

Auvelity™
(dextromethorphan HBr and bupropion HCl)
extended-release tablets 45mg/105mg

NOT JUST ANOTHER ANTIDEPRESSANT

FOR NOT JUST
ANOTHER **JILL OF ALL TRADES**



Actor Portrayal

WHAT IS AUVELITY (aw-VEHL-ah-tee)?

It is a prescription oral medicine used to treat adults with major depressive disorder (MDD). It is not known if Auvelity is safe and effective in children. Auvelity is not approved for uses other than the treatment of MDD. The ingredients in Auvelity, bupropion and dextromethorphan, are the same ingredients found in some other medicines approved for other uses.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AUVELITY?

Auvelity and other antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults, especially within the first few months of treatment or when the dose is changed. Auvelity is not for use in children.

You should pay close attention to any new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions. This is very important when starting or changing the dose of an antidepressant medicine.

Please see additional Important Safety Information on the following pages, and full [Prescribing Information](#), including [Boxed Warning](#) for suicidal thoughts and behaviors and [Medication Guide](#).

Auvelity: The only antidepressant tablet of its kind.

Here's something you might not have known: for 60 years, oral antidepressants have all been thought to work in generally the same way.

Until Auvelity.

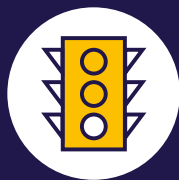
Auvelity is an oral antidepressant that acts on receptors in the brain called NMDA receptors, among others. While the exact way Auvelity works to treat depression is unclear, it affects certain brain chemicals thought to be involved in depression.



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How does Auvelity work differently?

Experts believe that depression involves certain brain chemicals. While the exact way that Auvelity works to treat depression is unclear, it acts on multiple receptors in the brain, which affect different brain chemicals.



One of these receptors is the NMDA receptor, which affects **glutamate**, your brain's primary "go" signal.



Auvelity is also thought to affect other brain chemicals you may have heard of including **dopamine** and **norepinephrine**.

By acting on the NMDA receptor, Auvelity works differently than any other oral antidepressant.

IMPORTANT SAFETY INFORMATION (CONT'D)

Call your healthcare provider (HCP) or get emergency help right away if you or your loved one have any of the following symptoms, especially if they are new, worse, or worry you:

- suicidal thoughts or actions
- new or worsening depression or anxiety
- agitation or restlessness
- trouble sleeping (insomnia)
- acting aggressive, being angry violent
- an extreme increase in activity and talking (mania)
- panic attacks
- new or worsening irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

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Auvelity can help relieve depression symptoms fast.

It's the first and only rapid-acting oral antidepressant labeled to start working at 1 week.*



People taking Auvelity saw **greater symptom improvement** at 6 weeks compared to those taking placebo.*

Auvelity was studied in a 6-week trial comparing it to placebo.*

Why Auvelity?



Started working at 1 week

On average, people taking Auvelity had a rapid improvement in their depressive symptom scores vs. placebo at 1 week.



Helped achieve remission at 2 weeks

More people taking Auvelity reached remission at Week 2 than those taking placebo.*†



Reduced depression scores seen up to 1 year

Average depression scores were reduced at 1 year in a long-term study where both researchers and patients knew they were taking Auvelity.‡

What did people taking Auvelity have to say?

In the study comparing Auvelity to placebo, people used a scale to rate how depression disrupted their:

- work/school
- social life
- family life/home responsibility

People taking Auvelity saw their total scores improve when measured at 6 weeks vs placebo.



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IMPORTANT SAFETY INFORMATION (CONT'D)

Do not take Auvelity if you:

- have or had a seizure disorder.
- have or had an eating disorder like anorexia or bulimia.
- have recently and suddenly stopped drinking alcohol or use medicines called benzodiazepines, barbiturates, or anti-seizure medicines, and you have recently suddenly stopped taking them.
- are taking a monoamine oxidase inhibitor (MAOI), have stopped taking an MAOI in the last 14 days, or are being treated with the antibiotic linezolid or intravenous methylene blue. Ask your HCP or pharmacist if you are unsure whether you take an MAOI. Do not start taking an MAOI until you have stopped taking Auvelity for at least 14 days.
- are allergic to dextromethorphan, bupropion, or any other ingredients in Auvelity.

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*Measured against placebo on a depression rating scale during a 6-week study of 327 adults with MDD. Symptom improvement was based on the overall change in a depression symptom scale that evaluated: sadness, inner tension, reduced sleep and appetite, difficulty concentrating, lack of interest, lack of energy/motivation and ability to feel, pessimism, and thoughts of suicide.

†The average baseline score for all patients was 33 on a depression symptom scale. Remission was defined as a score ≤ 10 . Many patients achieving this score may still have some symptoms of depression.

‡A study of 609 adults with MDD. This study was not designed to evaluate the long-term effectiveness of Auvelity. Patients were removed from the study after 6 weeks if they did not experience at least a 25% improvement in their depression score. 341 patients were evaluated at Month 9 and 29 were evaluated at Month 12.

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How do I take Auvelity?

Take Auvelity exactly as your doctor says. It's recommended that you take it once a day for the first 3 days, then twice a day, with at least 8 hours in between. Don't take more than 2 tablets within 24 hours.



Before starting Auvelity, tell your doctor about any medications you're currently taking, including any that contain bupropion or dextromethorphan. Also be sure to give your doctor a detailed medical history, including a personal or family history of bipolar disorder, mania, or hypomania. Your doctor should take your blood pressure both before and during treatment with Auvelity.



You can take Auvelity with or without food. Swallow the tablets whole; don't crush, divide or chew them.



Don't take more than 1 tablet at a time. If you miss a dose, don't take an extra one. Take your next dose at the regular time.

What are the possible side effects?

During a 6-week clinical study, the most common side effects experienced by 5% or more of people taking Auvelity (and at least twice the rate of placebo) were: dizziness, headache, diarrhea, feeling sleepy, dry mouth, sexual function problems, and excessive sweating.

What about sexual problems and weight gain?

We know they can be top of mind when it comes to antidepressants. In a 6 week study:



People taking Auvelity lost about half a pound, while those taking placebo gained about 1 pound, on average.



Auvelity can be associated with sexual side effects. Sexual side effects were reported in 6% of people taking Auvelity.* Sexual side effects may include: erectile dysfunction, decreased libido, and problems with orgasm.

*Sexual side effects are generally underreported because people may be hesitant to talk about them.

With Auvelity, help is On My Side



To download a Savings Card, visit [Auvelity.com/Save](https://www.aavelity.com/Save) or text **SAVE to 61489***†



Join the **Auvelity On My Side** program at [Auvelity.com/OnMySide](https://www.aavelity.com/OnMySide) for helpful resources and more



IMPORTANT SAFETY INFORMATION (CONT'D)

Auvelity may cause serious side effects. Ask your HCP how to recognize the serious side effects below and what to do if you think you have one:

Seizures. There is a risk of seizures during treatment with Auvelity. The risk is higher if you take higher doses of Auvelity, have certain medical problems, or take Auvelity with certain other medicines. **Do not take Auvelity with other medicines unless your healthcare provider tells you to.**

If you have a seizure during treatment with Auvelity, stop taking Auvelity and call your HCP right away. **Do not take Auvelity again if you have a seizure.**

Increases in blood pressure (hypertension). Some people may get high blood pressure during treatment with Auvelity. Your HCP should check your blood pressure before you start taking and during treatment with Auvelity.

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*Subject to eligibility.

†By texting SAVE to 61489 you agree to receive recurring automated Copay Savings Program messages, which may include savings alerts, refill reminders, and other messages related to your participation in the copay program. Consent to receiving SMS messages is not a condition of purchase of goods or services. Msg. & data rates may apply. Msg. frequency varies. Text STOP to opt out. Text HELP for help. Terms & Conditions apply. See [T&C](#) and [Privacy Notice](#).

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IMPORTANT SAFETY INFORMATION (CONT'D)

Auvelity may cause serious side effects. Ask your HCP how to recognize the serious side effects below and what to do if you think you have one:

Manic episodes. Manic episodes may happen in people with bipolar disorder who take Auvelity. Symptoms may include:

- greatly increased energy
- racing thoughts
- unusually grand ideas
- talking more or faster than usual
- severe trouble sleeping
- reckless behavior
- excessive happiness or irritability

Unusual thoughts or behaviors. One of the ingredients in Auvelity (bupropion) can cause unusual thoughts or behaviors, including delusions (believing you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your HCP.

Eye problems (angle-closure glaucoma). Auvelity may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your HCP if you have eye pain, changes in your vision, or swelling or redness in or around the eye.

Dizziness. Auvelity may cause dizziness which may increase your risk for falls.

Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome can happen when you take Auvelity with certain other medicines. **Call your HCP or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms:

- agitation
- hallucinations
- confusion
- coma
- fast heartbeat
- blood pressure changes
- dizziness
- sweating
- flushing
- high body temperature (hyperthermia)
- shaking (tremors), stiff muscles, or muscle twitching
- loss of coordination
- seizures
- nausea, vomiting, diarrhea

COMMON SIDE EFFECTS

The most common side effects of Auvelity include dizziness, headache, diarrhea, feeling sleepy, dry mouth, sexual function problems, and excessive sweating.

These are not all the side effects of Auvelity. Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.

BEFORE USING

- Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- It is important to tell your HCP if you are taking:
 - other medicines containing bupropion or dextromethorphan
 - medicines to treat depression, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants
 - theophylline
 - corticosteroids
 - oral diabetes medicines or use insulin to control your blood sugar
 - medicines to control appetite (anorectic)
 - nicotine medicines to help you stop smoking
 - street (illicit) drugs
 - benzodiazepines, sedative-hypnotic (sleep medicines), or opiates
- If you are unsure if you take any of these medicines, ask your HCP. They can tell you if it is safe to take Auvelity with your other medicines.
- Tell your HCP if you are pregnant or plan to become pregnant. Auvelity may harm your unborn baby if you take it during pregnancy. Auvelity is not recommended during pregnancy. Your HCP will prescribe another treatment for females who plan to become pregnant.

- One of the ingredients in Auvelity passes into your breast milk. Do not breastfeed during treatment with Auvelity and for 5 days after the final dose.

Tell your HCP about all your medical conditions, including if you:

- have problems with your liver or kidneys.
- have diabetes, heart disease, or high blood pressure.
- have a history of seizure, stroke, eating disorder, head injury, or have a tumor in your brain or spinal cord.
- have a history of alcohol or drug abuse.
- have a history of seizure, eating disorder, or abuse alcohol or drugs.
- have low blood sugar, low blood sodium levels, or a history of falls.
- you take certain other medicines that could interact with Auvelity.
- have or had a condition known as bipolar disorder, a family history of bipolar disorder, suicide, or depression.
- have high pressure in the eye (glaucoma).

Review the list below with your HCP. Auvelity may not be right for you if:

- you drink a lot of alcohol.
- you abuse prescription or street drugs.
- you are pregnant or plan to become pregnant.
- you are breastfeeding or plan to breastfeed.

HOW TO TAKE

- Auvelity is available by prescription only.
- Take Auvelity exactly as instructed by your HCP.
- Take Auvelity 1 time a day for 3 days, then increase your dose to 2 times a day (taken at least 8 hours apart). Do not take more than 2 Auvelity tablets in 24 hours.
- If you miss a dose, do not take an extra dose. Wait and take your next dose at the regular time. Do not take more than 1 dose of Auvelity at a time.
- Do not change your dose or stop taking Auvelity without talking to your HCP.
- Swallow Auvelity tablets whole. Do not crush, chew, or divide the tablets.
- Do not give Auvelity to other people.
- If you take too much Auvelity call your HCP or seek medical advice promptly.

LEARN MORE

For more information about Auvelity, call 866-496-2976 or visit Auvelity.com.

This summary provides basic information about Auvelity but does not include all information known about this medicine. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other HCP about Auvelity and how to take it. Your HCP is the best person to help you decide if Auvelity is right for you.

Please see full [Prescribing Information](#), including [Boxed Warning for suicidal thoughts and behaviors](#), and [Medication Guide](#).

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