Getting Started with

A Care Partner Checklist for Supporting Your Loved One's Treatment Journey

This checklist can help you feel more informed and prepared as your loved one begins and continues on COBENFY. Use it as a guick guide for reminders, conversations, and support.



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| Before Starting Treatmen | nt | |
| Some questions you can ask the doctor about your loved one's treatment plan | What is the dosing schedule?When should we expect to notice symptom changes? | What happens if a dose is missed?What side effects should I watch for and report? |
| During the First Few Weeks of Treatment | | |
| Taking 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 mea | 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 |
| Set reminders to take medication | Set reminders, like a phone alarm or sticky notes, or use a routine habit (such as brushing teeth) to remind them to take their medication as prescribed | |
| Tracking side effects and symptoms | Look out for common side effects (such as nausea, upset stomach, or constipation*) and ask a healthcare provider about options that may help Write down any changes in symptoms or new side effects (examples noted above) to bring up at the next doctor's visit *Not an exhaustive/full list of side effects | |
| Helping them stay on track with treatment | If your loved one misses a dose or feels unwell, encourage them to speak with their doctor. You can help start that call | |
| Use the tools available to you | Download the <u>Symptom Tracker</u> to help monitor any changes so your loved one can have more informed conversations with their doctor Explore resources like the <u>Care Partner Brochure</u> for FAQs and support tips Print the <u>Care Partner Worksheet</u> to help you and your loved one stay connected to each other throughout the journey | |
| Support Tips Throughout | t Treatment | |
| Encourage open communication | Create a safe space where your loved one can talk about what they're feeling without pressure or judgment | |
| Take notes for doctor visits | Bring your observations to appointments to help shape the care plan | |
| Take care of yourself | Make time for yourself, including getting rest and connecting with others | |

WHAT IS COBENFY (co-BEN-fee)?

COBENFYTM (xanomeline and trospium chloride) is a prescription medicine used to treat schizophrenia in adults. It is not known if COBENFY is safe and effective in children.

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 additional Important Safety Information on the next page and <u>Full Prescribing Information</u>, including <u>Patient Information</u>.

IMPORTANT SAFETY INFORMATION (continued)

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
- · 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.

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
- urination in a weak stream or drips
- urinating frequently
- full bladder and difficulty emptying your bladder
- pain when you urinate
- · 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
- stomach pain that spreads to your back - light-colored stools
- chills

- part of your eyes
- or to below your right shoulder
- tiredness

- dark urine - pain and swelling in
- itchina
- the upper right part of your stomach
- nausea or vomiting - loss of appetite
- (abdomen) fever

- · 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
- pain in the upper right part of vour 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

- stomach (abdominal) pain - 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

- nausea

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

- eye pain or discomfort
- blurred vision
- nausea or vomiting - severe headache

- seeing halos or bright colors around lights

- · 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
- · stomach (abdominal) pain
- diarrhea
- · increased heart rate
- (dyspepsia) constipation dizziness
- vomiting
 - · heartburn (gastrointestinal
- · high blood pressure 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.

Please see the U.S. Full Prescribing Information, including the Patient Information, for COBENFY