

COBENFY

(xanomeline and trospium chloride) capsules

50mg/20mg, 100mg/20mg, 125mg/30mg

Feel the relief of improved schizophrenia symptoms

Actor portrayals.

WHAT IS COBENFY (co-BEN-fee)?

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

Please see Important Safety Information throughout and [Full Prescribing Information](#), including [Patient Information](#).

Feel the relief of improved schizophrenia symptoms

Schizophrenia can be disruptive to your daily life. Even though it's not a cure, COBENFY may help you feel relief of your 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

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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COBENFY is not an antipsychotic.

It works differently

COBENFY is a unique combination of 2 medicines, **xanomeline** and **trospium chloride**:



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



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

The exact way COBENFY works is not fully understood.

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.*

*Receptors are small proteins (or small structures) found on the cells in your brain and body. Certain medicines can interact with receptors to “activate” them. This may change how your cells function. Muscarinic acetylcholine receptors are types of receptors.

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.

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Visit **COBENFY.com** for more information on how COBENFY works.

- 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.

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

Possible side effects of COBENFY

The most common side effects of COBENFY include:

- Nausea
- Stomach upset or burning (dyspepsia)
- Constipation
- Vomiting
- High blood pressure
- Stomach (abdominal) pain
- Diarrhea
- Increased heart rate
- Dizziness
- Heartburn (gastrointestinal reflux disease)

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

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

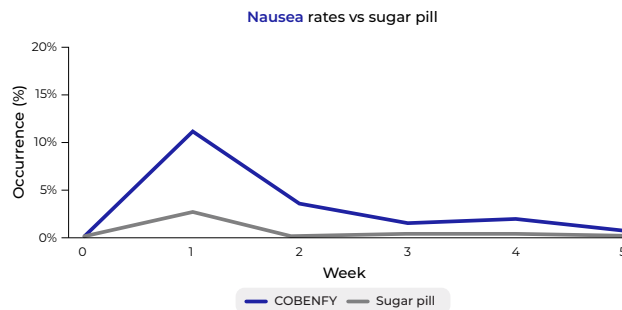
Similar rates of uncontrolled facial or body movements while taking COBENFY (2%) vs taking a sugar pill (<1%).

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



If you experience nausea or vomiting, ask your healthcare provider about options that may help.

COBENFY effects on weight

Average weight change in 5-week studies



Average weight change in 1-year studies*†



*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.

Please see Important Safety Information throughout and [Full Prescribing Information](#), including [Patient Information](#).

Start and end your day with COBENFY

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



1 pill
when you wake up



1 pill
before bed



Taken on an empty stomach

COBENFY should not be taken with meals. Take COBENFY 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.



Dosing options for you

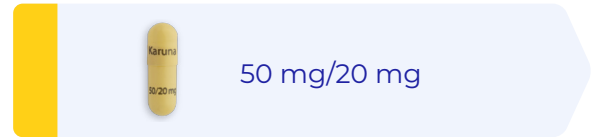
COBENFY is made of xanomeline and trospium chloride. Your healthcare provider will determine which dose is right for you and may change your dose over time.

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.

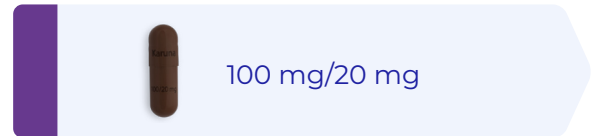
Starting COBENFY

1. Starting dose for at least 2 days



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

2. Increased dose for at least 5 days



Then your healthcare provider may increase your dose to 100 mg/20 mg twice daily for at least 5 days.

3. Ongoing dose



Your healthcare provider will determine the correct dose.

Pills not shown at actual size.

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

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COBENFY Cares[™] offers support with you in mind

Once you have a prescription, you are eligible to enroll in COBENFY Cares. Champions* are available 24/7 to:

- Help you enroll in COBENFY Cares
- Answer commonly asked questions about COBENFY
- Provide resources for care partners who support someone taking COBENFY
- Offer support in English, Spanish, and other languages



Want tips for remembering to take your medicine regularly? Ask a COBENFY Cares Champion about the tools that are available.

*COBENFY Cares Champions are available to provide support to patients who have 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.

Please see [COBENFY Terms and Conditions](#).

Sign up for our Co-Pay Card

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

If you have private or commercial health insurance, you 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.

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

Important Safety Information (cont'd)

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.

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. 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
- full bladder and difficulty emptying your bladder
- urination in a weak stream or drips
- pain when you urinate
- urinating frequently

• 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. 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
- itching
- dark urine
- nausea or vomiting
- pain and swelling in the upper right part of your stomach (abdomen)
- loss of appetite
- stomach pain that spreads to your back or to below your right shoulder
- fever
- chills
- light-colored stools
- tiredness

• 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. Tell your healthcare provider if you get any signs or symptoms of biliary disorders during treatment with COBENFY, including:

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

• 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
- stomach (abdominal) pain
- vomiting
- a feeling of fullness after eating just a few bites
- nausea
- stomach (abdominal) bloating
- acid reflux

• 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:

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

Please see Important Safety Information throughout and [Full Prescribing Information](#), including [Patient Information](#).

Important Safety Information (cont'd)

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
- **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.
- **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?**"

The most common side effects of COBENFY include:

- | | |
|--|---|
| • nausea | • diarrhea |
| • stomach upset or burning (dyspepsia) | • increased heart rate |
| • constipation | • dizziness |
| • vomiting | • heartburn (gastrointestinal reflux disease) |
| • high blood pressure | |
| • 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.

Notes:

For additional safety information, please see the [Full Prescribing Information](#), including [Patient Information](#).

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Ask your healthcare
provider if COBENFY
may be right **for you**



Scan the QR code
or go to **COBENFY.com**
to learn more.

 Bristol Myers Squibb[®]

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