

MEDICATION GUIDE**ZUBSOLV® (Zub-solve) (buprenorphine and naloxone) Sublingual Tablet, CIII**

IMPORTANT: Keep ZUBSOLV in a secure place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally uses ZUBSOLV, get emergency help or call 911 right away. Tell your healthcare provider if you are living in a household where there are small children.

What is the most important information I should know about ZUBSOLV?

- ZUBSOLV contains a medicine called buprenorphine. Buprenorphine is an opioid that can cause serious and life-threatening breathing problems, especially if you take or use certain other medicines or drugs.
- Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the emergency treatment of an opioid overdose, including accidental use of ZUBSOLV sublingual tablet by a child. If naloxone is given, you must call 911 or get emergency medical help right away to treat an overdose or accidental use of an opioid.
- ZUBSOLV may cause serious and life-threatening breathing problems. Get emergency help right away if:
 - feel faint
 - feel dizzy
 - are confused
 - feel sleepy or uncoordinated
 - have blurred vision
 - have slurred speech
 - are breathing slower than normal
 - cannot think well or clearly
- **Do not take ZUBSOLV with certain medicines. Taking ZUBSOLV with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.**
- **Do not inject (“shoot-up”) ZUBSOLV.** Injecting ZUBSOLV may cause life-threatening infections and other serious health problems, Injecting ZUBSOLV may cause sudden serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.
- Do not switch from ZUBSOLV to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of ZUBSOLV is not the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of buprenorphine that may be different than other buprenorphine containing medicines you may have been taking.
- Do not stop taking ZUBSOLV suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine (physical dependence). Physical dependence is not the same as drug addiction.
- In an emergency, have family members tell the emergency department staff that you are physically dependent on an opioid and are being treated with ZUBSOLV.
- Never give anyone else your ZUBSOLV. They could die from taking it. Selling or giving away ZUBSOLV is against the law.
- Store ZUBSOLV securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

What is ZUBSOLV?

- ZUBSOLV is a prescription medicine used to treat opioid addiction in adults and is part of a complete treatment program that also includes counseling and behavioral therapy.

Who should not take ZUBSOLV?

Do not take ZUBSOLV if you are allergic to buprenorphine or naloxone.

What should I tell my doctor before taking ZUBSOLV?

Before taking ZUBSOLV, tell your healthcare provider about all of your medical conditions, including if you have:

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|-----------------------------------------------------|------------------------------------------|-------------------------------------------|
| • trouble breathing or lung problems | • an enlarged prostate (men) | • a head injury or brain problem |
| • a curve in your spine that affects your breathing | • problems urinating | • mental health problems |
| • Addison’s disease | • liver, kidney, or gallbladder problems | • adrenal gland or thyroid gland problems |
| | • alcoholism | |

Tell your healthcare provider if you are:

- **pregnant or plan to become pregnant.** If you take ZUBSOLV while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- **breastfeeding.** ZUBSOLV can pass into your breast milk and harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take ZUBSOLV. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with ZUBSOLV.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

How should I take ZUBSOLV?

Read the Instructions for Use at the end of this Medication Guide for detailed instructions on how to take ZUBSOLV

- Take ZUBSOLV exactly as prescribed by your healthcare provider. Your healthcare provider may change your dose after seeing how it affects you. Do not change your dose unless your healthcare provider tells you to change it.
- Do not take ZUBSOLV more often than prescribed by your healthcare provider.
- **ZUBSOLV is not for occasional or “as needed” use**
- You may be prescribed a dose of 2 or more ZUBSOLV sublingual tablets at the same time.
- After induction (your first day of dosing), take ZUBSOLV 1 time a day.
- Use the entire ZUBSOLV tablet. Do not cut, chew, or swallow the tablet.
- If you miss a dose of ZUBSOLV, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time unless your healthcare provider tells you to. If you are not sure about your dosing, call your healthcare provider.
- Dispose of expired, unwanted, or unused ZUBSOLV by promptly flushing down the toilet (if a drug take-back option is not readily available). Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.
- **If you take too much ZUBSOLV or overdose, get emergency medical help right away.**

What should I avoid while taking ZUBSOLV?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how ZUBSOLV affects you.** Buprenorphine can cause drowsiness and slow reaction times. ZUBSOLV can make you sleepy, dizzy, or lightheaded.
- **You should not drink alcohol** or use prescription or over-the-counter medicines that contain alcohol while taking ZUBSOLV, because this can lead to loss of consciousness or even death.

What are the possible side effects of ZUBSOLV?

ZUBSOLV can cause serious side effects, including:

- **Trouble breathing.** Taking ZUBSOLV with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants can cause breathing problems that can lead to coma and death.
- **Sleepiness, dizziness, and problems with coordination.**
- **Physical dependence or abuse.**
- **Liver problems.** Call your healthcare provider right away if you notice any of these symptoms:
 - your skin or the white part of your eyes turns yellow (jaundice)
 - dark or “tea-colored” urine
 - light colored stools (bowel movements)
 - loss of appetite
 - pain, aching, or tenderness on the right side of your stomach area
 - nausea
- Your healthcare provider should do blood tests to check the liver before you start taking and while you take ZUBSOLV.
- **Allergic reaction.** You may have a rash, hives, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.
- **Opioid withdrawal.** Call your healthcare provider right away if you get any of these symptoms:
 - shaking
 - sweating more than normal
 - feeling hot or cold more than normal
 - runny nose
 - watery eyes
 - goose bumps
 - diarrhea
 - vomiting
 - muscle aches
- **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.
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- **The most common side effects of ZUBSOLV include:**

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- headache
 - nausea
 - vomiting
 - constipation
 - ZUBSOLV sublingual tablet may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.
 - These are not all the possible side effects of ZUBSOLV.
- pain
 - increased sweating
 - decrease in sleep (insomnia)

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ZUBSOLV.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZUBSOLV for a condition for which it was not prescribed. Do not give ZUBSOLV to other people, even if they have the same symptoms you have. It may harm them and it is **against the law**. You can ask your doctor or pharmacist for information that is written for health professionals.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

INSTRUCTIONS FOR USE
ZUBSOLV® (Zub-solve) (buprenorphine and naloxone) Sublingual Tablet, CIII

This “Instructions for Use” contains information on how to correctly take ZUBSOLV sublingual tablets.

Important Information You Need to Know Before Taking ZUBSOLV sublingual tablets:

- Your healthcare provider should show you how to take **ZUBSOLV sublingual tablets** the right way.

Preparing to take ZUBSOLV sublingual tablets:

- Follow the same instructions every time you take a dose of ZUBSOLV.
- ZUBSOLV comes in a blister pack with 10 blister units. Each blister unit contains a ZUBSOLV tablet.
- Take the dose prescribed by your doctor as follows:
 - Pull apart 1 of the blister units from the blister pack by tearing along the dotted lines (perforations) until it is fully separated (See Figure A).

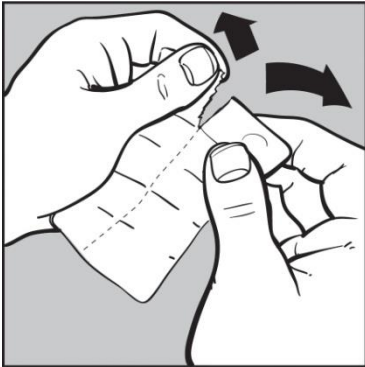


Figure A

- When the blister unit is fully separated, fold the single unit down at dotted line toward the blister (See Figure B).

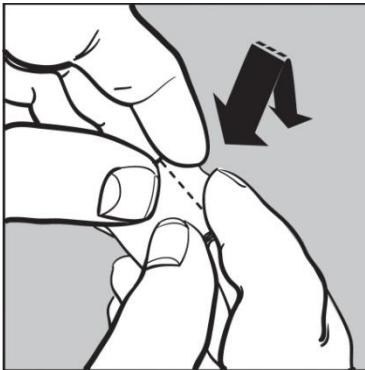


Figure B

- Slowly tear down at notch to open the blister unit (See Figure C).

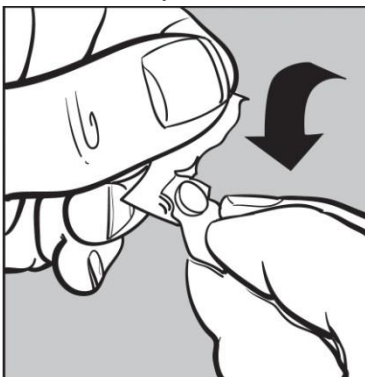


Figure C

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- Do not push ZUBSOLV tablets through the foil. This could cause the tablet to break.
- As soon as you remove your prescribed dose of ZUBSOLV from the blister pack place the tablet under your tongue (See Figures D, E, and F). If more than 1 tablet is required, place the tablets in different places under your tongue at the same time.

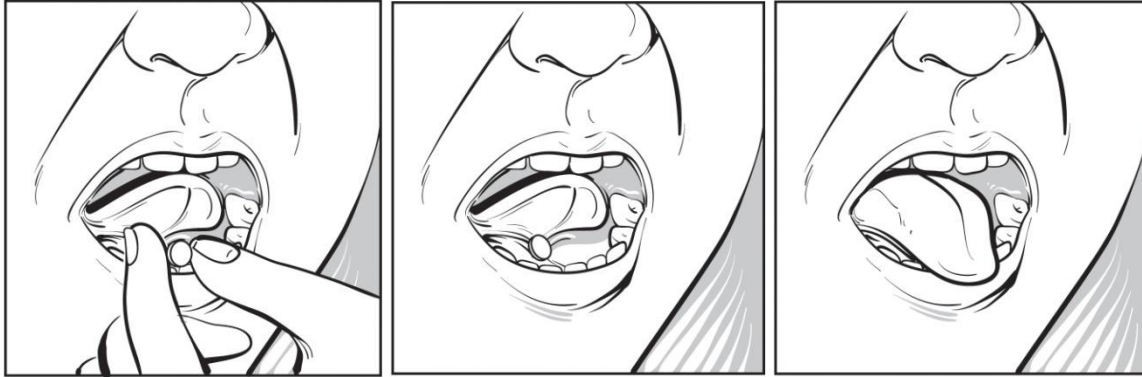


Figure D

Figure E

Figure F

- Let the tablet dissolve completely. ZUBSOLV usually dissolves in your mouth within 5 minutes. If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water and dry your hands if they are wet before you place the ZUBSOLV tablet under your tongue.
- While ZUBSOLV is dissolving, do not chew or swallow the tablet because the medicine will not work as well.
- Do not eat or drink anything until the ZUBSOLV tablet has completely dissolved.
- Talking while the tablet is dissolving can affect how well the medicine in ZUBSOLV is absorbed.
- If you miss a dose of ZUBSOLV, take your medicine when you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time unless your doctor tells you to. If you are not sure about your dosing, call your doctor.
- Do not stop taking ZUBSOLV suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine. Physical dependence is not the same as drug addiction. Your doctor can tell you more about the differences between physical dependence and drug addiction. To have fewer withdrawal symptoms, ask your doctor how to stop using ZUBSOLV the right way.

If you take too much ZUBSOLV go to the nearest hospital emergency room right away.

Storing ZUBSOLV sublingual tablets?

- Store ZUBSOLV at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep ZUBSOLV in a safe place, out of the sight and reach of children.**

Disposing of ZUBSOLV sublingual tablets?

- Dispose of expired, unwanted, or unused ZUBSOLV by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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