

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE



Calcium, Magnesium, Potassium, and Sodium Oxybates Solution

Read this carefully before you start taking **XYWAV** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **XYWAV**.

Serious Warnings and Precautions

Abuse and Misuse:

The main active component of XYWAV is oxybate, or gamma-hydroxybutyrate (GHB), a known drug of abuse. Abuse or misuse of GHB, either alone or when taken with other central nervous system (CNS) depressants may cause serious medical problems including seizures, difficulty breathing (respiratory depression), decreases in the level of consciousness, coma, and death. **Do NOT take XYWAV with alcohol or other CNS depressants.** This includes the following examples of CNS depressants:

- opioids,
- benzodiazepines,
- barbiturates,
- ketamine,
- muscle relaxants,
- cannabis, and
- other sedatives.

Due to these risks, you must be enrolled in a program to receive XYWAV. During your treatment, your healthcare professional will also regularly monitor your health. However, if you notice any side effects, tell your healthcare professional. If you have any questions about XYWAV, ask your healthcare professional or call the program at 1-866-599-7365.

CNS Depression:

XYWAV is a CNS depressant. CNS depressants slow your brain down, relax your muscles, and can slow breathing. Taking XYWAV may lead to difficulty breathing (respiratory depression) and a reduced level of alertness (obtundation).

What is XYWAV used for?

XYWAV is used to treat cataplexy (suddenly weak or paralyzed muscles) in adults with narcolepsy (a type of sleep disorder).

How does XYWAV work?

The exact way XYWAV works to reduce the number of cataplexy attacks is not known.

What are the ingredients in XYWAV?

Medicinal ingredients: calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate.

Non-medicinal ingredients: purified water and sucralose.

XYWAV comes in the following dosage forms:

Oral solution: 0.5 g/mL of total salts (as 0.234 g calcium oxybate, 0.096 g magnesium oxybate, 0.13 g potassium oxybate, and 0.04 g sodium oxybate).

Do not use XYWAV if:

- you are allergic to calcium oxybate, magnesium oxybate, potassium oxybate, sodium oxybate, or to any of the other ingredients in XYWAV.
- you are taking or plan to take medicines that can cause sleepiness (e.g., other sleep medicines or sedatives).
- you are drinking or plan to drink alcohol. Do **not** consume any alcohol while taking XYWAV.
- you have a rare disorder called succinic semialdehyde dehydrogenase deficiency.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XYWAV. Talk about any health conditions or problems you may have, including if you:

- have past or current depression. You may be more likely to get depressed taking XYWAV. XYWAV should not be used if you have major depression.
- have liver problems because your dosage of XYWAV may need to be reduced.
- have breathing or lung problems.
- have snoring problems or sleep apnea (a sleep disorder which causes pauses in breathing or shallow breathing while sleeping). You may be more likely to get serious side effects.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. XYWAV can pass through your milk and may harm the baby.
- have a history of substance use problems.
- have had previous thoughts or attempts of suicide.
- have or had behaviour or other psychiatric problems such as:
 - seeing or hearing things that are not real (hallucinations)
 - feeling more suspicious (paranoia)
 - being out of touch with reality (psychosis)
 - acting aggressive
 - agitation
 - anxiety

Other warnings you should know about:

Dependence and addiction: The active ingredient in XYWAV, GHB, has been used illegally for its sedating effects. When GHB is used illegally (usually at higher doses and frequencies), dependence and craving for GHB have been reported. Acute withdrawal symptoms have also been reported after repeated illicit use. It is important that you talk to your healthcare professional if you have questions or concerns about abuse, addiction, or dependence. Always use XYWAV as prescribed.

Driving and using machinery: XYWAV can affect your mental alertness, judgment, thinking, and movement. Do **NOT** drive or do tasks that require special attention for at least 6 hours after taking XYWAV. In addition, before you drive or do tasks that require special attention the next day, wait until you know how you respond to XYWAV. This is especially important when you first start taking XYWAV.

Unusual behaviours during sleep: XYWAV can cause unwanted events or experiences that occur during sleep, including walking while being asleep. Tell your doctor if you develop any abnormal movements or behaviours while sleeping.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Serious drug interactions exist with XYWAV and CNS depressants (used to slow your brain down, relax your muscles, and/or provide a sense of calm). Do **not** take XYWAV with the following CNS depressants:

- alcohol or medicines with alcohol;
- sleep medicines or sedatives used to help with sleeping and anxiety;
- barbiturates used to relax the body and help with sleeping;
- benzodiazepines used to help you sleep or that help reduce anxiety.

Other CNS depressants are not recommended for use with XYWAV. These include:

- sedating antidepressants used to treat depression;
- sedating antiepileptic drugs used to prevent seizures;
- sedating antipsychotics used to treat mental health disorders (e.g., ketamine);
- general anesthetics used during surgery;
- illicit CNS depressants;
- muscle relaxants used to treat muscle spasms and back pain;
- medicines used to help with sleep (e.g., zopiclone, eszopiclone, and lemborexant);
- cannabis (marijuana);
- opioid analgesics used to relieve pain.

Talk to your healthcare professional if you take or plan to take any CNS depressants.

The following may also interact with XYWAV:

- anticonvulsants used to prevent or treat certain types of seizures (e.g., divalproex sodium, ethosuximide, phenytoin, topiramate, and valproate).
- herbal products such as sleep-aids (e.g., melatonin, valerian, and kava) or St. John's Wort.

How to take XYWAV:

- The program will teach you about the safe and proper use of XYWAV.
- Take XYWAV two times each night exactly as prescribed by your healthcare professional. The first dose is taken at bedtime and the second dose is taken 2.5 to 4 hours later both while sitting in bed. You may need to set an alarm to awaken for the second dose.

- You should stop eating at least 2 hours before taking the first dose of XYWAV at bedtime. A regular evening routine should be established to help with the timing of meals and ensure the proper use of XYWAV.
- You should lie down and remain in bed after taking your first and second dose of XYWAV. XYWAV can cause you to fall asleep quickly. Falling asleep while standing or while rising from the bed has led to falls and injuries which has required hospitalization.
- Prepare both doses of XYWAV before bedtime. Each dose of XYWAV must be diluted with a quarter (¼) cup (approximately 60 mL) of water in the empty pharmacy-provided containers prior to ingestion and sealed with the child-resistant cap. The second dose should be placed in close proximity to your bed.

Instructions for use:

CAUTION: Be very careful not to leave your XYWAV in a place where children, pets, or people whom this product is not prescribed can get to it.

Before starting your treatment with XYWAV, be certain that you are completely familiar with the supplies needed for mixing and taking XYWAV and the steps for preparation and use of XYWAV.

Supplies you will need for mixing and taking XYWAV (also see **Figure A**):

- the XYWAV bottle;
- a dosing syringe for measuring and dispensing the XYWAV doses;
- two **empty** pharmacy containers with child-resistant caps for mixing, storing, and taking the XYWAV doses;
- the Patient Medication Information leaflet;
- a measuring cup that can measure about a quarter (¼) cup (approximately 60 mL) of water.

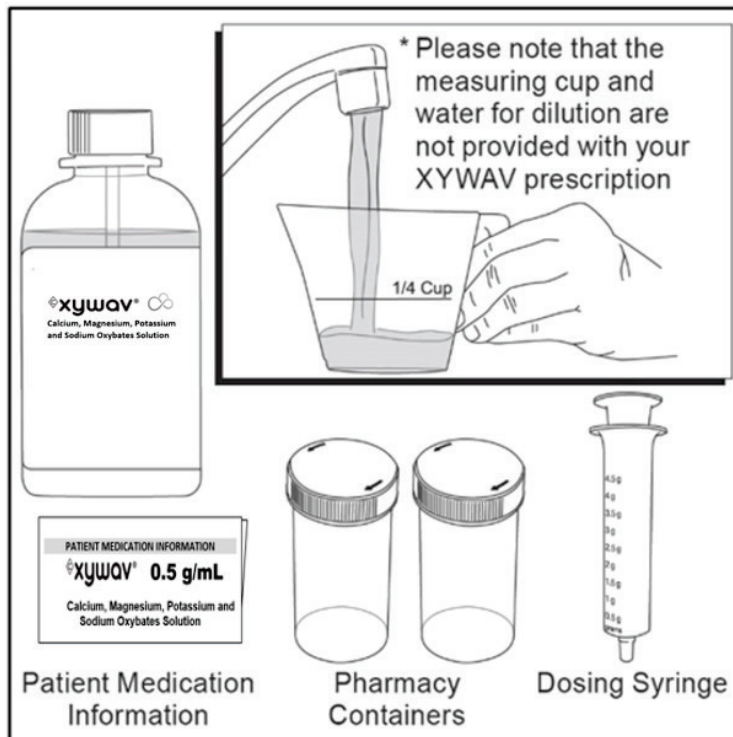


Figure A

Step 1: Setup

- Remove the plastic wrapper from the syringe. Only use the syringe provided with your XYWAV prescription.
- Fill a measuring cup with about a quarter ($\frac{1}{4}$) cup (approximately 60 mL) of water.
- Open both pharmacy containers by pressing down on the child-resistant locking cap and turning the cap counterclockwise to the left (see **Figure B**). **Make sure the pharmacy containers are empty.**

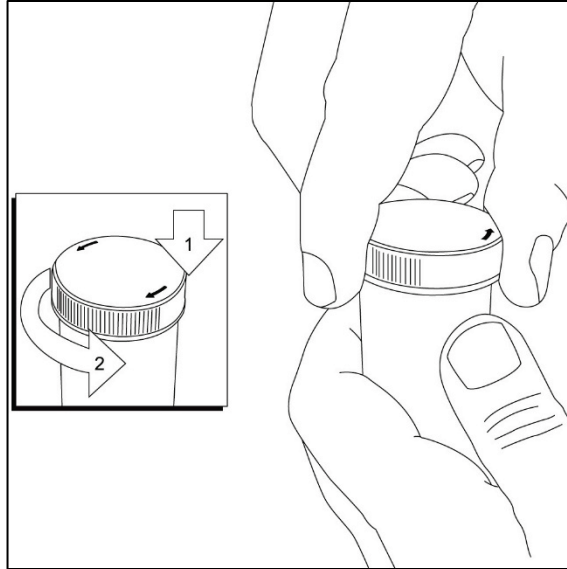


Figure B

- d. Remove the tamper evident band from the XYWAV bottle by pulling at the perforations and then remove the child-resistant bottle cap by pushing down while turning the cap counterclockwise to the left (see **Figure C**).

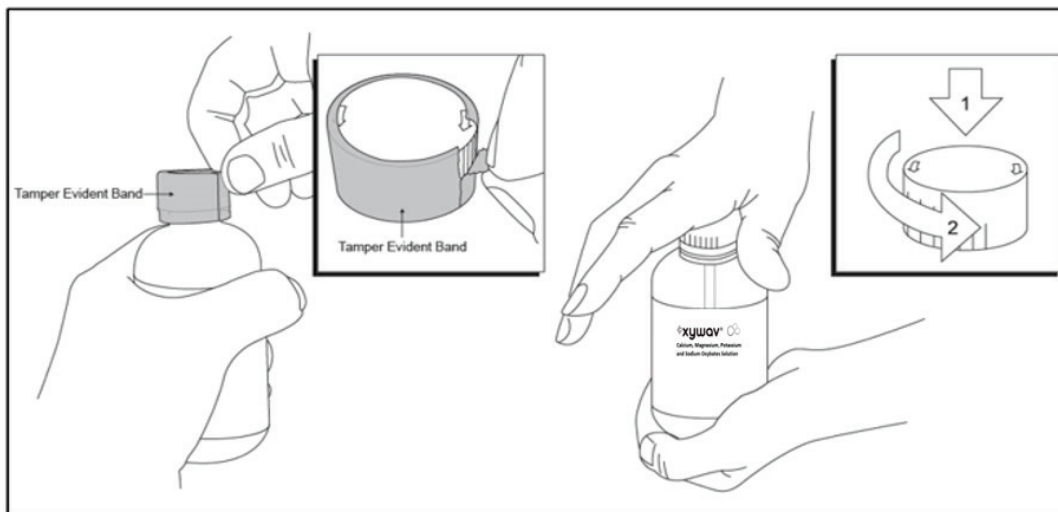


Figure C

- e. After removing the cap, set the bottle upright on a tabletop.

Step 2: Preparation of the First XYWAV Dose (prepare before bedtime)

The two doses of XYWAV are prepared separately. To prepare the first dose:

- a. Place the XYWAV bottle on a hard, flat surface and grip the bottle with one hand.

- b. Firmly press the syringe into the center opening of the bottle with your other hand (see **Figure D**).

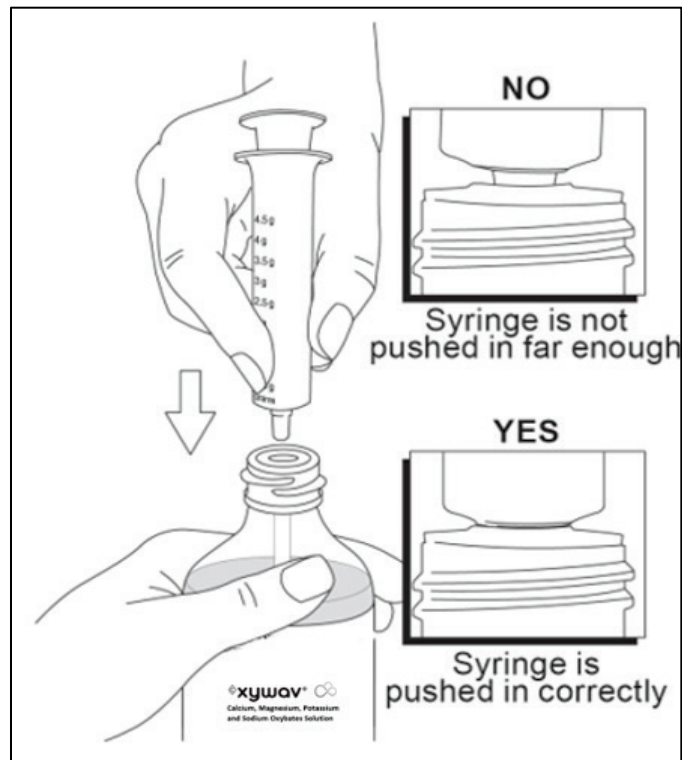


Figure D

- c. On the syringe, identify the specific amount in grams (g) that matches your prescribed dose.

The measuring device is a syringe with markings only in grams. In case you need the dose in millilitres (mL), you can consult the conversion tables below:

Single dose in grams (to be taken twice per night)	Single dose in mL (to be taken twice per night)
1.5 grams	3 mL
2.25 grams	4.5 mL
3 grams	6 mL
3.75 grams	7.5 mL
4.5 grams	9 mL

Total dose per night in grams	Total dose per night in mL
3 grams	6 mL
4.5 grams	9 mL
6 grams	12 mL
7.5 grams	15 mL
9 grams	18 mL

- d. Pull up on the plunger on the syringe until the medicine flows into the syringe and the liquid level is lined up with the marking on the syringe that matches your prescribed dose (see **Figure E**). Keep the bottle upright so that the XYWAV medicine will flow into the syringe.

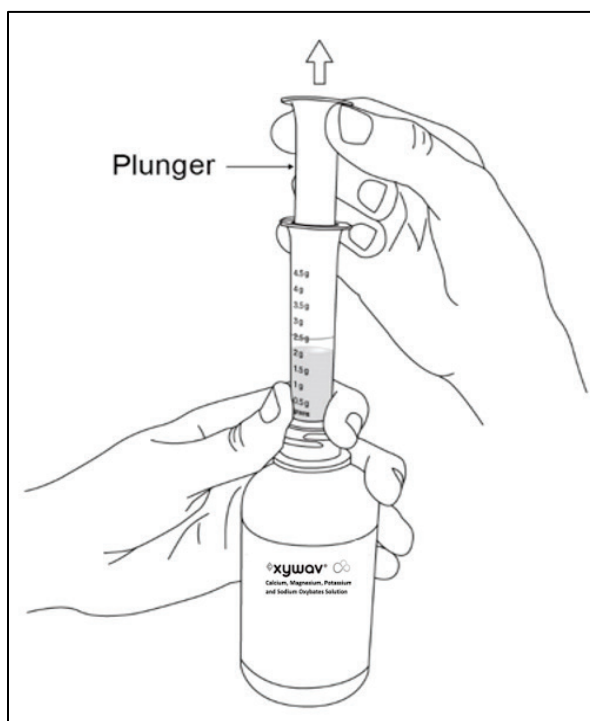


Figure E

Note: Make sure that the **liquid level** lines up with the marking on the syringe that matches your prescribed dose even if an air space forms between the plunger and the liquid (see **Figure F** for an example of drawing up 2.25 g).

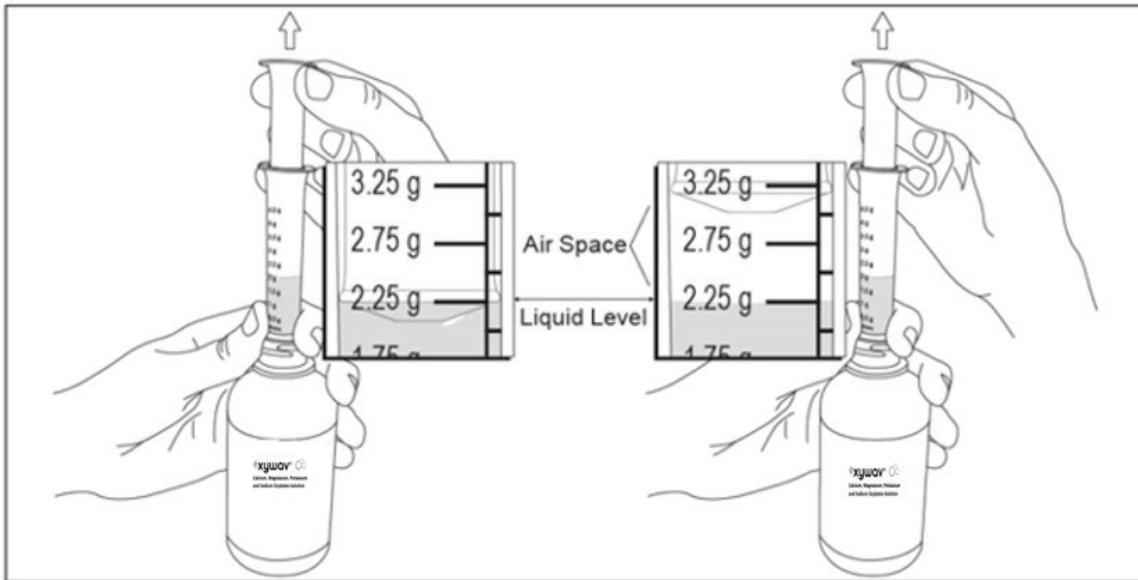


Figure F

- e. After you draw up the first dose, remove the syringe from the opening of the XYWAV bottle.
- f. Empty all of the medicine from the syringe into one of the provided **empty** pharmacy containers by pushing down on the plunger until it stops (see **Figure G**).

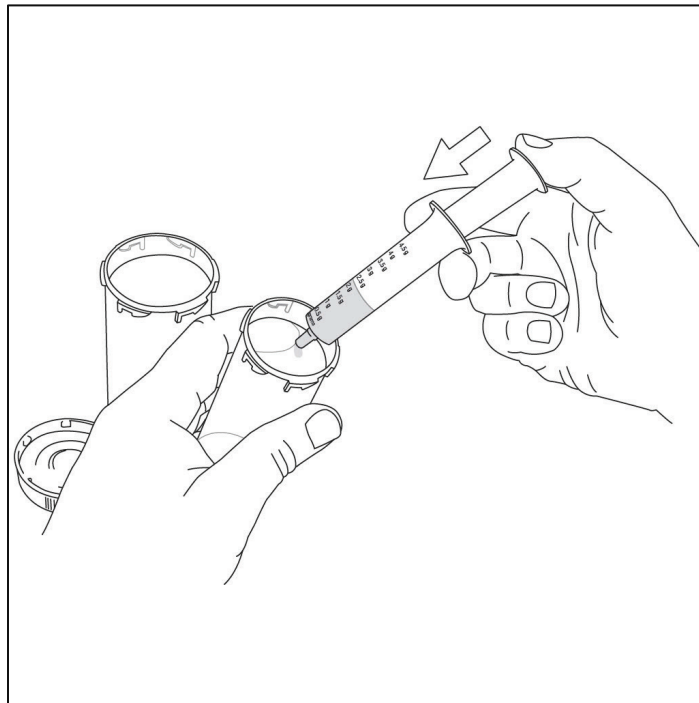


Figure G

- g. Using a measuring cup, pour about a quarter ($\frac{1}{4}$) cup (approximately 60 mL) of water into the pharmacy container with the first dose of XYWAV solution. **Be careful to add only water to the**

pharmacy container and not more XYWAV.

- h. Place the child-resistant cap on the pharmacy container and turn the cap clockwise to the right until it clicks and locks into its child-resistant position (see **Figure H**).

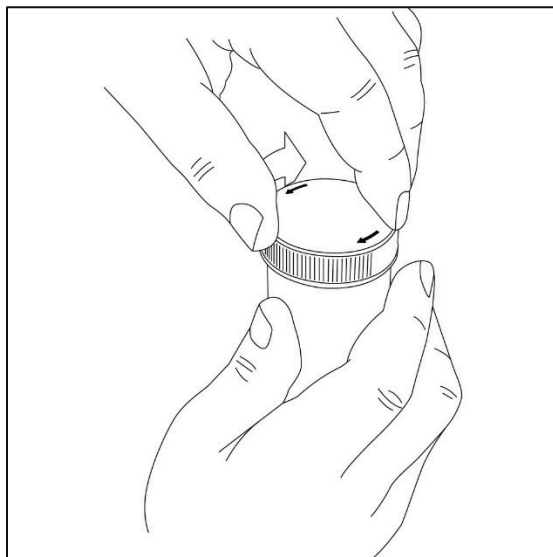


Figure H

Step 3: Preparation of the Second XYWAV Dose (prepare before bedtime)

- a. Repeat **Step 2** drawing up the amount of medicine prescribed for your second dose.
- b. Empty the syringe into the second pharmacy container.
- c. Add a quarter ($\frac{1}{4}$) cup (approximately 60 mL) of water into the pharmacy container with the second dose of XYWAV solution. **Be careful to add only water to the pharmacy container and not more XYWAV.**
- d. Place the child-resistant cap on the pharmacy container and turn the cap clockwise to the right until it clicks and locks into its child-resistant position (see **Figure H**).

Step 4: Storing the Prepared XYWAV Doses and Cleaning the Syringe

- a. Put the cap back on the XYWAV bottle and store the XYWAV bottle and both prepared doses in a safe and secure place. Store in a locked place if needed.
- b. The prepared XYWAV doses should be taken within 24 hours.
- c. Keep the XYWAV bottle and both prepared XYWAV doses out of the reach of children and pets.
- d. Rinse the syringe out with water and squirt the liquid into the sink drain by pushing down on the plunger until it stops.

Step 5: Taking the First XYWAV Dose

- a. At bedtime, and before you take the first XYWAV dose, put the second XYWAV dose in a secure location (locked up if appropriate) near your bed. You may want to set an alarm clock for 2.5 to 4 hours later to make sure you wake up to take the second dose.
- b. When it is time to take the first XYWAV dose, remove the cap from the pharmacy container by pressing down on the child-resistant locking cap and turning the cap counterclockwise to the

- left.
- c. Drink all of the first XYWAV dose while sitting in bed. Put the cap back on the first pharmacy container and immediately lie down to sleep.
 - d. You should fall asleep soon. Some people fall asleep within 5 minutes and most fall asleep within 15 minutes. Some patients take less time to fall asleep, and some take more time. The time it takes you to fall asleep might be different from night to night.

Step 6: Taking the Second XYWAV Dose

- a. When you wake up 2.5 to 4 hours later for your second dose of XYWAV, take the cap off the second pharmacy container by pressing down on the child-resistant locking cap and turning the cap counterclockwise to the left.
- b. If you wake up before the alarm and it has been at least 2.5 hours since the first XYWAV dose, turn off the alarm and take the second XYWAV dose.
- c. Drink all of the second XYWAV dose while sitting in bed. Put the cap back on the second pharmacy container and immediately lie down to continue sleeping.

Usual dose:

Your healthcare professional will decide the right dose of XYWAV for you. This will depend on your condition, age, health, and if you take certain other medications.

You will discuss your response to XYWAV with your healthcare professional and they may adjust your dose every week. Never change or stop your dose of XYWAV yourself.

Overdose:

If you think you, or a person you are caring for, have taken too much XYWAV, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, do not take two doses at one time.

- If the first dose is missed or delayed, take it as soon as you remember. A second dose may be taken 2.5 to 4 hours later only if there is sufficient sleep time prior to waking up, otherwise, the second dose should be skipped.
- If a first dose is taken and the second dose is missed or delayed, it should only be taken if there is sufficient sleep time prior to waking up. If there is insufficient sleep time prior to waking up, skip the second dose.

If insufficient sleep time has passed since the last dose has been taken, do NOT drive or engage in activities that require complete mental alertness.

What are possible side effects from using XYWAV?

These are not all the possible side effects you may have when taking XYWAV. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of XYWAV may include:

- acne;
- altered sense of taste;
- body pain;
- constipation;
- diarrhea;
- dizziness;
- dry mouth;
- falls;
- fever;
- hair loss;
- headache;
- muscle cramps including leg cramps;
- loss of coordination;
- palpitations;
- ringing in the ears;
- shortness of breath.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Sleeping problems: abnormal dreams, nightmares, sleep walking, sleep apnea (stop breathing for short periods during your normal nightly sleep), insomnia (hard to fall asleep and hard to stay asleep), or confused behaviour occurring at night.		✓	
COMMON			
Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives, rash, or swelling of the face, lips, tongue or throat.			✓
Behavioural or mental changes: psychosis, paranoia, hallucinations, anxiety, irritability, hostility, aggression, agitation, memory impairment, confusion, increased libido (sex drive), or abnormal thinking.		✓	
Central nervous system (CNS) depression (brain slows down): respiratory depression (slow, shallow or weak breathing), low blood pressure, drowsiness, loss of consciousness, or coma.			✓
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social		✓	

situations, family, gatherings and activities with friends, reduced libido (sex drive), or thoughts of death or suicide.			
Eye problems: vision blurred in one or both eyes, or vision changes.	✓		
Seizures (fit): loss of consciousness with uncontrollable shaking.			✓
Urinary problems: pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine, unable to control the bladder leading to urine leaks, or needing to wake up more often at night to urinate.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Always store XYWAV in the original bottle at room temperature (15°C to 30°C). Once the bottle is opened use within 95 days.
- After preparing the XYWAV solution in the provided containers, they should be taken within 24 hours as directed by your healthcare professional.
- Return any unused XYWAV to your pharmacy for proper disposal. Do not pour it down the drain.
- Always keep XYWAV and your nightly doses out of the reach and sight of children and pets in a safe and secure place (locked up if appropriate).

If you want more information about XYWAV:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.jazzpharma.com, or by calling the program at 1-866-599-7365.

This leaflet was prepared by Jazz Pharmaceuticals Ireland Ltd.

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