



• **Cobenfy™**

- Oral capsule (Capsule Therapy Pack): 50/20 mg and 100/20 mg
- Oral capsule: 50/20 mg and 125/30 mg

If you or someone you know is in crisis, please call/text 988 to speak with a trained crisis counselor 24/7 and/or call 911 for emergency services. A helpline and other resources are also available through the National Alliance on Mental Illness at nami.org.



What is xanomeline and trospium and what does it treat?

Xanomeline and trospium is a medication that works in the brain to treat schizophrenia. It is a first medication in this new class, offering an approach by selectively activating small proteins in the brain called muscarinic acetylcholine receptors. When the xanomeline component activates receptors in the brain, it may help to adjust levels of important chemical messengers involved in schizophrenia. Trospium may help prevent xanomeline from working outside your brain so that other parts of your body are less likely to be impacted. It is the first new medicine for psychosis that does not act on dopamine. Xanomeline and trospium offers a new option for managing schizophrenia, especially for patients who have not responded well to traditional treatments or have experienced severe side effects.

Symptoms of schizophrenia include:

- Hallucinations – imagined voices or images that seem real
- Delusions - beliefs that are not true (e.g., other people are reading your thoughts)
- Disorganized thinking or trouble organizing your thoughts and making sense
- Little desire to be around other people
- Trouble speaking clearly
- Lack of motivation

Xanomeline and trospium may help some or all of these symptoms

What is the most important information I should know about xanomeline and trospium?

Schizophrenia requires long-term treatment. Do not stop taking xanomeline and trospium, even when you feel better.

With input from you, your health care provider will assess how long you will need to take the medication

Missing doses of xanomeline and trospium may increase your risk for a relapse in your symptoms

Do not stop taking xanomeline and trospium or change your dose without talking with your health care provider first. Discontinuation or tapering must be done carefully under a health care provider's guidance to prevent the return of psychotic symptoms or withdrawal effects. Given that xanomeline and trospium are acting on the muscarinic receptors in the brain, their effects can impact cognition and mood.

For xanomeline and trospium to work properly, it should be taken every day as ordered by your health care provider. This medication should be taken on an empty stomach.

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

Are there specific concerns about xanomeline and trospium and pregnancy?

If you are planning on becoming pregnant, notify your health care provider to best manage your medications. People living with schizophrenia who wish to become pregnant face important decisions. This is a complex decision since untreated schizophrenia has risks to the fetus, as well as the mother. It is important to discuss the risks and benefits of treatment with your doctor and caregivers.

Caution is advised with breastfeeding since it is not known if xanomeline and trospium passes into breast milk

Tell your health care provider if you become pregnant during treatment with xanomeline and trospium. Data collection to monitor pregnancy and infant outcomes following exposure to psychiatric medication is ongoing. Pregnancy patients ≤ 45 years of age with a history of psychiatric illness are encouraged to enroll in the National Pregnancy for Psychiatric Medications (1-866-961-2388 or at <https://womensmentalhealth.org/research/pregnancyregistry/atypicalantipsychotic/>)

What should I discuss with my health care provider before taking xanomeline and trospium?

- Symptoms of your condition that bother you the most
- If you have increased thoughts of suicide, be sure to call your physician or 988
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you have any of these health problems: glaucoma, liver disease, slow clearing of the stomach, trouble passing urine, kidney disease, gallstones or other gallbladder problems
- If you experience side effects from your medications; some may pass with time, others may require changes in the medication
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you smoke, drink alcohol, or use illegal drugs

How should I take xanomeline and trospium?

Xanomeline and trospium is taken on an empty stomach; take at least one hour before a meal or at least two hours after a meal

Typically patients begin with a 50/20 mg capsule for two days or more and the dose is increased slowly over several weeks

The maximum dose is 125/30 mg twice daily; it is important to not open the capsules up but to swallow whole

Use a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member or a friend to remind you or check in with you to be sure you are taking your medication.

Keep taking medication as you have been told by your doctor or other health care provider, even if you feel well

What happens if I miss a dose of xanomeline and trospium?

If you miss a dose of xanomeline and trospium, take it as soon as you remember, unless it is closer to the time of your next dose. Discuss this with your health care provider. Do not double your next dose or take more than what is prescribed.

What should I avoid while taking xanomeline and trospium?

Avoid drinking alcohol or using illegal drugs while you are taking xanomeline and trospium. They may decrease the benefits (e.g., worsen your confusion) and increase adverse effects (e.g., sedation) of the medication.

Avoid driving and doing other tasks or actions that call for you to be alert until you see how this medication affects you

What happens if I overdose with xanomeline and trospium?

If an overdose occurs, call your doctor or 911; you may need urgent medical care

You may also contact the poison control center at 1-800-222-1222

A specific treatment to reverse the effects of xanomeline and trospium does not exist

What are the possible side effects of xanomeline and trospium?

Common side effects

- Constipation, diarrhea, stomach pain, upset stomach, or throwing up, dry mouth, feeling dizzy or sleeping, high blood pressure, increased heart rate, heartburn (gastrointestinal reflux disease, also known as GERD)
- To lower the feeling of dizziness, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.

Rare/serious side effects

- Signs of an allergic reaction (i.e. rash, hives, itching, unusual hoarseness or swelling of the mouth, face, lips, tongue, or throat)
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight
- Signs of urinary tract infection like blood in urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, or dark-colored stools
- Signs of gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes, fever with chills, bloating, or very upset stomach or throwing up
- Acid reflux, heartburn that is severe or happens often, or feeling of full after eating just a few bites
- Fast or abnormal heartbeat
- Hallucinations that are new or worse after starting this drug
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking
- Change in eyesight, eye pain, red eyes, or seeing halos or bright colors around lights. These may be signs of a type of glaucoma. If left untreated, this can lead to lasting eyesight loss.

Are there any risks for taking xanomeline and trospium for long periods of time?

It is unknown if there are any risks for taking xanomeline and trospium for long periods of time. Do not change the dose or stop taking xanomeline and trospium without first talking to your health care provider. Since xanomeline and trospium is used in the treatment of schizophrenia, discontinuation or tapering must be done carefully under a health care provider's guidance to prevent the return of psychotic symptoms or withdrawal effects.

What other medications may interact with xanomeline and trospium?

Some medications may **increase** the levels and effects of xanomeline and trospium include: bupropion (Wellbutrin®), duloxetine (Cymbalta®), escitalopram (Lexapro®), fluoxetine (Prozac®), and sertraline (Zoloft®). This is not an exhaustive list.

Taking xanomeline and trospium with certain other medications may increase your risk of side effect from xanomeline and trospium or other medicines and affect how xanomeline and trospium or your other medicines work. Keep a list of the medicines you take and show to your health care provider and pharmacist when you start taking xanomeline and trospium or any other medicine.

How long does it take for xanomeline and trospium to work?

It is important to tell your doctor how you feel things are going the first few weeks after you start taking xanomeline and trospium. It will probably take several weeks to see big enough changes in your symptoms to decide if xanomeline and trospium is right for you.

Treatment is generally needed lifelong for those with schizophrenia. Your doctor can best discuss the duration of treatment you need based on your symptoms and illness.

- Hallucinations, disorganized thinking, and delusions may improve in the first 1-2 weeks; sometimes these symptoms do not completely go away
- Motivation and desire to be around other people can take at least 1-2 weeks to improve; symptoms continue to get better the longer you take xanomeline and trospium. It may take 2-3 months before you get the full benefit of xanomeline and trospium

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.