

A care partner's guide to COBENFY

COBENFY is a prescription oral medicine used to treat schizophrenia in adults.

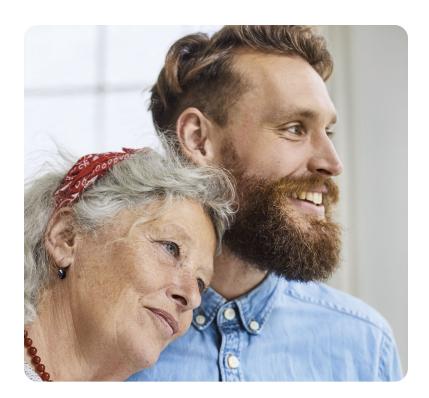


COBENFY is an oral prescription medicine used to treat schizophrenia in adults. It is not known if COBENFY is safe and effective in children.

SELECT IMPORTANT SAFETY INFORMATION Do not take COBENFY if you:

- have urinary retention problems that cause your bladder to not empty completely or not empty at all
- have moderate or severe liver problems (impairment)
- have gastric retention problems that cause your stomach to empty slowly
- are allergic to COBENFY, xanomeline, or trospium chloride, or any of the ingredients in COBENFY
- have an eye problem called untreated narrow-angle glaucoma

Helping you help them



As a care partner, you're constantly balancing the demands of supporting your loved one and keeping up with your own day-to-day life. While it's not always easy, what you do truly makes a difference in helping them manage schizophrenia.

Explore how COBENFY may help bring relief of schizophrenia symptoms to your loved one. This brochure can help deepen your understanding of the condition and provide resources, specifically for care partners like you—all right here.

SELECT IMPORTANT SAFETY INFORMATION

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

- · have an enlarged prostate, problems passing urine, or a blockage in your urinary bladder
- have liver problems
- · have or have had gallstones or problems with your bile ducts or pancreas
- · have stomach or intestinal problems, including constipation, ulcerative colitis, slow emptying of your stomach, or myasthenia gravis
- · have an eye condition called narrow-angle glaucoma
- have kidney problems



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SELECT IMPORTANT SAFETY INFORMATION

Before taking COBENFY, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- · are pregnant or plan to become pregnant. It is not known if COBENFY may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with COBENFY.
- There is a pregnancy exposure registry for women who take COBENFY during pregnancy. The purpose of this registry is to collect information about the health of women exposed to COBENFY and their baby. If you become pregnant during treatment with COBENFY, your healthcare provider will register you by calling 1-866-961-2388 or online at https://womensmentalhealth.org/research/pregnancyregistry/atypicalantipsychotic/
- · are breastfeeding or plan to breastfeed. It is not known if COBENFY passes into your breast milk or if it can harm your baby.

Feel the relief of improved schizophrenia symptoms

Schizophrenia can be disruptive to daily life for both you and your loved one. Even though it's not a cure, COBENFY may help them feel relief of their schizophrenia symptoms.

In 2 clinical studies, COBENFY*:



Delivered **significant symptom relief** vs placebo (sugar pill)



Showed overall **improvement in a range of symptoms**, including positive symptoms, like hallucinations and delusions, and negative symptoms, like lack of interest or emotion

In 1 clinical study, COBENFY†:



Reduced the overall severity of schizophrenia

COBENFY was studied in two 5-week clinical studies with 470 adults aged 18 to 65 diagnosed with schizophrenia. Participants either took COBENFY or a sugar pill. Individual results may vary.

*A schizophrenia rating scale was used to compare meaningful changes in symptoms overall. These symptoms included positive, negative, and general psychopathology symptoms.

†Another schizophrenia rating tool was used to evaluate meaningful overall changes in the severity of schizophrenia.

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking COBENFY with certain other medicines may increase your risk of side effects from COBENFY or the other medicine and may affect the way COBENFY or the other medicine works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.



What healthcare providers are saying

Healthcare providers who have studied COBENFY are excited about its potential to help people with schizophrenia.



I'm encouraged by the results my patients saw during clinical studies. COBENFY provided significant symptom relief. It is the first and only FDA-approved schizophrenia medication that is thought to work by activating muscarinic acetylcholine receptors."

—Rishi Kakar, MD, Investigator in the COBENFY clinical study program*



Schizophrenia is such a debilitating disease. In clinical trials, COBENFY reduced the severity of schizophrenia and significantly improved symptoms, offering a compelling option for my patients."

—David Walling, PhD, Investigator in the COBENFY clinical study program*



I was one of the privileged Principal Investigators in the COBENFY open-label clinical trial and, among the clinical team, we were struck by how this compound, with its combination of xanomeline and trospium chloride, showed significant improvement in schizophrenia symptoms and reduction in the overall severity of the condition."

—Elan Cohen, PhD, Investigator in the COBENFY clinical study program

SELECT IMPORTANT SAFETY INFORMATION

What should I avoid while taking COBENFY?

Do not drive, operate heavy machinery, or do other dangerous activities until you know how COBENFY affects you. COBENFY may cause dizziness, confusion, seeing or hearing things that are not real (hallucinations), and sleepiness.

Please see Important Safety Information throughout and <u>Full Prescribing</u> <u>Information</u>, including <u>Patient Information</u>.

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^{*}Paid consultant for Bristol Myers Squibb.

COBENFY is not an antipsychotic. It works differently

COBENFY is a different approach to schizophrenia treatment. COBENFY is a unique combination of 2 medicines: **xanomeline** and **trospium chloride**.







Xanomeline (Za-NO-muh-leen) is thought to activate muscarinic receptors in the brain to help adjust important chemical messengers related to schizophrenia symptoms.

Trospium (TRO-spee-um) chloride may help prevent xanomeline from working outside the brain so that other parts of the body are less likely to be impacted.

The exact way COBENFY works is not fully understood.

What are receptors?

Receptors are small proteins (or small structures) found on the cells in the brain and body. Certain medicines can interact with receptors to "activate" them. This may change how the cells function.

Muscarinic acetylcholine receptors are types of receptors.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including:

• Problems with emptying your bladder (urinary retention). See "Do not take COBENFY if you:" COBENFY may cause your bladder to not empty completely or not empty at all. You are at increased risk for urinary retention if you are elderly, have a blockage in your bladder, have an enlarged prostate called benign prostatic hyperplasia (BPH), have bladder emptying problems from diabetes, or are taking higher doses of COBENFY. Urinary retention may increase your risk for getting a urinary tract infection.



COBENFY is the first and only FDA-approved schizophrenia medicine that is thought to work by activating small proteins in the brain called muscarinic acetylcholine receptors.

The xanomeline component of COBENFY activates specific muscarinic receptors in the brain that may be related to schizophrenia symptoms

in the **brain**

The types of muscarinic receptors activated by COBENFY are thought to be found in **specific areas of the brain** associated with schizophrenia symptoms. Symptoms can happen when these areas have too many or too few important chemical messengers.

When the xanomeline component of COBENFY activates receptors in the brain, it may help to adjust the levels of important chemical messengers involved in schizophrenia.



SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

- Problems with emptying your bladder (urinary retention) (cont'd).

 Call your healthcare provider or get emergency help right away if you get any signs or symptoms of urinary retention during treatment with COBENFY, including:
- difficulty urinating
- urination in a weak stream or drips
- urinating frequently

- full bladder and difficulty emptying your bladder
- pain when you urinate



Possible side effects of COBENFY

Most common side effects experienced by 5% or more of people taking COBENFY

Adverse reaction	COBENFY (n=251)	Sugar pill (n=253)
Nausea	19%	4%
Stomach upset or burning (dyspepsia)	18%	5%
Constipation	17%	7%
Vomiting	15%	1%
High blood pressure	11%	2%
Stomach (abdominal) pain	8%	4%
Diarrhea	6%	2%
Increased heart rate	5%	2%
Dizziness	5%	2%
Heartburn (gastrointestinal reflux disease)	5%	<1%

Similar rates of uncontrolled facial or body movements while taking COBENFY (2%) vs taking a sugar pill (<1%).

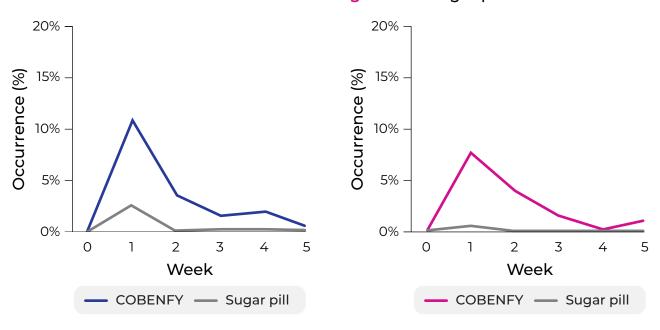
SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including:

Problems with emptying your bladder (urinary retention), risks in people with liver problems, risks in people with bile duct and gallbladder problems (biliary disease), slow emptying of your stomach (decreased gastrointestinal motility), serious allergic reactions (angioedema), an eye problem called narrow-angle glaucoma, increases in heart rate, side effects in people with kidney problems, and central nervous system problems.

Nausea and vomiting often occurred within the first 2 weeks of treatment and generally decreased over time

Nausea and vomiting rates vs sugar pill



If your loved one experiences nausea or vomiting, ask their healthcare provider about options that may help.

Average weight change in 5-week studies Average weight change in 1-year studies*† COBENFY +3.04 lbs *The results are from 1-year studies where people knew they were taking COBENFY. These ongoing studies are less rigorous, and the data is not yet finalized. 17.6% of people lost weight, while 4.1% gained weight.

Start and end the day with COBENFY

COBENFY is taken twice daily. Take COBENFY exactly as prescribed.



T pill when they wake up



Defore bed



Taken on an empty stomach

COBENFY should not be taken with meals. COBENFY should be taken by mouth at least 1 hour before or at least 2 hours after meals. Eating food too close to taking COBENFY can make side effects worse.



Ways to help your loved one stay on track:

- · Set repeat reminders on their phone to take COBENFY
- · Place their medication in a visible area, like a nightstand
- Sign up for the COBENFY Cares™ support program to get access to additional tips that may help your loved one take their medication on time. Learn more on page 12

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

• Risks in people with liver problems. See "Do not take COBENFY if you:" It is not recommended that people with mild liver problems (impairment) take COBENFY because they have an increased risk of getting side effects from COBENFY. Your healthcare provider will check the liver enzyme levels in your blood before starting treatment and as needed during treatment with COBENFY.





Dosing options

COBENFY is made of xanomeline and trospium chloride. A healthcare provider will determine which dose is right and may change their dose over time.

1. Starting dose for at least 2 days



50 mg/ 20 mg

2. Increased dose for at least 5 days



100 mg/ 20 mg

3. Ongoing dose



When starting COBENFY, the recommended dose is 50 mg/20 mg twice daily for at least 2 days.

may increase their dose to 100 mg/20 mg twice daily for at least 5 days.

Their healthcare provider will determine the correct dose.

Pills not shown at actual size.

Do not let your loved one change the dose, stop taking COBENFY without talking to their healthcare provider, or open the capsules. If they take too much COBENFY, call their healthcare provider or the Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Then their healthcare provider

SELECT IMPORTANT SAFETY INFORMATION

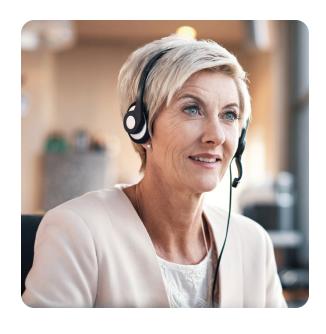
COBENFY may cause serious side effects, including (cont'd):

- Risks in people with liver problems. (cont'd)
 Tell your healthcare provider if you get any signs or symptoms of liver problems during treatment with COBENFY, including:
 - yellowing of your skin or the white part of your eyes
 - dark urine
 - pain and swelling in the upper right part of your stomach (abdomen)
 - stomach pain that spreads to your back or to below your right shoulder
 - itching

- nausea or vomiting
- loss of appetite
- fever
- chills
- light-colored stools
- tiredness



COBENFY Cares[™] offers support with your loved one in mind



Once your loved one has a prescription, COBENFY Cares Champions* are available 24/7 and can:

- Help them enroll in COBENFY Cares
- Answer commonly asked questions about COBENFY
- Provide resources for you to help care for a loved one taking COBENFY
- Offer support in English, Spanish, and other languages



Does your loved one want tips for remembering to take their medicine regularly? Ask a COBENFY Cares Champion about the tools that are available.

*COBENFY Cares Champions are available to provide support to your loved one who has been prescribed COBENFY. Champions do not provide medical advice or care. COBENFY Cares Champions are provided as a service by Bristol Myers Squibb. Patients should discuss any questions about their medical conditions and treatment options with their healthcare providers.



You or your loved one can sign up for our Co-Pay Card

Eligible participants may pay as little as \$0[†]

If your loved one has private or commercial health insurance, they may be eligible to pay as little as \$0 per month through a co-pay savings offer. Certain terms and conditions apply.





Scan or call **1-877-COBENFY** (1-877-262-3639) to learn more about savings and support and enroll in COBENFY Cares.

†Eligible participants may pay as little as \$0 per 30-day supply, subject to a maximum annual benefit of \$10,000. Other restrictions may apply. Participant is responsible for applicable taxes, if any. Offer not applicable to co-pays of \$0 or less.



Frequently asked questions

Q: What is COBENFY?

COBENFY is a prescription medicine used to treat adults with schizophrenia. COBENFY is a unique combination of 2 medicines, xanomeline (Za-NO-muh-leen) and trospium (TRO-spee-um) chloride.

Q: Is COBENFY an antipsychotic?

No, COBENFY is not an antipsychotic. COBENFY is the first and only FDA-approved schizophrenia medicine that is thought to work by activating small proteins in the brain called muscarinic acetylcholine receptors. The exact way COBENFY works is not fully understood.

Q: Does COBENFY need to be refrigerated?

No, COBENFY should not be refrigerated. It should be kept at room temperature (68 ° F-77 ° F).

• How long will my loved one need to take COBENFY?

COBENFY should be taken as long as their healthcare provider feels it is necessary. They should not stop taking COBENFY without first talking to their healthcare provider.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

Risks in people with bile duct and gallbladder problems (biliary disease).
 COBENFY may cause a blockage in your bile ducts that could lead to gallstones, pancreatitis, and increases in your liver enzymes. Your healthcare provider will check your liver enzyme and bilirubin levels in your blood before starting treatment and as needed during treatment with COBENFY.

How do I know COBENFY is working for my loved one, and how fast may we see results?

Individual results vary, but most people in the clinical trials saw a significant improvement in 5 weeks. Ask the healthcare provider when to expect results and to clarify the goals of your loved one's treatment, including what you should look for to know if it's working.

Should COBENFY be taken with food?

COBENFY should be taken by mouth on an empty stomach—at least 1 hour before a meal or at least 2 hours after a meal. Eating food too close to taking COBENFY can make side effects worse.

Is there a certain amount of time that needs to pass in between doses? (For example: Can they take their AM pill at 9 AM and their PM pill at 1 PM?)

COBENFY is taken 2 times a day. This may help keep COBENFY at a consistent level in their body throughout the day. We recommend creating a routine where they take COBENFY at the start and end of the day. COBENFY Cares™ offers support that can help remind them to take COBENFY at the same time each day.

What should they do if they miss a dose of COBENFY?

If your loved one misses a dose of COBENFY, they should talk to their healthcare provider.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

Risks in people with bile duct and gallbladder problems (biliary disease)
 (cont'd). Tell your healthcare provider if you get any signs or symptoms of biliary disorders during treatment with COBENFY, including:

stomach upset or burning
 (dyspepsia)
 nausea
 vomiting
 pain in the upper right
 part of your stomach



Frequently asked questions (cont'd)

If my loved one experiences nausea and/or vomiting, should they stop taking COBENFY?

A: If your loved one experiences nausea and/or vomiting, they should talk to their healthcare provider before they stop taking COBENFY. Learn more about potential side effects on page 9.

What support is available for people on COBENFY?

COBENFY Cares[™] is a patient support program for those who have been prescribed COBENFY. COBENFY Cares Champions are available to answer questions, help identify financial resources and support, and assist in following a medication schedule as their healthcare provider has prescribed. For questions about the program, please call 1-877-COBENFY (1-877-262-3639).

• How can I learn more about cost and savings options?

There may be different cost-saving options for COBENFY, depending on insurance coverage and financial needs. If your loved one has been prescribed COBENFY, contact COBENFY Cares to learn about the options available to them.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

- Slow emptying of your stomach (decreased gastrointestinal motility). See "Do not take COBENFY if you:" You are at increased risk for getting decreased gastrointestinal motility if you have ulcerative colitis, already have problems with slow stomach emptying, and have myasthenia gravis. Tell your healthcare provider if you get any signs and symptoms of decreased gastrointestinal motility during treatment with COBENFY, including:
 - constipation
 - vomiting
 - nausea
 - stomach (abdominal) bloating
- stomach (abdominal) pain
- a feeling of fullness after eating just
- a few bites
- acid reflux

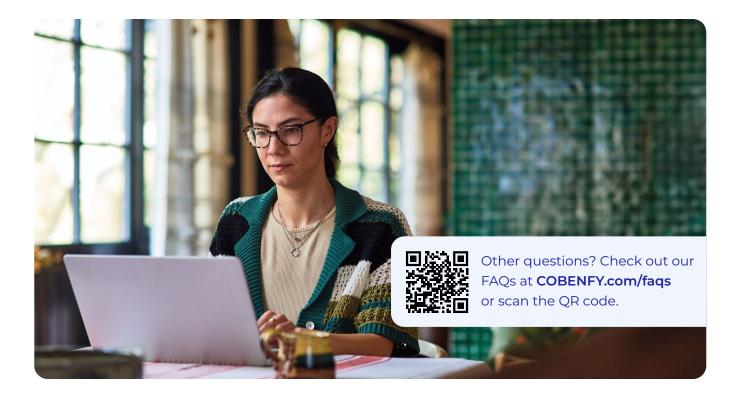
• How do I use the COBENFY Co-Pay Card?

Bring the COBENFY Co-Pay Card to the pharmacy counter at the time the prescription is filled. Eligible participants may pay as little as \$0 per 30-day supply. Please see COBENFY Terms and Conditions in the pocket. For questions about the program, including savings on mail-order prescriptions, please call **1-877-COBENFY** (1-877-262-3639).

How can I share my COBENFY story?

Are you or a loved one taking COBENFY to treat schizophrenia? Do you have an interest in sharing your story? If you're a U.S. resident and 18 years or older, please call 1-855-436-5866 to find out if you are eligible to participate in our Ambassador Program.

Please note that not all candidates will be selected to participate in the program.



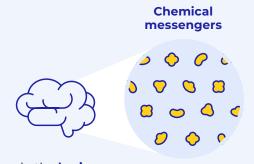
Discussing schizophrenia with others

Schizophrenia is a complex condition that may not be well understood by others who interact with your loved one. This introduction to schizophrenia may help you explain to others what your loved one may be experiencing in simpler terms.

How does the brain work?

The brain is made up of billions of cells that help you think, learn, move, sleep, and more.

These cells need to work together and communicate with each other. They do this by sending each other chemical messengers.



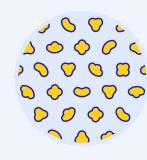
in the **brain**

What's happening in the brain when you have schizophrenia?

Schizophrenia is a serious mental health condition that's connected to what's happening in the brain.

When you have schizophrenia, the amounts of certain kinds of chemical messengers in the brain may be too high or too low. This may lead to symptoms like hallucinations, feeling unmotivated, and having trouble with memory and learning.





messengers

Too many chemical messengers



Schizophrenia affects people of all ages, but with treatment, it can be managed.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

· Serious allergic reactions (angioedema). Angioedema may happen during treatment with COBENFY and can be life threatening. Stop taking COBENFY and call your healthcare provider or get emergency help right away if you get any of the following signs or symptoms of a serious allergic reaction during treatment with COBENFY, including:



Three types of symptoms



Positive symptoms are additional experiences that your brain creates

- · Hallucinations Seeing, hearing, feeling, tasting, or smelling something that is not there
- · Delusions Holding beliefs that are not true or based in reality
- Difficulty thinking or speaking



Negative symptoms are like missing pieces of your usual self

- Difficulty staying motivated to complete tasks
- Decreased sense of joy or happiness
- · Showing little emotion, not smiling or using facial expressions
- · Social withdrawal



Cognitive symptoms affect how you think and process information

- Trouble with memory
- · Difficulty understanding and making decisions
- · Difficulty paying attention

This is not a complete list of symptoms, and everyone living with schizophrenia experiences symptoms differently.



Log your loved one's symptoms to guide a productive conversation with their healthcare provider. Scan the QR code to print the Symptom Tracker or visit COBENFY.com/resources.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

- Serious allergic reactions (angioedema) (cont'd).
 - hives

- swelling of your throat
- swelling of your face, lips, mouth, or tongue
- hoarseness or difficulty speaking
- breathing problems



The majority of care partners for people with schizophrenia are family members like parents, siblings, spouses, and children. Many report that their psychological, emotional, physical, social, and financial lives are impacted by schizophrenia.

Here are some of the challenges they faced, according to a survey of approximately 250 care partners by the National Alliance on Mental Illness (NAMI).

Challenges faced by care partners



55% were challenged to find time to take care of their own health



>70% felt sad, protective, or frustrated when others talked about the person in their care who has schizophrenia



79% had difficulty finding specialized services

Join a community that understands what you're going through and find support through advocacy groups dedicated to helping you. Discover organizations on pages 22-23.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

- An eye problem called narrow-angle glaucoma. See "Do not take COBENFY if you:" If you already have narrow angles in your eyes, COBENFY may cause a sudden attack (acute angle closure) of glaucoma. Tell your healthcare provider if you get any signs or symptoms of narrow-angle glaucoma during treatment with COBENFY, including:
- red eyes
- blurred vision
- seeing halos or bright colors around lights
- eye pain or discomfort
- nausea or vomiting
- severe headache



Taking care of you

Supporting a loved one who has schizophrenia is a full-time commitment. Don't forget to take care of yourself, too!

Make yourself a priority by:

- ✓ Asking for help when you need it
- ✓ Creating your own support team
- ✓ Prioritizing your physical and mental health
- ✓ Spending time on the things you love to do
- ✓ Getting consistent sleep every night
- ☑ Exercising multiple times a week
- ✓ Keeping a healthy diet
- ✓ Using relaxation techniques
- ✓ Avoiding use of alcohol or other substances



Schedule activities you love into your routine. Being off "care partner mode" for even a little while can help you recharge.



Advocacy groups for you and your loved one

We understand that you both may need a helping hand sometimes. These advocacy organizations* can help connect you to in-person and online support groups.



American Foundation for Suicide Prevention afsp.org



Clubhouse International clubhouse-intl.org



Caregiver Action Network caregiveraction.org/schizophrenia



CURESZ Foundation curesz.org



Mental Health America mhanational.org

*Bristol Myers Squibb does not endorse these organizations. The information/links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician's medical advice.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

• Increases in heart rate. COBENFY may increase your heart (pulse) rate. Your healthcare provider should check your heart rate before you start treatment and during treatment as needed. Tell your healthcare provider if you get a racing or pounding feeling in your chest during treatment with COBENFY.





National Alliance on Mental Illness nami.org



Students With Psychosis sws.ngo



Schizophrenia & Psychosis Action Alliance sczaction.org



This Is My Brave thisismybrave.org



Explore more resources available at COBENFY.com/resources.

*Bristol Myers Squibb does not endorse these organizations. The information/links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician's medical advice.

SELECT IMPORTANT SAFETY INFORMATION

COBENFY may cause serious side effects, including (cont'd):

- Side effects in people with kidney problems. People with kidney problems may
 have an increased risk of getting dry mouth, constipation, stomach upset or burning,
 urinary tract infection, and urinary retention during treatment with COBENFY.
- Central nervous system problems. See "What should I avoid while taking COBENFY?"



Getting help in a crisis

Schizophrenia is a serious mental health condition. If you fear you or your loved one is at risk, contact the National Hotline For Mental Health Crises, which is available 24/7.

- 988 Suicide and Crisis Lifeline (also known as 1-800-273-TALK (8255))
- · Para Español: 1-888-628-9454
- Options for deaf and hard of hearing: 1-800-799-4889
- · Veterans crisis line: Dial 1-800-273-8255, then press 1
- Don't want to talk? Text "HOME" to 741741
- · Another option is to call 911



SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of COBENFY include:

nausea

- diarrhea
- stomach upset or burning (dyspepsia)
- · increased heart rate

constipation

dizziness

vomiting

high blood pressure

- · heartburn (gastrointestinal reflux disease)
- · stomach (abdominal) pain

Your healthcare provider may lower your dose or stop treatment with COBENFY if you get certain side effects.

These are not all of the possible side effects of COBENFY.

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

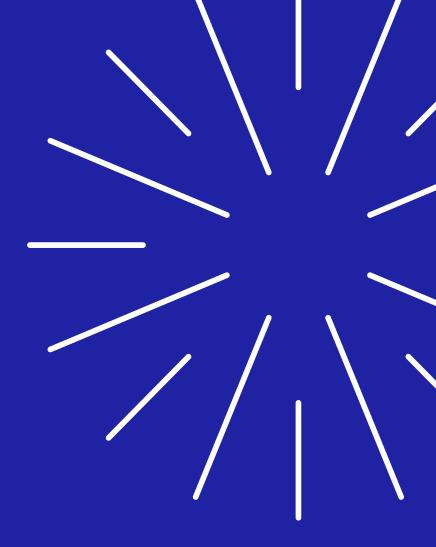
Please see Important Safety Information throughout and Full Prescribing Information, including Patient Information.

Emergency contacts

important to be prepared with this information.
Doctors' names and numbers:
Therapist/counselors' names and numbers:
Locations of nearby emergency rooms:
Names and numbers of other supportive people:
Additional notes:

Your loved one may require emergency help from time to time, so it's







Sign up for the COBENFY Cares™ support program today.



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