PATIENT & CAREGIVER EDUCATION Buprenorphine and Naloxone

This information from Lexicomp[®] explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Bunavail [DSC]; Suboxone; Zubsolv

Brand Names: Canada

PMS-Buprenorphine-Naloxone; Suboxone; TEVA-Buprenorphine/Naloxone

What is this drug used for?

- It is used to treat opioid use disorder. Opioid drugs include heroin and prescription pain drugs like oxycodone and morphine.
- Do not use for pain relief or on an as needed basis.
- This drug is not approved for use in children. However, the doctor may decide the benefits of taking this drug outweigh the risks. If your child has been given this drug, ask the doctor for information about

the benefits and risks. Talk with the doctor if you have questions about giving this drug to your child.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has liver disease.
- If your child has not been taking an opioid drug.
- If your child has taken certain drugs for depression or certain other health problems in the last 14 days. This includes isocarboxazid, phenelzine, or tranylcypromine. Very high blood pressure may happen.
- If your child is taking any of these drugs: Linezolid or methylene blue.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- This drug may be habit-forming with long-term use.
- This drug has a risk of misuse. Give this drug only as you were told by the doctor. Tell the doctor if your child has ever had alcohol or drug use disorder.
- Your child will be watched closely to make sure your child does not misuse this drug or develop drug use disorder.
- Have your child avoid tasks or actions that call for alertness until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.
- To lower the chance of feeling dizzy or passing out, have your child rise slowly if your child has been sitting or lying down. Have your child be careful going up and down stairs.

- The doctor may order naloxone to help treat an opioid overdose if needed. Opioid overdose may happen if your child starts taking opioid drugs again or if too much of this drug is taken. If you have questions about how to get or use naloxone, talk with the doctor or pharmacist. If you think there has been an opioid overdose, get medical care right away even if naloxone has been used.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Do not stop giving this drug to your child all of a sudden without calling the doctor. Your child may have a greater risk of side effects. If your child needs to stop this drug, you will want to slowly stop it as told by the doctor.
- Long-term use of an opioid drug may lead to lower sex hormone levels. Call your child's doctor if your child has a lowered interest in sex, fertility problems, no menstrual period, or ejaculation problems.
- Even one dose of this drug may be deadly if it is taken by someone else or by accident, especially in children. If this drug is taken by someone else or by accident, get medical help right away.
- Signs of opioid withdrawal have happened with this

drug. Call your child's doctor right away if your child has more sweating, chills, diarrhea or stomach pain that is not normal, anxiety, feeling irritable, or yawning.

- This drug has an opioid in it. Severe side effects have happened when opioid drugs were used with benzodiazepines, alcohol, marijuana, other forms of cannabis, or street drugs. This includes severe drowsiness, breathing problems, and death.
 Benzodiazepines include drugs like alprazolam, diazepam, and lorazepam. If you have questions, talk with the doctor.
- Many other drugs interact with this drug. These drugs can raise the chance of this drug's side effects. Talk with your child's doctor and pharmacist to make sure that it is safe for your child to use this drug with other drugs.
- Be sure your child does not drink alcohol or use products that have alcohol in them. Unsafe and sometimes deadly effects may happen.

If your child is pregnant or breast-feeding a baby:

• If your child is pregnant or plans to get pregnant, talk with your child's doctor right away. Using this drug

for a long time during pregnancy may lead to withdrawal in the newborn baby. Withdrawal in the newborn can be life-threatening if not treated.

• Tell your child's doctor if your child is breast-feeding a baby. This drug passes into breast milk and may harm your child's baby.

What are some side effects that I need to call my child's doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child's doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low blood sugar like dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating.
- Change in eyesight.

- Feeling nervous and excitable.
- Change in balance.
- Depression or other mood changes.
- Feeling confused, not able to focus, or change in behavior.
- Extra muscle action or slow movement.
- Slurred speech.
- Feeling sluggish, drunk, or out of sorts.
- A heartbeat that does not feel normal.
- Noisy breathing.
- Breathing problems during sleep (sleep apnea).
- This drug may cause very bad and sometimes deadly breathing problems. Call the doctor right away if your child has slow, shallow, or trouble breathing.
- Get medical help right away if your child does not respond, answer, or react like normal; feels very sleepy or dizzy; passes out; or will not wake up.
- Liver problems have rarely happened with this drug. Sometimes, this has been deadly. Call your child's doctor right away if your child has signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

- A severe and sometimes deadly problem called serotonin syndrome may happen if your child takes this drug with certain other drugs. Call your child's doctor right away if your child has agitation; change in balance; confusion; hallucinations; fever; fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; severe diarrhea, upset stomach, or throwing up; or severe headache.
- Taking an opioid pain drug like this drug may lead to a rare but severe adrenal gland problem. Call the doctor right away if your child feels very tired or weak, passes out, or has severe dizziness, very upset stomach, throwing up, or decreased appetite.
- Dental problems like cavities, infections, and loss of teeth have happened with buprenorphine products that are dissolved in the mouth. This has even happened in people who did not already have dental problems. Call the doctor and dentist right away if your child has any problems with the teeth or gums.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

All products:

- Feeling dizzy, sleepy, tired, or weak.
- Trouble sleeping.
- Headache.
- Constipation, diarrhea, stomach pain, upset stomach, or throwing up.
- Sweating a lot.
- Flushing.
- Back pain.

Under the tongue (sublingual) film:

- Burning.
- Numbness or tingling in the mouth.
- Pain where it was placed.
- Redness.

These are not all of the side effects that may occur. If you have questions about side effects, call your child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health

agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

All products:

- Give this drug at the same time of day.
- Do not let your child chew, cut, or swallow this drug.
- Do not let your child eat, drink, smoke, or talk while this drug is dissolving.
- Give this drug by mouth only. Very bad and sometimes deadly side effects may happen if this drug is injected.
- After this drug has dissolved, have your child take a large sip of water, swish it around in the mouth, and swallow. Have your child wait at least 1 hour before brushing their teeth.
- Take care of your child's teeth. See a dentist often.

All film products:

- Open right before use.
- Be sure your hands are dry before you touch this drug.
- This drug must be taken whole. Do not cut or tear this

drug. Do not touch the film with your tongue or finger once it has been placed.

Under the tongue (sublingual) film:

- Some products need to be placed under the tongue. Some products may be placed under the tongue or on the inside of the cheek. Be sure you know how this drug needs to be taken. If you are not sure, check with the pharmacist.
- If your child is using under the tongue, have your child wet mouth with water. Place film under the tongue close to the base on the left or right side and have your child let it dissolve.
- If your child is using on the inside of the cheek, have your child wet the inside of the cheek with the tongue or water. Place the film inside the mouth on a wet cheek and have your child let it dissolve.
- If using 2 films, place on opposite sides. Try not to let films touch.
- If using 3 films, place the third film under the tongue after the first 2 films have dissolved.

Cheek film:

• Have your child wet the inside of the cheek with the tongue or water.

- Place the film inside the mouth on a wet cheek. Hold for 5 seconds so it sticks to the cheek. Let it dissolve.
- Place the side of the film with the writing against the inside of the cheek.
- If using 2 films, place on opposite sides. If using many films, do not place more than 2 films on the inside of 1 cheek at a time.

Under the tongue (sublingual) tablet:

- Place tablet under the tongue and let dissolve.
- If the doctor tells you to give more than 1 tablet at a time, ask the doctor how to give them.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 2 doses at the same time or extra doses.
- If you are not sure what to do if your child misses a dose, call the doctor.

How do I store and/or throw out this drug? All products:

- Store at room temperature in a dry place. Do not store in a bathroom.
- Store this drug in a safe place where children cannot see or reach it, and where other people cannot get to it. A locked box or area may help keep this drug safe. Keep all drugs away from pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

All film products:

- Do not freeze.
- Store in foil pouch until ready for use.

General drug facts

- If your child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not

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Last Reviewed Date

2024-01-29

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

Buprenorphine and Naloxone - Last updated on December 12, 2022

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