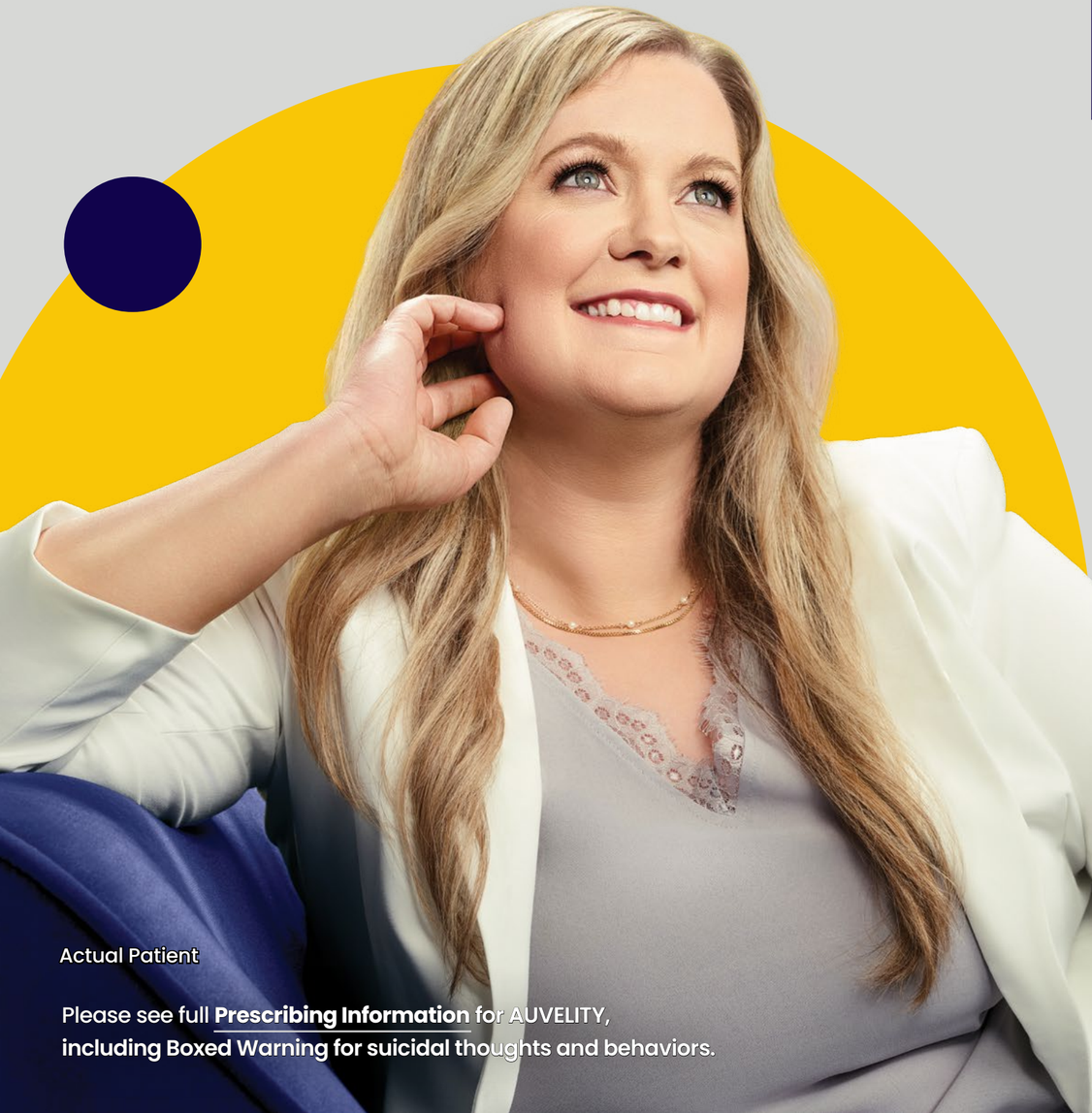
Auvelity®

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



Actual Patient

Please see full **Prescribing Information** for AUVELITY, including Boxed Warning for suicidal thoughts and behaviors.

Quick Start Guide

Answers to common questions

Things you need to know about the AUVELITY Coverage Process.

Prior Authorization: Reference Information

This section outlines potential PA submission or Step Edit requirements for patients starting on Auvelity. A Medical Necessity Letter may also be required during formulary placement review or if Auvelity is not covered.

INDICATION

AUVELITY is indicated for the treatment of major depressive disorder (MDD) in adults.*

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies.**
- **Closely monitor all antidepressant-treated patients for clinical worsening, and emergence of suicidal thoughts and behaviors.**
- **Auvelity is not approved for use in pediatric patients.**

Ensure adult patient has the correct diagnosis (ICD-10 code):

ICD-10 codes for MDD:

MDD, single episode

F32.0	Major depressive disorder, single episode, mild
F32.1	Major depressive disorder, single episode, moderate
F32.2	Major depressive disorder, single episode, severe without psychotic symptoms
F32.3	Major depressive disorder, single episode, severe with psychotic symptoms
F32.4	Major depressive disorder, single episode, in partial remission
F32.5	Major depressive disorder, single episode, in full remission
F32.9	Major depressive disorder, single episode, unspecified

MDD, recurrent

F33.0	Major depressive disorder, recurrent, mild
F33.1	Major depressive disorder, recurrent, moderate
F33.2	Major depressive disorder, recurrent, severe without psychotic symptoms
F33.3	Major depressive disorder, recurrent, severe with psychotic symptoms

MDD, recurrent, in remission

F33.40	Major depressive disorder, recurrent, in remission, unspecified
F33.41	Major depressive disorder, recurrent, in partial remission
F33.42	Major depressive disorder, recurrent, in full remission
F33.9	Major depressive disorder, recurrent, unspecified

ICD-10=International Classification of Diseases, Tenth Revision

*Please refer to the Important Safety Information on page 11.

Disclaimer: These codes are presented for informational purposes only. They represent no statement, promise, or guarantee by Axsome concerning coverage and/or levels of reimbursement, payment, or charge and are not intended to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for service provided to his or her patient. Laws, regulations, and policies concerning reimbursement are complex and updated frequently. Although we have made an effort to be current as of October 2024, the information may not be current or comprehensive when you view it. Please consult the applicable payer organization with regard to local or actual coverage, reimbursement policies, and determination process.

Steps in the PA Process

Is a PA required? Here's what to do.

Step 1

Complete PA Request

- **Obtain the proper PA form for the specific health plan.**
  - *You may start a PA request through CoverMyMeds or submit to PhilRx (as outlined later in this guide).*
- **It is important to fill out the form completely. Missing information can lead to a PA rejection.**
- **Prepare supplemental documents to justify the use of Auvelity.**

Documents required are unique to each health plan, but may include:

- **Patient clinical notes**
- **Clinical studies or peer-reviewed journal articles stating medical effectiveness**

Step 2

Submit the PA Request

Choose to submit all information, including supplemental documents, by phone, fax, email, CoverMyMeds, or the health plan's website (see form for this info).

- **Keep a copy of everything you submit with the request for reference.**

Please note: HCP is responsible for completing and submitting PA request form.

Step 3

Track the Status of the Request

Keep a detailed log of all PA submissions and denials for each patient.

Step 4

Follow Up as Needed

Submit any additional documentation requested as soon as possible.

covermymeds®

Questions? CoverMyMeds can help.
Live support available:
1-866-452-5017 or chat at
covermymeds.com
Resources:
go.covermymeds.com/help

Prior Authorization Support

- Offers a streamlined process for submitting PA requests
- Available at no cost to providers and their staff
- Receive faster PA determinations, often in real time*
- Submit requests for any medication and all plans

*compared to phone and fax

Need more information?
Visit **www.auvelityhcp.com/samples-support**
for resources, such as:
Prior Authorization Appeals Template
Letter of Medical Necessity Template

The minimum information required for most PAs

Step 1

Provide the appropriate dosing information

Below is the usual dosing for Auvelity. Check the patient's prescription and medical history to determine necessary modifications.

National Drug Code (NDC):
81968-045-60

Medication and Strength:
Auvelity 45mg/105mg

Frequency/Directions for Use:
1 tablet PO daily x 3 days,
then 1 tablet PO BID

Quantity: 60

Day Supply: 30

PO=by mouth; BID=twice daily

Step 2

Check history of patient's previous therapies

Below are the most commonly prescribed generics that may satisfy Step Edit requirements:

- **Sertraline**
- **Escitalopram**
- **Fluoxetine**
- **Bupropion**
- **Trazodone**
- **Duloxetine**
- **Venlafaxine**
- **Citalopram**
- **Mirtazapine**
- **Buspirone**
- **Paroxetine**

Refer to patient notes for additional information, such as specific dates within the "lookback period" that the patient was on the medication and reasons why the patient switched therapies.

Step 3

Common Mistakes During Initial PA Submission

- Incorrect ICD code
- Incomplete PA field

Disclaimer: The completion and accuracy of this form is the sole responsibility of the healthcare provider.

Receive a PA Denial?

This could be why:

- Incomplete or inaccurate information on the PA form. (this is the #1 reason, so check this carefully!)
  - Incomplete information on form
  - Inaccurate information on form
- Clinical reasons regarding medical necessity of Auvelity, which may require additional information.

Proving Medical Necessity

For a How-to Guide: Letter of Medical Necessity

- Visit **www.auvelityhcp.com/samples-support** for the following resources:

  Letter of Medical Necessity Template for Auvelity

Next steps if the PA is denied

- Appeal the decision by contacting the health plan directly to have a peer-to-peer discussion regarding the patient, clinical issues, and reasons for requesting Auvelity.
- If a phone call isn't possible, you may submit an appeal. Visit **www.auvelityhcp.com/samples-support** for the following resources:

  Appeals Guide: Key Steps in Appealing a Denial and Process Checklist for Auvelity

  Letter of Appeals Template

CoverMyMeds or PhilRx may also provide possible next steps for a denied PA.

Actual Patient

Guidance for Insurance Letters

Tips for Developing a Letter of Appeal

Summarize the background and status of your patient's condition

- Cite diagnostic evidence of MDD, including baseline functional exam results
- List their current and prior treatment(s) and reasons why it is not sufficient, including any side effects, lack of response or disease progression

Review the health plan's denial and justify why you believe Auvelity is the appropriate treatment for your patient

- Address the details of the denial and provide clinical justification that supports its repeal, citing any relevant literature and documentation.

- **If denied due to incomplete information, review health plan's criteria to ensure everything is provided.**

- **If denied due to absence of plan's preferred formulary agents** (including completion of step therapy or formulary exclusions), provide clinical rationale for why these agents aren't appropriate for the patient
  - Address each specific preferred agent in the denial
  - Include documentation of any prior trial/failures with required formulary alternatives
  - Provide relevant medical notes supporting clinical rationale for not prescribing preferred alternatives

When submitting the appeal, follow these steps:

Step 1
Populate the template as medically appropiate

Step 2
Delete any specific instructions for completion, disclaimers, trademarks, and document numbers

Step 3
Submit the letter of appeal with the appropiate appeal form and any supplemental documents

The content in this document is not an attempt to provide specific guidance. It is merely for your consideration and review. Please make all changes that you believe to be appropriate or disregard as needed. The medical professional is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. Please see the FDA-approved label for information relevant to any prescribing decisions.

Fields required for customization are in blue text in brackets.

Please place template on official letterhead (if applicable).

<Date>
ATTENTION: <Medical Director Name and/or Medical Review/Appeals>
<Payer/Health Plan Name>
<Payer Address>

Ensure health plan information is correct. This can be found on the appeal form or the health plan's website.

REGARDING: Denied Claim for Auvelity® (dextromethorphan-bupropion) extended-release tablets
PATIENT NAME: <Patient Name>
DATE OF BIRTH: <Patient Date of Birth>
POLICY ID NUMBER: <Patient Policy ID Number>
PROVIDER ID NUMBER: <Provider ID Number>
<Optional: Claim rejection number>

Fill out the patient information completely and accurately. Ensure the policy ID number matches the patient's insurance card.

Please provide claim rejection number (if applicable).

Dear <Health Plan Contact Name>:

I am writing to appeal the denied claim for AUVELITY for my patient, <Patient Name>, for which the reason for denial was <quote the specific reason for denial in denial letter>. I have prescribed AUVELITY because this patient has been diagnosed with major depressive disorder (MDD). Attached to this request are clinical notes regarding this patient's disease state and the AUVELITY package insert.

It's important to understand and state the reason for denial specifically. If it's unclear, you can call and speak to the health plan directly.

AUVELITY is indicated for the treatment of MDD in adults. The following is the medical history of <Patient Name> and the rationale for treatment with AUVELITY.

Date of Diagnosis	<MM/DD/YY>
Diagnosis	<ICD-10 code>
Summary of clinical symptoms	• <Patient's current condition, including an overview of symptoms and quality of life or functional impairment as applicable> • <Evaluation test score(s)> • <Prognosis without treatment>
Previous and current treatment regimens	<If applicable, include previous and current pharmacologic treatments for MDD, including drug name, dates of use, and reasons for stopping>

Fill out the table with objective, patient-specific information.

<Restate the denial reason and your clinical rationale for why the denial should be overturned and why AUVELITY is medically necessary for this patient.>

Only include rationale addressing the specific denial reason. Excess information may influence payer to deny coverage again.

Thank you for taking the time to read this letter. I believe treatment with AUVELITY is appropriate for this patient. I look forward to your prompt review of this request.

Best regards,

<Physician Signature>
<Physician Name>
<Physician Contact Information>

Include your office/clinic's phone number, fax number, and email.

ATTACHMENTS:
• AUVELITY package insert/prescribing information
• Patient clinical notes and other relevant supporting documentation

Update the list of attachments to only include documents being sent with the request.

Visit **www.auvelityhcp.com/samples-support** to download this sample letter template.

Tips for Developing a Letter of Medical Necessity

Summarize the background and status of your patient's condition

- Cite diagnostic evidence of Major Depressive Disorder (MDD), including baseline functional exam results
- List their current and prior treatments and provide reasons why it is not sufficient, including any side effects, lack of response, or disease progression

Justify why you believe Auvelity is the appropriate treatment for your patient

- Provide clinical justification supporting Auvelity treatment for your patient, citing any relevant literature
- State any patient-specific reasons for the treatment choice, such as expected effect of treatment
- Review the health plan's criteria. Point out the specific criteria your patient meets and reasons for exclusion from those they don't

Provide additional documentation that supports your decision

- Review the health plan's requirements to ensure that all requested information is incorporated. This may include:
  - Patient clinical notes, such as relevant medical records and treatment history
  - Clinical studies or peer-reviewed journal articles documenting the medical effectiveness of Auvelity

When submitting the letter, follow these steps:

Step 1
Populate the template as medically appropiate

Step 2
Delete any specific instructions for completion, disclaimers, trademarks, and document numbers

Step 3
Submit the letter of medical necessity with the appropiate form for the PA request and any supplemental documents

For independent consideration and review, please make all changes that you believe to be appropriate or disregard these suggestions in their entirety. The medical professional is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. Please see the FDA-approved label for information relevant to any prescribing decisions.

All bracketed blue text is a required customization field.

Please place template on official letterhead (if applicable).

<Date>
ATTENTION: <Medical Director Name and/or Medical Review/Appeals>
<Payer/Health Plan Name>
<Payer Address>

Reference the health plan's appeal form or website to ensure all information is correct.

REGARDING: Request for Medical Necessity for Auvelity (dextromethorphan-bupropion) extended-release tablets
PATIENT NAME: <Patient Name>
DATE OF BIRTH: <Patient Date of Birth>
POLICY ID NUMBER: <Patient Policy ID Number>
PROVIDER ID NUMBER: <Provider ID Number>

Fill out the patient information completely and accurately. Ensure the policy ID number matches the patient's insurance card.

<Optional: Claim rejection number>

Please provide claim rejection number (if applicable).

Dear <Health Plan Contact Name>:

I am writing this letter of medical necessity in support of my request to treat <Patient Name> with Auvelity for the treatment of major depressive disorder (MDD) in adults.

As a <board-certified> <Field of Certification> with <##> years caring for patients with MDD, I believe that treatment with Auvelity is warranted, appropriate, and medically necessary for this patient based on my clinical judgment and expertise.

It's important to understand and state the reason for denial specifically. If it's unclear, you can call and speak to the health plan directly.

The following is the medical history of <Patient Name> and the rationale for treatment with Auvelity. I have also attached to this letter the clinical findings that summarize my patient's current medical condition and the Auvelity package insert/prescribing information.

Date of Diagnosis	<MM/DD/YY>
Diagnosis	<ICD-10 code>
Summary of clinical symptoms	• <Patient's current condition, including an overview of symptoms and quality of life or functional impairment as applicable> • <Evaluation test score(s)> • <Prognosis without treatment>
Previous and current treatment regimens	<If applicable, include previous and current pharmacologic treatments for MDD, including drug name, dates of use, and reasons for stopping>

Fill out the table with objective, patient-specific information.

I would like to prescribe Auvelity for <Patient Name> because I have concluded that it is a medically appropriate and necessary therapeutic option for the following reason(s):

<Rationale for treating the patient with Auvelity. In this rationale, include a description of the patient's disease state, treatment history, comorbid health issues, and any other factors that have influenced your treatment decision.>

Only include rationale addressing the specific denial reason. Excess information may influence payer to deny coverage again.

<You may wish to include relevant background or clinical trial information about Auvelity in the letter. For additional information, please refer to the Auvelity Prescribing Information.>

Strengthen your request by including clinical trial information about Auvelity, specifically in similar patient populations.

Given the patient's history, <his/her/their> current condition, and the data of the effects of Auvelity in patients with MDD, I believe that treatment of <Patient Name> with this product is warranted, appropriate, and medically necessary. The totality of the data available to date supports the potential benefit of <treatment/continuing treatment> with Auvelity.

Choose the correct language based on whether your patient is initiating or continuing treatment with Auvelity.

Please call my office at <telephone number> if I can provide you with any additional information. I look forward to receiving your timely response.

Best regards,

<Physician Signature>

<Physician Name>
<Physician Contact Information>

Include your office/clinic's phone number, fax number, and email.

ATTACHMENTS:
- Auvelity package insert/prescribing information
- Patient clinical notes and other relevant supporting documentation

Please update the list of attachments to only include documents being sent with the request.

Visit **www.auvelityhcp.com/samples-support** to download this sample letter template.

How to Use PhilRx

When you send a patient's prescription to PhilRx, they will send your office the plan-specifc PA form ready for you to review and submit.

Why use PhilRx?

- **No hub forms needed (prescribe via EHR)**
- **Reimbursement support for PA and beyond**
- **Visibility into patient prescription journey via fax or email summaries**

How to use PhilRx

Step 1

Send Rx to PhilRx. Your patient can expect a text within minutes.

- Search "PhilRx" in your EHR's retail pharmacy finder
- You can also send an Rx via Phone or Fax:
  Phone: 855-977-0975, option 1
  Fax: 888-975-0603
- To minimize callbacks, include patient phone number, chart notes, prior tried/failed, and ICD-10 in the Rx note to pharmacist

Step 2

Submit PA when required

PhilRx will pre-populate the PA form prepared based on the information you provide and provide you the CMM key for you to review the form and submit after you approve.

Step 3

Review Weekly Patient Journey Report fax or email

This includes successful dispenses, pending patient enrollment or payment, PA submissions needed, etc.

CMM=CoverMyMeds; EHR=electronic health record; ICD-10=International Classification of Diseases, 10th Revision

To locate PhilRx in the EHR, use the following details:

Type: Retail Pharmacy
Name: PhilRx
NPI: 1487163598

Address: 150 E. Campus View Blvd.
Suite 210
Columbus, OH 43235

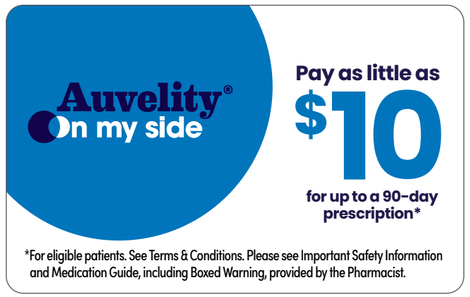
For any questions, email mdhelp@phil.us.

Please see **Important Safety Information** for AUVELITY at the end of this document and **full Prescribing Information**, including Boxed Warning for suicidal thoughts and behaviors.

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

Co-Pay Assistance Program

On My Side is a comprehensive patient support program designed to help patients get the most out of their treatment.



Ways a Patient May Get a Savings Card

Patients may download the Auvelity On My Side Savings Card by visiting Auvelity.com/savings.

If they're eligible, the savings offer may be downloaded and ready to use immediately.

AUVELITY® (dextromethorphan HBr and bupropion HCl) Savings Card Terms & Conditions

This Co-Pay Assistance Program is designed to assist eligible commercially insured patients who have been prescribed an Axsome medicine for an FDA-approved indication.

Patient Benefit:

- Eligible patients will pay as little as $10 for up to a 90-day supply with a valid prescription for an FDA approved indication; monthly, annual, and/or per-claim maximum program benefits may apply and vary depending on the patients' specific terms of their prescription drug plan and to ensure that the funds are used for the benefit of the patient, based on factors determined by Axsome.

Program Eligibility Requirements and Benefits:

- Patients must have commercial (private) health insurance. This program is not valid where the entire cost of the medication is reimbursed by insurance or where insurance does not cover the medication.
- Offer not valid for patients with prescription insurance through federal or state healthcare programs, including but not limited to Medicaid, Medicare drug benefit plan, Tricare, or other federal or state health programs (such as medical assistance programs).
- Some prescription drug plans have implemented programs commonly known as "co-pay maximizer" or "accumulator" programs. These programs adjust the patient's out-of-pocket cost to reflect the availability of financial support received from a co-pay support program, so that out-of-pocket payments that are subsidized by a manufacturer's co-pay program are not treated as a patient's out-of-pocket payments. Patients enrolled in these types of programs may receive benefits from the Axsome Co-Pay Program that vary over time to ensure funds are used for the benefit of the patient.
- This offer may not be redeemed for cash.
- Patient must be a resident of the United States or U.S. territories.
- Patient or patient's guardian must be 18 years of age or older.
- Patients with questions about the Auvelity On My Side Savings Offer please call 1-800-805-8621.

Additional Terms & Conditions of Program:

- By using this offer, the patient and pharmacist certify that the patient meets the eligibility criteria and will comply with all the terms and conditions.
- Cash Discount Cards and other non-insurance plans are not valid as primary insurer under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer.
- This offer is not transferable and is limited to one offer per patient. This co-pay offer cannot be combined with any other savings, free trial, or similar offer(s) for the specified prescription.
- Void where prohibited by law. Not valid if reproduced.
- **This program is not insurance.**
- Axsome Therapeutics reserves the right to rescind, revoke or amend this offer without notice at any time.

To the Pharmacist:

- When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any federal, state, or other governmental programs for this prescription.
- Participation in this program must comply with all applicable laws and regulations as a pharmacy provider. You are certifying that you will comply with the terms and conditions described in the Restrictions section.
- For any questions regarding ConnectiveRx online processing, please call the Concierge Desk at 1-800-641-4654.

By using this card, you and your pharmacist understand and agree to comply with these eligibility requirements and terms of use.

Please see Important Safety Information for AUVELITY at the end of this document and full Prescribing Information, including Boxed Warning for suicidal thoughts and behaviors.

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

Learn More

Auvelity® (dextromethorphan HBr and bupropion HCl) extended-release tablets

Auvelity is a combination of dextromethorphan, an uncompetitive N-methyl D-aspartate (NMDA) receptor antagonist and sigma-1 receptor agonist, and bupropion, an aminoketone and CYP450 2D6 inhibitor.

How Is Auvelity Supplied?

AUVELITY (dextromethorphan hydrobromide and bupropion hydrochloride) extended-release tablets are beige, film-coated, round, bilayer tablets with "45/105" debossed on one side. AUVELITY is supplied in the following package configuration: Dextromethorphan hydrobromide 45mg/bupropion hydrochloride 105 mg bottles of 60 tablets.

60 Count NDC Number
NDC 10: 81968-045-60
NDC 11: 81968-0045-60

Example of a 60-day supply

Example of a sample package

Need to order samples?

Two Ways to Request Auvelity Samples
(if regulations in your state allow the use of samples)

1. If you're not registered

Contact your sales representative.

2. If you're already registered

Log in to the ordering portal at:
axsomehcpsamples.qpharmacorp.com
to place your order.
Have questions or need to register for access? Please contact Axsome@qpharmacorp.com or call 973-644-2378.

Pharmacy Ordering Questions:

If your pharmacy needs to order Auvelity stock, it may contact its preferred distributor below to order.

- **Anda Inc.**
  [www.andanet.com] 1-800-647-0575
- **Cencora**
  [www.cencora.com] 1-877-679-8835
- **Cardinal Health**
  [www.cardinalhealth.com] 1-800-926-3161
- **Dakota Drug Inc.**
  [www.dakdrug.com] 1-866-210-5887
- **Louisiana Wholesale Drug Co.**
  [www.lwdrx.com] 1-800-960-3784
- **McKesson**
  [www.mckesson.com]
  - Independent Pharmacies: 1-855-625-7385
  - Retail National Account: 1-855-625-6285
  - Hospitals & Health Systems: 1-855-625-4677
- **Morris & Dickson Co.**
  [www.morrisdickson.com] 1-800-388-3833
- **Mutual Drug**
  [www.mutualdrug.com] 1-800-800-8551
- **Smith Drug Co.**
  [www.smithdrug.com]
  - Spartanburg, SC: 1-800-542-1216
  - Paragould, AR: 1-866-346-9147
  - Carey, OH: 1-833-570-1757
  - Milton, VT: 1-800-338-8703
- **Value Drug Co.**
  [www.valuedrugco.com] 1-800-252-3786

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies.**
- **Closely monitor all antidepressant-treated patients for clinical worsening, and emergence of suicidal thoughts and behaviors.**
- **Auvelity is not approved for use in pediatric patients.**

CONTRAINDICATIONS

Seizure: Do not use Auvelity in patients with a seizure disorder.

Current or prior diagnosis of bulimia or anorexia nervosa: A higher incidence of seizure was observed in such patients treated with bupropion.

Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs: Due to risk of seizure.

Monoamine Oxidase Inhibitors (MAOIs): Do not use Auvelity concomitantly with, or within 14 days of stopping, an MAOI due to the risk of serious and possibly fatal drug interactions, including hypertensive crisis and serotonin syndrome. Conversely, at least 14 days must be allowed after stopping Auvelity before starting an MAOI antidepressant. Do not use Auvelity with reversible MAOIs such as linezolid or intravenous methylene blue.

Hypersensitivity: Do not use in patients with known hypersensitivity to dextromethorphan, bupropion, or any component of Auvelity. Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported with bupropion. Arthralgia, myalgia, fever with rash, and other serum sickness-like symptoms suggestive of delayed hypersensitivity have also been reported with bupropion.

WARNINGS AND PRECAUTIONS

Suicidal Thoughts and Behaviors in Pediatrics and Young Adults: Monitor all antidepressant-treated patients for any indication for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing Auvelity, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Seizure: Bupropion, a component of Auvelity, can cause seizure and the risk is dose related. Because the risk of seizure with bupropion is dose-related, screen patients for use of other bupropion-containing products prior to initiating Auvelity. If concomitant use of Auvelity with other bupropion-containing products is clinically warranted, inform patients of the risk. Discontinue Auvelity and do not restart treatment if the patient experiences a seizure.

Increased Blood Pressure and Hypertension: Treatment with bupropion, a component of Auvelity, can cause elevated blood pressure and hypertension. The risk of hypertension is increased if Auvelity is used concomitantly with MAOIs or other drugs that increase dopaminergic or noradrenergic activity. Assess blood pressure before initiating treatment with Auvelity and monitor periodically during treatment. Monitor blood pressure, particularly in patients who receive the combination of bupropion and nicotine replacement.

Activation of Mania/Hypomania: Antidepressant treatment can precipitate a manic, mixed, or hypomanic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating Auvelity, screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder (e.g., family history of bipolar disorder, suicide, or depression). Auvelity is not approved for use in treating bipolar depression.

Psychosis and Other Neuropsychiatric Reactions: Auvelity contains bupropion and dextromethorphan. Depressed patients treated with bupropion have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment. Dextromethorphan overdose can cause toxic psychosis, stupor, coma, and hyperexcitability. Because the risks of neuropsychiatric reactions are dose-related, screen patients for use of other bupropion- or dextromethorphan-containing products prior to initiating Auvelity. If concomitant use of Auvelity with other bupropion- or dextromethorphan-containing products is clinically warranted, monitor patients for neuropsychiatric reactions and instruct patients to contact a healthcare provider if such reactions occur.

Angle-Closure Glaucoma: The pupillary dilation that occurs following use of many antidepressants, including Auvelity, may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including Auvelity, in patients with untreated anatomically narrow angles.

Dizziness: Auvelity may cause dizziness. Precautions to reduce the risk of falls should be taken, particularly for patients with motor impairment affecting gait or a history of falls. Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that Auvelity therapy does not affect them adversely.

Serotonin Syndrome: Auvelity contains dextromethorphan. Concomitant use with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk of serotonin syndrome, a potentially life-threatening condition. Prior to initiating therapy with Auvelity, screen patients for use of other dextromethorphan-containing products. If concomitant use of Auvelity with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome, and monitor for symptoms. Discontinue Auvelity and/or concomitant serotonergic drug(s) immediately if symptoms of serotonin syndrome occur and initiate supportive symptomatic treatment.

Embryo-fetal Toxicity: Based on animal studies, Auvelity may cause fetal harm when administered during pregnancy. Discontinue treatment in pregnant females and advise the patient about the potential risk to a fetus. Use alternative treatment for females who are planning to become pregnant.

DRUG INTERACTIONS

Strong Inhibitors of CYP2D6: Concomitant use with Auvelity increases plasma concentrations of dextromethorphan. Dosage adjustment is necessary. Monitor patients for adverse reactions potentially attributable to dextromethorphan, such as somnolence and dizziness.

Strong CYP2B6 Inducers: Concomitant use with Auvelity decreases plasma concentrations of dextromethorphan and bupropion and may decrease efficacy of Auvelity. Avoid co-administration of Auvelity.

CYP2D6 Substrates: Concomitant use with Auvelity can increase the exposures of drugs that are substrates of CYP2D6. It may be necessary to decrease the dose of CYP2D6 substrates, particularly for drugs with a narrow therapeutic index.

Digoxin: Concomitant use with Auvelity may decrease plasma digoxin levels. Monitor plasma digoxin levels in patients treated concomitantly with Auvelity.

Drugs that Lower Seizure Threshold: Concomitant use with Auvelity may increase risk of seizure. Use Auvelity with caution. Discontinue Auvelity and do not restart treatment if the patient experiences a seizure.

Dopaminergic Drugs: Concomitant use with Auvelity can result in central nervous system toxicity. Use Auvelity with caution.

USE IN SPECIFIC POPULATIONS

Lactation: Because of the potential for neurotoxicity, advise patients that breast-feeding is not recommended during treatment with Auvelity and for 5 days following final dose.

Renal Impairment: Dosage adjustment is recommended in patients with moderate renal impairment (eGFR 30 to 59 mL/minute/1.73 m2). Auvelity is not recommended in patients with severe renal impairment (eGFR 15 to 29 mL/minute/1.73 m2).

Hepatic Impairment: Auvelity is not recommended in patients with severe hepatic impairment.

ADVERSE REACTIONS

Most common adverse reactions (≥5% and twice the rate of placebo): dizziness (16%), headache (8%), diarrhea (7%), somnolence (7%), dry mouth (6%), sexual dysfunction (6%), and hyperhidrosis (5%).

Please see accompanying full Prescribing Information, including **Boxed Warning** for suicidal thoughts and behaviors in the pocket.

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