

MEDICATION GUIDE
AUVELITY® (aw - VEHL - ah- tee)
(dextromethorphan hydrobromide / bupropion hydrochloride)
extended-release tablets, for oral use

What is the most important information I should know about AUVELITY?

AUVELITY may cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions.** AUVELITY and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed. AUVELITY is not for use in children.**

- Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

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

- | | |
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| ○ thoughts about suicide or dying | ○ suicide attempts |
| ○ new or worse depression | ○ new or worse anxiety |
| ○ feeling very agitated or restless | ○ panic attacks |
| ○ trouble sleeping (insomnia) | ○ new or worse irritability |
| ○ acting aggressive, being angry, or violent | ○ acting on dangerous impulses |
| ○ an extreme increase in activity and talking (mania) | ○ other unusual changes in behavior or mood |

See **“What are the possible side effects of AUVELITY?”** for more information about side effects.

What is AUVELITY?

AUVELITY is a prescription medicine used:

- to treat a certain type of depression called Major Depressive Disorder (MDD) in adults.
- to treat agitation that may happen with dementia due to Alzheimer’s disease.

AUVELITY should not be used as an “as needed” treatment for agitation that may happen with dementia due to Alzheimer’s disease.

It is not known if AUVELITY is safe and effective for use in children.

The ingredients in Auvelity, bupropion and dextromethorphan, are ingredients found in some other medicines approved for other uses. AUVELITY is not approved for other uses.

Do not take AUVELITY if you:

- have or had a seizure disorder.
- have or had an eating disorder such as anorexia nervosa or bulimia.
- have recently suddenly stopped drinking alcohol or use medicines called benzodiazepines, barbiturates, or anti-seizure medicines, and you have recently suddenly stopped taking them.
- take a monoamine oxidase inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue
- are allergic to dextromethorphan, bupropion, or any of the ingredients in AUVELITY. See the end of this Medication Guide for a complete list of ingredients in AUVELITY.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI or one of these medicines, including the antibiotic linezolid or intravenous methylene blue.

Do not start AUVELITY if you stopped taking an MAOI in the last 14 days.

Do not start taking an MAOI for at least 14 days after you stop treatment with AUVELITY.

Before taking AUVELITY, tell your healthcare provider about all your medical conditions, including if you:

- have or had seizures or convulsions
- have or had an eating disorder

- have or had a head injury
- have had a heart attack or have heart problems
- have a tumor in your nervous system (brain or spine)
- have had a stroke
- have low blood sugar
- have low sodium levels in your blood
- have liver problems
- have kidney problems
- drink a lot of alcohol
- abuse prescription medicines or street drugs
- have diabetes and take oral diabetes medicines or use insulin to control your blood sugar
- have high blood pressure
- have problems walking or a history of falls
- have or had bipolar disorder, or have a family history of bipolar disorder, suicide, or depression
- have high pressure in the eye (glaucoma)
- are pregnant or plan to become pregnant. AUVELITY may harm your unborn baby if you take AUVELITY during pregnancy. AUVELITY is not recommended during pregnancy.
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with AUVELITY. Your healthcare provider will prescribe another treatment for females who plan to become pregnant.
 - There is a pregnancy exposure registry for females who are exposed to AUVELITY during pregnancy. The purpose of the registry is to collect information about the health of females exposed to AUVELITY and their baby. If you become pregnant during treatment with AUVELITY, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at <https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/>.
- are breastfeeding or plan to breastfeed. One of the ingredients in AUVELITY, bupropion, passes into your breast milk. Do not breastfeed during treatment with AUVELITY and for 5 days after the final dose.

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

AUVELITY and some other medicines may affect each other causing possible serious side effects. AUVELITY may affect the way other medicines work and other medicines may affect the way AUVELITY works.

Especially tell your healthcare provider if you take:

- other medicines containing bupropion or dextromethorphan
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), MAOIs, and tricyclic antidepressants
- medicines used to treat migraine headaches called triptans
- 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, sedatives-hypnotics (sleep medicines), or opiates
- central nervous system (CNS) stimulants
- digoxin
- levodopa
- amantadine

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take AUVELITY with your other medicines.

Do not start or stop any other medicines during treatment with AUVELITY without talking to your healthcare provider first. Stopping AUVELITY suddenly may cause you to have serious side effects. See, **“What are the possible side effects of AUVELITY?”**

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take AUVELITY?

- Take AUVELITY exactly as your healthcare provider tells you to take it.
- Your healthcare provider may increase your dose of AUVELITY during treatment. Follow the directions provided by your healthcare provider. Do not change your dose of AUVELITY without first talking to your healthcare provider.
- If you take AUVELITY 1 time a day, take your tablet in the morning.
- If your healthcare provider increases your dose to 2 times a day, take the AUVELITY tablets at least 8 hours apart.
- Do not take more than 2 AUVELITY tablets in 24 hours.
- Swallow AUVELITY tablets whole. Do not crush, chew, or divide AUVELITY tablets.
- AUVELITY may be taken with or without food.
- If you miss a dose, do not take an extra dose to make up for the dose you missed. Wait and take your next dose at the regular time. **Do not** take more than 1 dose of AUVELITY at a time.
- If you take too much AUVELITY, call your Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking AUVELITY?

- Limit or avoid using alcohol during treatment with AUVELITY. If you usually drink a lot of alcohol, talk with your healthcare provider before suddenly stopping. If you suddenly stop drinking alcohol, you may increase your chance of having seizures.
- Do not drive a car or use heavy machinery until you know how AUVELITY affects you. AUVELITY can affect your ability to do these things safely.

What are possible side effects of AUVELITY?

AUVELITY may cause serious side effects, including:

- See “**What is the most important information I should know about AUVELITY**”
- **Seizures.** There is a risk of seizures during treatment with AUVELITY. The risk is higher in people who:
 - take higher doses of AUVELITY
 - have certain medical problems
 - take AUVELITY with certain other medicines or alcohol

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 healthcare provider right away. **Do not** take AUVELITY again if you have a seizure.
- **Increases in blood pressure (hypertension).** Your healthcare provider 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	○ severe trouble sleeping
○ racing thoughts	○ reckless behavior
○ unusually grand ideas	○ excessive happiness or irritability
○ talking more or faster than usual	
- **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 healthcare provider.
- **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 healthcare provider 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 healthcare provider or go to the nearest hospital emergency room right away** if you develop any of the following signs and symptoms of serotonin syndrome:

○ agitation	○ sweating
○ seeing or hearing things that are not there (hallucinations)	○ flushing
○ confusion	○ high body temperature (hyperthermia)
○ coma	○ shaking (tremors), stiff muscles, or muscle twitching

- fast heartbeat
- changes in blood pressure
- dizziness
- loss of coordination
- seizures
- nausea, vomiting, diarrhea

- **Low levels of salt (sodium) in your blood.** Symptoms of this may include: headache, difficulty concentrating, memory changes, confusion, weakness and unsteadiness on your feet. Symptoms of severe or sudden cases of low salt levels in your blood may include: hallucinations (seeing or hearing things that are not real), fainting, seizures and coma. If not treated, severe low sodium levels can cause death. Elderly people and people who take diuretics or who become dehydrated may be at greater risk for this. Tell your healthcare provider if you develop signs and symptoms of low sodium levels.

The most common side effects of AUVELITY in MDD include:

- dizziness
- headache
- diarrhea
- feeling sleepy
- dry mouth
- sexual function problems
- excessive sweating

The most common side effects of AUVELITY in agitation that may happen with dementia due to Alzheimer's disease include:

- dizziness
- stomach upset or pain

AUVELITY may also cause allergic reactions. Allergic reactions can happen right after you start taking AUVELITY or develop later during AUVELITY treatment. Tell your healthcare provider right away if you develop any of the following signs and symptoms at any time during AUVELITY treatment:

- skin rash
- itching
- hives
- chest pain
- swelling
- shortness of breath
- muscle or joint pain
- fever

These are not all the possible side effects of AUVELITY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AUVELITY?

- Store AUVELITY at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep AUVELITY in the bottle that it comes in.
- **Keep AUVELITY and all medicines out of the reach of children.**

General information about the safe and effective use of AUVELITY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AUVELITY for a condition for which it was not prescribed. Do not give AUVELITY to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about AUVELITY that is written for health professionals.

If you take a urine drug screening test, AUVELITY may make the test result positive for amphetamines. If you tell the person giving you the drug screening test that you are taking AUVELITY, they can do a more specific drug screening test that should not have this problem.

What are the ingredients in AUVELITY?

Active ingredients: dextromethorphan hydrobromide / bupropion hydrochloride.

Inactive ingredients: carbomer homopolymer, colloidal silicon dioxide, crospovidone, glyceryl monocaprylocaprate, l-cysteine hydrochloride monohydrate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium lauryl sulfate, stearic acid, talc, and titanium dioxide. Beige tablets also contain red iron oxide and yellow iron oxide.

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For more information about AUVELITY, visit AUVELITY.com or call 1-866-496-AXSM (1-866-496-2976).