- Inform patients that buprenorphine and naloxone sublingual tablets can cause drug dependence and that withdrawal signs and symptoms may occur when the medication is discontinued.
- Advise patients seeking to discontinue treatment with buprenorphine for opioid dependence to work closely with their healthcare provider on a tapering schedule and inform them of the potential to relapse to illicit drug use associated with discontinuation of opioid agonist/partial agonist medication-assisted treatment.
- Advise patients that, like other opioids, buprenorphine and naloxone sublingual tablets may produce orthostatic hypotension in ambulatory individuals *[see Warnings and Precautions (5.14)]*.
- Advise patients to inform their healthcare provider if any other prescription medications, over-the- counter medications, or herbal preparations are prescribed or currently being used *[see Drug Interactions (7)]*.
- Advise women that if they are pregnant while being treated with buprenorphine and naloxone sublingual tablets, the baby may have signs of withdrawal at birth and that withdrawal is treatable *[see Warnings and Precautions (5.5), Use in Specific Populations (8.1)]*.
- Advise women who are breastfeeding to monitor the infant for drowsiness and difficulty breathing *[see Use in Specific Populations (8.2)]*.
- Inform patients that chronic use of opioids may cause reduced fertility. It is not known whether these effects on fertility are reversible *[see Use in Specific Populations (8.3)]*.
- Advise patients to inform their family members that, in the event of emergency, the treating healthcare provider or emergency room staff should be informed that the patient is physically dependent on an opioid and that the patient is being treated with buprenorphine and naloxone sublingual tablets.

Manufactured by:

Wes Pharma Inc

Westminster, MD 21157

Rev. 10/2020

Dispense with Medication Guide available at
www.accordhealthcare.us/medication-guides
MEDICATION GUIDE
BUPRENORPHINE (byoo-pre-NOR-feen) AND NALOXONE (nah-LOX-own)
SUBLINGUAL TABLETS (CIII)

IMPORTANT
Keep buprenorphine and naloxone sublingual tablets 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 buprenorphine and naloxone sublingual tablets, get emergency help or call 911 right away. Tell your healthcare provider if you are living in a household where there are small children.

Read this Medication Guide that comes with buprenorphine and naloxone sublingual tablets before you start taking them and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor. Talk to your doctor or pharmacist if you have questions about buprenorphine and naloxone sublingual tablets.
Share the important information in this Medication Guide with members of your household.

What is the most important information I should know about buprenorphine and naloxone sublingual tablets? Buprenorphine and naloxone sublingual tablet contains a medicine called buprenorphine. Buprenorphine is an opioid that can cause serious and life-threatening problems, especially if you take or use certain other medicines or drugs. Call your healthcare provider right away or get emergency help if you:

-
  - feel faint or dizzy
  - have mental changes such as confusion
  - have slower breathing than you normally have
  - have severe sleepiness
  - have blurred vision
  - have problems with coordination
  - have slurred speech
  - cannot think well or clearly
  - have slowed reflexes
  - have a high body temperature
  - feel agitated
  - have stiff muscles
  - have trouble walking
- 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 Buprenorphine and naloxone sublingual tablet by a child.
- Do not switch from buprenorphine and naloxone sublingual tablets to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of buprenorphine and naloxone sublingual tablets is not the same as the amount of buprenorphine in other medicines that contain buprenorphine. Your doctor will prescribe a starting dose of buprenorphine and naloxone sublingual tablets that may be different than other buprenorphine containing medicines you may have been taking.
- Buprenorphine and naloxone sublingual tablets contain an opioid that can cause physical dependence.
  - Do not stop taking buprenorphine and naloxone sublingual tablets without talking to your doctor. You could become sick with uncomfortable withdrawal signs and symptoms because your body has become used to this medicine.
  - Physical dependence is not the same as drug addiction.
  - Buprenorphine and naloxone sublingual tablets are not for occasional or “as needed” use.
  - An overdose and even death can happen if you take benzodiazepines, sedatives, tranquilizers, antidepressants, or alcohol while using buprenorphine and naloxone sublingual tablets. Ask your doctor what you should do if you are taking one of these.
  - Call a doctor or get emergency help right away if you:
    - Feel sleepy and uncoordinated
    - Have blurred vision
    - Have slurred speech
    - Cannot think well or clearly
    - Have slowed reflexes and breathing
  - Do not inject (“shoot-up”) or snort buprenorphine and naloxone sublingual tablets.
    - Injecting buprenorphine and naloxone sublingual tablets may cause life-threatening infections and other serious health problems.
    - Crushing and/or dissolving buprenorphine and naloxone sublingual tablets and then injecting it (“shooting up”) could cause serious precipitated withdrawal (sudden, serious, withdrawal symptoms such as pain, cramps, vomiting and diarrhea) in people who are physically dependent on other opioids.

Snorting buprenorphine and naloxone sublingual tablets could cause precipitated withdrawal. In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with buprenorphine and naloxone sublingual tablets.

What are buprenorphine and naloxone sublingual tablets?

- Buprenorphine and naloxone sublingual tablets are a prescription medicine used to treat adults who are addicted to (dependent on) opioid drugs (either prescription or illegal) as part of a complete treatment program that also includes counseling and behavioral therapy.

Buprenorphine and naloxone sublingual tablets are a controlled substance (CIII) because they contains buprenorphine, which can be a target for people who abuse prescription medicines or street drugs. Keep your buprenorphine and naloxone sublingual tablets in a safe place to protect them from theft. Never give your buprenorphine and naloxone sublingual tablets to anyone else; they can cause death or harm them. Selling or giving away this medicine is against the law.

- It is not known if buprenorphine and naloxone sublingual tablets are safe or effective in children.

Who should not take buprenorphine and naloxone sublingual tablets?
Do not take buprenorphine and naloxone sublingual tablets if you are allergic to buprenorphine or naloxone.

What should I tell my doctor before taking buprenorphine and naloxone sublingual tablets?
Buprenorphine and naloxone sublingual tablets may not be right for you. Before taking buprenorphine and naloxone sublingual tablets, tell your doctor if you:

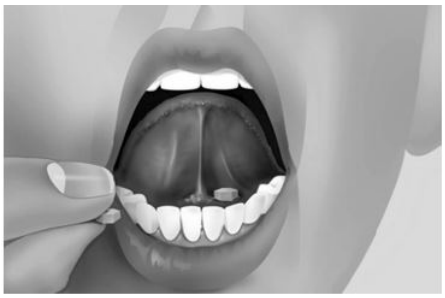
- Have liver or kidney problems
- Have trouble breathing or lung problems
- Have an enlarged prostate gland (men)
- Have a head injury or brain problem
- Have problems urinating
- Have a curve in your spine that affects your breathing
- Have gallbladder problems
- Have adrenal gland problems
- Have Addison's disease
- Have low thyroid (hypothyroidism)
- Have a history of alcoholism
- Have mental problems such as hallucinations (seeing or hearing things that are not there)
- Have any other medical condition
- Are pregnant or plan to become pregnant. If you take buprenorphine and naloxone sublingual tablets while pregnant, your baby may have signs of opioid withdrawal at birth. Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. Talk to your doctor if you are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. Buprenorphine and naloxone can pass into your milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take buprenorphine and naloxone sublingual tablets. Monitor your baby for increased sleepiness and breathing problems.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Buprenorphine and naloxone sublingual tablets may affect the way other medicines work and other medicines may affect how buprenorphine and naloxone sublingual tablets works. Some medicines may cause serious or life-threatening medical problems when taken with buprenorphine and naloxone sublingual tablets. Sometimes the doses of certain medicines and buprenorphine and naloxone sublingual tablets may need to be changed if used together. Do not take any medicine while using buprenorphine and naloxone sublingual tablets until you have talked with your doctor. Your doctor will tell you if it is safe to take other medicines while you are taking buprenorphine and naloxone sublingual tablets.
Be especially careful about taking other medicines that may make you sleepy, such as muscle relaxants, pain medicines, tranquilizers, antidepressant medicines, sleeping pills, anxiety medicines or antihistamines.
Know the medicines you take. Keep a list of them to show your doctor or pharmacist each time you get a new medicine.

How should I take buprenorphine and naloxone sublingual tablets?

- Always take buprenorphine and naloxone sublingual tablets exactly as your doctor tells you. Your doctor may change your dose after seeing how it affects you. Do not change your dose unless your doctor tells you to change it.
- Do not take buprenorphine and naloxone sublingual tablets more often than prescribed by your doctor.
- If you are prescribed a dose of 2 or more buprenorphine and naloxone sublingual tablets at the same time:
  - Ask your doctor for instructions on the right way to take buprenorphine and naloxone sublingual tablets
  - Follow the same instructions every time you take a dose of buprenorphine and naloxone sublingual tablets

Put the tablets under your tongue. Let them dissolve completely



- While buprenorphine and naloxone sublingual tablets are dissolving, do not chew or swallow the tablets because the medicine will not work as well. Talking while the tablets are dissolving can affect how well the medicine in buprenorphine and naloxone sublingual tablets are absorbed. If you miss a dose of buprenorphine and naloxone sublingual tablets, 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 buprenorphine and naloxone sublingual tablets 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 buprenorphine and naloxone sublingual tablets the right way. If you take too much buprenorphine and naloxone sublingual tablets or overdose, call Poison Control or get emergency medical help right away.

What should I avoid while taking buprenorphine and naloxone sublingual tablets?

- Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medication affects you. Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative drugs when you take buprenorphine and naloxone sublingual tablets.
- You should not drink alcohol while using buprenorphine and naloxone sublingual tablets, as this can lead to loss of consciousness or even death.

What are the possible side effects of buprenorphine and naloxone sublingual tablets?
Buprenorphine and naloxone sublingual tablets can cause serious side effects including:

- **See "What is the most important information I should know about buprenorphine and naloxone sublingual tablets?"**
- **Respiratory problems.** You have a higher risk of death and coma if you take **buprenorphine and naloxone sublingual tablets** with other medicines, such as benzodiazepines.
- **Sleepiness, dizziness**, and problems with coordination
- **Dependency or abuse**
- **Liver problems.** Call your doctor right away if you notice any of these signs of liver problems:
- Your skin or the white part of your eyes turning yellow (jaundice), urine turning dark, stools turning light in color, you have less of an appetite, or you have stomach (abdominal) pain or nausea. Your doctor should do tests before you start taking and while you take buprenorphine and naloxone sublingual tablets.
- **Allergic reaction.** You may have a rash, hives, swelling of the face, wheezing, or a loss of blood pressure and consciousness. Call a doctor or get emergency help right away.
- **Opioid withdrawal.** This can include: shaking, sweating more than normal, feeling hot or cold more than normal, runny nose, watery eyes, goose bumps, diarrhea, vomiting and muscle aches. Tell your doctor if you develop any of these symptoms.
- **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.

Common side effects of buprenorphine and naloxone sublingual tablets include:

- Nausea
- Vomiting
- Drug withdrawal syndrome
- Headache
- Sweating
- Numb mouth
- Constipation
- Swollen and/or painful tongue
- The inside of your mouth is more red than normal
- Intoxication (feeling lightheaded or drunk)
- Disturbance in attention
- Irregular heart beat (palpitations)
- Decrease in sleep (insomnia)
- Blurred vision
- Back pain
- Fainting
- Dizziness
- Sleepiness

Tell your doctor about any side effect that bothers you or that does not go away.
These are not all the possible side effects of buprenorphine and naloxone sublingual tablets. For more information, ask your doctor or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store buprenorphine and naloxone sublingual tablets?

- Store buprenorphine and naloxone sublingual tablets at room temperature between 68°F to 77°F (2°C to 25°C).
- **Keep buprenorphine and naloxone sublingual tablets in a safe place, out of the sight and reach of children.**

How should I dispose of unused buprenorphine and naloxone sublingual tablets?

- Dispose of unused buprenorphine and naloxone sublingual tablets as soon as you no longer need them.
- Dispose of expired, unwanted or unused buprenorphine and naloxone sublingual tablets 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 need help with disposal of buprenorphine and naloxone sublingual tablets, call 1-888-212-6921.

General information about the safe and effective use of buprenorphine and naloxone sublingual tablets. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take buprenorphine and naloxone sublingual tablets for a condition for which they were not prescribed. Do not give buprenorphine and naloxone sublingual tablets to other people, even if they have the same symptoms you have. It may harm them and it is against the law.
This Medication Guide summarizes the most important information about buprenorphine and naloxone sublingual tablets. If you would like more information, talk to your doctor or pharmacist. You can ask your doctor or pharmacist for information that is written for health professionals. For more information, call 1-888-212-6921.

What are the ingredients in buprenorphine and naloxone sublingual tablets?
Active Ingredients: buprenorphine and naloxone.
Inactive Ingredients: citric acid anhydrous, crospovidone, lactose monohydrate, magnesium stearate, mannitol, corn syrup solids, modified food starch, natural lemon flavor, pregelatinized starch (maize), povidone, sodium citrate dihydrate, and sucralose.
Manufactured by: WES Pharma Inc Westminster, MD 21157
Distributed by: Accord Healthcare, Inc., Durham, NC 27703

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 10/2020

Principal Display Panel

Buprenorphine and Naloxone sublingual tablets, USP

2 mg/0.5 mg

NDC 16729-**549**-10

Buprenorphine and Naloxone sublingual tablets, USP

8 mg/2 mg

NDC 16729-**550**-10

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE DIHYDRATE

buprenorphine hydrochloride and naloxone hydrochloride dihydrate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16729-549
Route of Administration	SUBLINGUAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUPRENORPHINE HYDROCHLORIDE (UNII: 56W8MW3EN1) (BUPRENORPHINE - UNII:40D3SCR4GZ)	BUPRENORPHINE	2 mg
NALOXONE HYDROCHLORIDE DIHYDRATE (UNII: 5Q187997EE) (NALOXONE - UNII:36B82AMQ7N)	NALOXONE	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	white (white to off-white)	**Score**	no score
Shape	ROUND (round biconvex)	**Size**	10mm
Flavor	LEMON	**Imprint Code**	W;21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16729-549-10	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209069	09/01/2020	

BUPRENORPHINE HYDROCHLORIDE AND NALOXONE HYDROCHLORIDE DIHYDRATE

buprenorphine hydrochloride and naloxone hydrochloride dihydrate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16729-550
Route of Administration	SUBLINGUAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BUPRENORPHINE HYDROCHLORIDE (UNII: 56W8MW3EN1) (BUPRENORPHINE - UNII:40D3SCR4GZ)	BUPRENORPHINE	8 mg
NALOXONE HYDROCHLORIDE DIHYDRATE (UNII: 5Q187997EE) (NALOXONE - UNII:36B82AMQ7N)	NALOXONE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	white (white to off-white)	**Score**	no score
Shape	ROUND (round biconvex)	**Size**	12mm
Flavor	LEMON	**Imprint Code**	W;22
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16729-550-10	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209069	09/01/2020	

Labeler - Accord Healthcare, Inc (604222237)

Registrant - WES PHARMA INC (078706898)

Establishment

Name	Address	ID/FEI	Business Operations
WES PHARMA INC		078706898	manufacture(16729-549, 16729-550)

Revised: 1/2021 Accord Healthcare, Inc