

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.

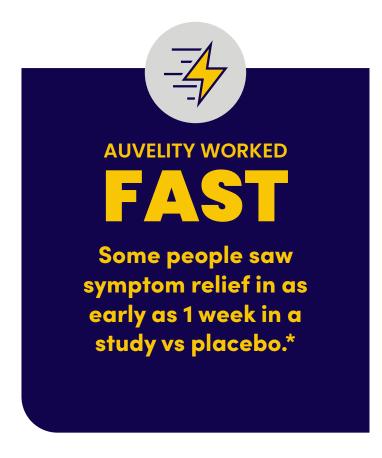
You should pay close attention to any new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions. This is very important when starting or changing the dose of an antidepressant medicine.

Please see full Important Safety Information throughout, full <u>Prescribing Information</u>, including **Boxed Warning** for suicidal thoughts and behaviors, and <u>Medication Guide</u>. (dextromethorphan HBr and bupropion HCI) extended-release tablets 45mg/105mg

Actor portrayal.

Depression symptom relief that's FAST & LASTS—to help you get your *GO* back







On average, significant symptom relief was seen at 6 weeks in a study vs placebo.*

*Measured against placebo on a depression symptom 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, reduced appetite, difficulty concentrating or doing daily activities, lack of interest, lack of energy/motivation, inability to feel, pessimism, and thoughts of suicide.

MDD=major depressive disorder.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AUVELITY? (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
 an extreme increase in
- new or worsening depression or anxiety
- agitation or restlessness
- trouble sleeping (insomnia) acting on dangerous
- acting aggressive, being angry, or 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

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.

Please see full Important Safety Information throughout, full <u>Prescribing Information</u>, including **Boxed Warning** for suicidal thoughts and behaviors, and <u>Medication Guide</u>.

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 certain brain chemicals.



One of these receptors is the NMDA receptor, which is activated by glutamate, your brain's most abundant neurotransmitter.

Another of these receptors, known as the sigma-1 receptor, is thought to help influence the release of neurotransmitters, which is how brain cells communicate between one another.



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





NMDA=N-methyl-D-aspartate.

Actor portrayal.

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

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.

Please see full Important Safety Information throughout, full Prescribing Information, including **Boxed Warning** for suicidal thoughts and behaviors, and Medication Guide.

How do I take AUVELITY?



Take AUVELITY exactly as your healthcare provider prescribes. Typically, when you start AUVELITY, you take it once a day for the first 3 days. After that, you take it 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 healthcare provider about any medications you're currently taking, including any that contain bupropion or dextromethorphan. Also be sure to give your healthcare provider a detailed medical history, including a personal or family history of bipolar disorder, mania, or hypomania. Your healthcare provider should take your blood pressure both before and during treatment with AUVELITY.



You can take AUVELITY with or without food, so you don't need to plan your meals around your medication. Swallow the tablets whole; don't crush, divide, or chew them.



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

Your healthcare provider may tell you to take AUVELITY differently if you are taking other medications or have certain medical conditions.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT AUVELITY? (CONT'D)

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

BEFORE USING

• Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

These are not all the possible side effects of AUVELITY. Tell

to report side effects of prescription drugs to the FDA. Visit

www.fda.gov/medwatch, or call 1-800-FDA-1088.

your doctor if you have any side effects. You are encouraged

- 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

COMMON SIDE EFFECTS

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

Please see full Important Safety Information throughout, full Prescribing Information, including Boxed Warning for suicidal thoughts and behaviors, and Medication Guide.

What are some of 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. These are not all the possible side effects of AUVELITY. For more information, talk to your healthcare provider and refer to the Medication Guide.

What about weight gain and sexual problems?

We know that when it comes to antidepressants, things like weight gain and sexual side effects can be top of mind. In a 6-week study:



On average, people taking AUVELITY lost about half a pound, while those taking placebo gained about 1 pound.



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



BEFORE USING (CONT'D)

- 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
- 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.

Please see full Important Safety Information throughout, full Prescribing Information, including **Boxed Warning** for suicidal thoughts and behaviors, and Medication Guide.

What do real people have to say about AUVELITY?





I got my game face back.



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 poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

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.

AUV CON BS 08/2024

Please see full Important Safety Information throughout, full <u>Prescribing Information</u>, including **Boxed Warning** for suicidal thoughts and behaviors, and <u>Medication Guide</u>.

There are 2 ways to save on your prescription





Option 1:



through PhilRx*

PhilRx takes care of the details, so eligible patients can get the lowest possible price for AUVELITY.





Please see full Important Safety Information throughout, full <u>Prescribing Information</u>, including **Boxed Warning** for suicidal thoughts and behaviors, and <u>Medication Guide</u>.

^{*}PhilRx is a third-party vendor.

[†]Terms and Conditions apply. The AUVELITY Savings Card will allow for up to 2 fills; afterwards, a prior authorization determination must be on file for continued support.



Saving on AUVELITY can be simple[†]

Scan the QR code or visit AUVELITY.com/save to download your Savings Card now.





Must have commercial insurance. Offer not available to patients with Medicare, Medicaid, or other government-funded insurance.
†Subject to eligibility.

Please see full Important Safety Information throughout, full <u>Prescribing Information</u>, including **Boxed Warning** for suicidal thoughts and behaviors, and Medication Guide.





AUVELITY, AXSOME, and their logos are trademarks or registered trademarks of Axsome Therapeutics, Inc. or its affiliates. Other trademarks are property of their respective owners.

© 2025 Axsome Therapeutics, Inc. All rights reserved. PP-AUV-US-2100064 04/2025