

PATIENT INFORMATION
COBENFY™ (co-BEN-fee)
(xanomeline and trospium chloride)
capsules

What is COBENFY?

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

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. See the end of this Patient Information leaflet for a complete list of ingredients in COBENFY.
- have an eye problem called untreated narrow-angle glaucoma

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 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
- 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.

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.

How should I take COBENFY?

- Take COBENFY exactly as your healthcare provider tells you. **Do not** change the dose or stop taking COBENFY without first talking to your healthcare provider.
- Take 1 COBENFY capsule 2 times each day.
- Take COBENFY by mouth at least 1 hour before a meal or at least 2 hours after a meal.
- **Do not** open the capsules.
- If you take too much COBENFY, call your healthcare provider or Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

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.

What are the possible side effects of COBENFY?

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
 - 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
- **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)
 - nausea
 - vomiting
 - 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
 - vomiting
 - nausea
 - stomach (abdominal) bloating
 - stomach (abdominal) pain
 - a feeling of fullness after eating just a few bites
 - 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
 - swelling of your face, lips, mouth, or tongue
 - swelling of your throat
 - hoarseness or difficulty speaking
 - breathing problems
- **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
- stomach upset or burning (dyspepsia)
- constipation
- vomiting
- high blood pressure
- stomach (abdominal) pain
- diarrhea
- increased heart rate
- dizziness
- heartburn (gastrointestinal reflux disease)

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.

How should I store COBENFY?

- Store COBENFY at room temperature between 68°F to 77°F (20°C to 25°C).

Keep COBENFY and all medicines out of the reach of children.

General information about the safe and effective use of COBENFY.

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

What are the ingredients in COBENFY?

Active ingredients: xanomeline and tropium chloride

Inactive ingredients: ascorbic acid, lactose monohydrate, microcrystalline cellulose, and talc

The capsule shell contains black iron oxide (only 100 mg/20 mg), hypromellose, red iron oxide, titanium dioxide, and yellow iron oxide (only 50 mg/20 mg and 100 mg/20 mg).

Marketed by:

Bristol-Myers Squibb Company

Princeton, NJ 08543 USA

COBENFY is a trademark of Karuna Therapeutics, Inc., a Bristol Myers Squibb company.

For more information, go to www.COBENFY.com or call 1-800-721-5072.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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