trials</u> of Azilect. Ask your doctor what treatment other than Azilect is right for you.

Compulsive behaviors. If you've had problems with risky or compulsive behaviors, taking Azilect may worsen your impulse control. After the drug was approved, there were reports of people using Azilect who weren't able to control their spending, gambling, binge eating, and sexual urges. These reports didn't occur in <u>clinical trials</u> of the drug.

Talk with your doctor if you have a history of risky or compulsive behaviors. They may ask your family members to report any new or increased compulsive behaviors you have after you start taking Azilect. This is because you may not recognize the behaviors yourself. If your impulse control worsens during treatment, your doctor may lower your dosage or have you stop taking the drug.

Allergic reaction. If you've had an <u>allergic reaction</u> to Azilect or any of its ingredients, you shouldn't take Azilect. Ask your doctor what other medications are better options for you.

Pregnancy. It isn't known if Azilect is safe to take while you're pregnant. For more information, see the "Azilect and pregnancy" section above.

Breastfeeding. It isn't known if Azilect is safe to take while you're breastfeeding. For more information, see the "Azilect and breastfeeding" section above.

Note: For more information about the potential negative effects of Azilect, see the "Azilect side effects" section above.

Azilect overdose

Using more than the recommended dosage of Azilect can lead to serious side effects. Do not use more Azilect than your doctor recommends.

Overdose symptoms

Symptoms of an overdose can include:

- drowsiness
- dizziness
- fainting
- irritability
- hyperactivity
- severe headache
- hallucinations
- trismus (lockjaw)
- spasms or convulsions
- coma
- rapid heartbeat
- spikes or drops in blood pressure
- high fever
- hyperhidrosis (excessive sweating)
- cool, clammy skin

What to do in case of overdose

If you think you've taken too much of this drug, call your doctor. You can also call the American Association of Poison Control Centers at 800-222-1222 or use their <u>online tool</u>. **But if your symptoms are severe, call 911 or your local emergency number, or go to the nearest emergency room right away.**

Azilect expiration, storage, and disposal

When you get Azilect from the pharmacy, the pharmacist will add an expiration date to the label on the bottle. This date is typically 1 year from the date they dispensed the medication.

The expiration date helps guarantee that the medication is effective during this time. The <u>current stance</u> of the Food and Drug Administration (FDA) is to avoid using expired medications. If you have unused medication that has gone past the expiration date, talk to your pharmacist about whether you might still be able to use it.

Storage

How long a medication remains good can depend on many factors, including how and where you store the medication.

You should store Azilect tablets at room temperature (77°F/25°C) in a tightly sealed container away from light. If needed, you can keep the medication at 59°F to 86°F (15°C to 30°C) for short periods of time. Avoid storing this medication in areas where it could get damp or wet, such as bathrooms.

Disposal

If you no longer need to take Azilect and have leftover medication, it's important to dispose of it safely. This helps prevent others, including children and pets, from taking the drug by accident. It also helps keep the drug from harming the environment.

This <u>article</u> provides several useful tips on medication disposal. You can also ask your pharmacist for information about how to dispose of your medication

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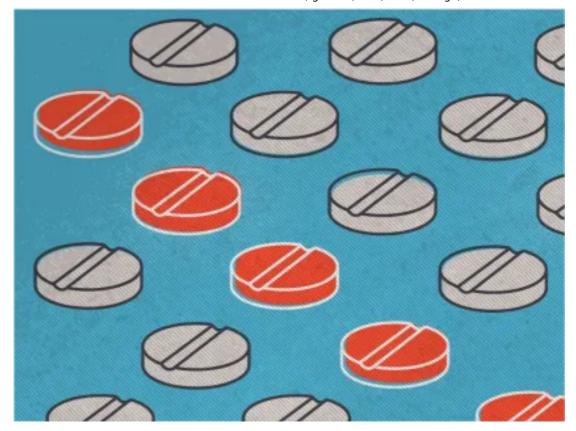
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