

MEDICATION GUIDE

BUNAVAIL™ (bue-nah-vale)
(buprenorphine and naloxone)
Buccal Film (CIII)

IMPORTANT:

Keep BUNAVAIL 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 BUNAVAIL, get emergency help right away.

Read this Medication Guide before you start taking BUNAVAIL 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 BUNAVAIL.

Share the important information in this Medication Guide with members of your household.

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

- BUNAVAIL can cause serious and life-threatening breathing problems. Call your doctor right away or get emergency help if:
 - o You feel faint, dizzy or confused
 - o Your breathing gets much slower than is normal for youThese can be signs of an overdose or other serious problems.
- Do not switch from BUNAVAIL to other medicines that contain buprenorphine without talking with your doctor. The amount of buprenorphine in a dose of BUNAVAIL is not the same as the amount of buprenorphine in other medicines that contain buprenorphine. Your doctor will prescribe a starting dose of buprenorphine that may be different than other buprenorphine containing medicines you may have been taking.
- BUNAVAIL contains an opioid that can cause physical dependence.
 - o Do not stop taking BUNAVAIL without talking to your doctor. You could become sick with uncomfortable withdrawal signs and symptoms because your body has become used to this medicine.
 - o Physical dependence is not the same as drug addiction.
 - o BUNAVAIL is not for occasional or “as needed” use.
- An overdose, and even death, can happen if you take benzodiazepines, sedatives, tranquilizers, or alcohol while using BUNAVAIL. 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:
 - o Feel sleepy and uncoordinated
 - o Have blurred vision
 - o Have slurred speech
 - o Cannot think well or clearly
 - o Have slowed reflexes and breathing

- Do not inject (“shoot-up”) BUNAVAIL.
 - o Injecting BUNAVAIL may cause life-threatening infections and other serious health problems.
 - o Injecting BUNAVAIL may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.
- In an emergency, have family members tell the emergency department staff that you are physically dependent on an opioid and are being treated with BUNAVAIL.

What is BUNAVAIL?

- BUNAVAIL is 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.

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

- It is not known if BUNAVAIL is safe or effective in children.

Who should not take BUNAVAIL?

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

What should I tell my doctor before taking BUNAVAIL?

BUNAVAIL may not be right for you. Before taking BUNAVAIL, tell your doctor if you:

- 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 liver or kidney problems
- 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. It is not known if BUNAVAIL will harm your unborn baby. If you take BUNAVAIL while pregnant, your baby may have symptoms of

withdrawal at birth. Talk to your doctor if you are pregnant or plan to become pregnant.

- Are breastfeeding or plan to breastfeed. BUNAVAIL can pass into your breast milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take BUNAVAIL. Monitor your baby for increased drowsiness and breathing problems.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BUNAVAIL may affect the way other medicines work and other medicines may affect how BUNAVAIL works. Some medicines may cause serious or life-threatening medical problems when taken with BUNAVAIL.

Sometimes the doses of certain medicines and BUNAVAIL may need to be changed if used together. Do not take any medicine while using BUNAVAIL until you have talked with your doctor. Your doctor will tell you if it is safe to take other medicines while you are taking BUNAVAIL.

Be especially careful about taking other medicines that may make you sleepy, such as 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 BUNAVAIL?

- Always take BUNAVAIL 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 BUNAVAIL more often than prescribed by your doctor.
- Take BUNAVAIL 1 time a day.
- You may be prescribed a dose of 2 or more BUNAVAIL buccal films to be taken at the same time.
- Use the entire BUNAVAIL buccal film. Do not cut, tear, chew, or swallow the buccal film. Your doctor should show you how to use BUNAVAIL the right way.
- Follow the same instructions every time you take a dose of BUNAVAIL buccal film.
- BUNAVAIL comes in a child-resistant foil package. Do not open the foil package until you are ready to use the BUNAVAIL buccal film. **After opening the foil package, use BUNAVAIL buccal film right away.**

Take the dose prescribed by your doctor as follows:

- o To open the BUNAVAIL buccal film foil package, fold along the dotted lines and tear down at slits or cut with scissors in the direction of the arrows (See **Figure A**).

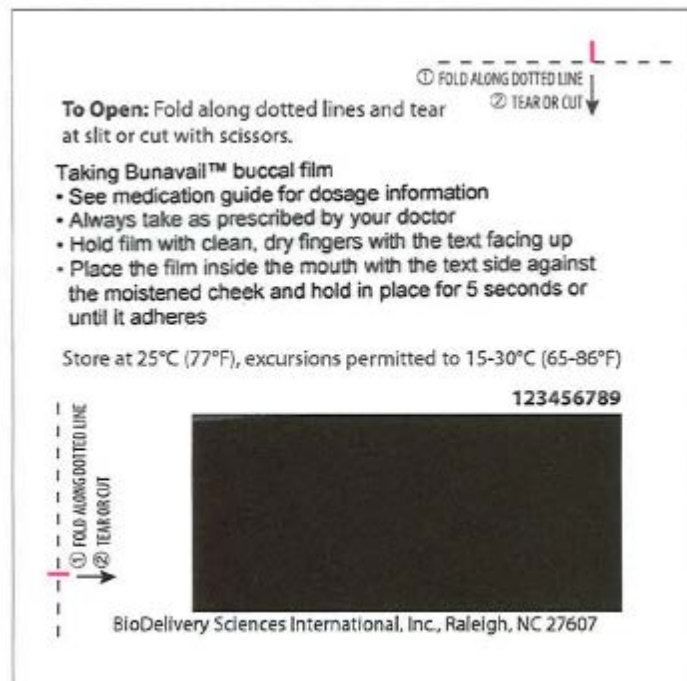


Figure A

- o Use your tongue to wet the inside of your cheek or rinse your mouth with water to moisten the area in your mouth before you place BUNAVAIL.
- o Hold the BUNAVAIL buccal film with clean, dry fingers with the text (BN2, BN4, or BN6) facing up (See **Figure B**).
- o Place the BUNAVAIL buccal film inside your mouth with the text (BN2, BN4, or BN6) against the inside of your moistened cheek (See **Figure C**).
- o With your finger, press the BUNAVAIL buccal film against your cheek. Hold it there for 5 seconds.
- o Take your finger away from the BUNAVAIL buccal film. It will stick to the inside of your cheek (See **Figure D**).
- o Leave the film in place until it dissolves.
- o If your doctor tells you to use more than one BUNAVAIL buccal film at the same time, place the next film on the inside of your other cheek following the instructions above. Do not place more than two buccal films to the inside of one cheek at a time.

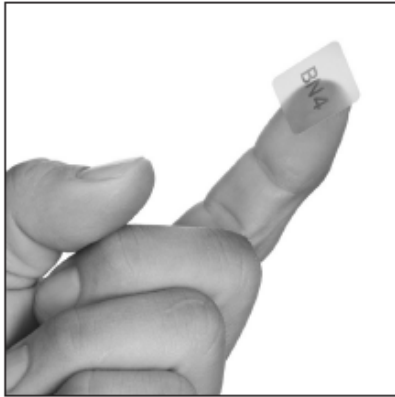


Figure B



Figure C

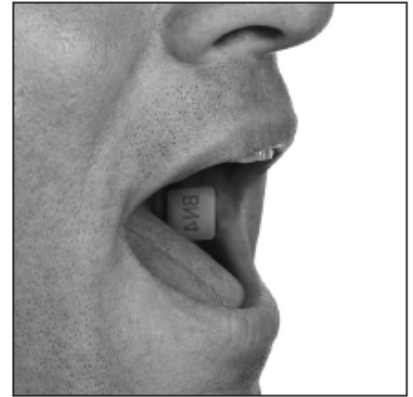


Figure D

- Avoid touching or moving the buccal film with your tongue or fingers.
- Avoid drinking or eating food until after the buccal film has dissolved.
- If you miss a dose of BUNAVAIL, 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 BUNAVAIL 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 BUNAVAIL the right way.
- **If you take too much BUNAVAIL or overdose, call Poison Control or get emergency medical help right away.**

What should I avoid while taking BUNAVAIL?

- **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 BUNAVAIL.
- **You should not drink alcohol** while using BUNAVAIL, as this can lead to loss of consciousness or even death.

What are possible side effects of BUNAVAIL?

BUNAVAIL can cause serious side effects including:

- **See “What is the most important information I should know about BUNAVAIL?”**
- **Respiratory problems.** You have a higher risk of death and coma if you take BUNAVAIL 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 BUNAVAIL.
- **Allergic Reaction.** You may have a rash, hives, swelling of your face, wheezing, or 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 BUNAVAIL include:

- Headache
- Drug withdrawal syndrome
- Nausea
- Decrease in sleep (insomnia)
- Vomiting
- Pain
- Increased sweating
- Constipation

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 BUNAVAIL. 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 BUNAVAIL?

- Store BUNAVAIL at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep BUNAVAIL dry.
- Do not freeze BUNAVAIL.
- Do not use BUNAVAIL buccal film if the foil package has been damaged.
- **Keep BUNAVAIL in a safe place, out of sight and reach of children.**

How should I dispose of unused BUNAVAIL?

- Dispose of unused BUNAVAIL buccal film as soon as you no longer need them.
- Remove the unused BUNAVAIL buccal film from the foil packages.
- Drop the BUNAVAIL buccal films into the toilet and flush.

- Do not flush the BUNAVAIL foil packages or cartons down the toilet.

If you need help with disposal of BUNAVAIL, call 1-800-469-0261.

General information about the safe and effective use of BUNAVAIL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BUNAVAIL for a condition for which it was not prescribed. Do not give BUNAVAIL 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 BUNAVAIL. 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 1-800-469-0261.

What are the ingredients in BUNAVAIL?

Active ingredients: buprenorphine hydrochloride, naloxone hydrochloride dihydrate

Inactive ingredients: carboxymethylcellulose sodium, citric acid, citrus blend flavor, dibasic sodium phosphate, blue ink, hydroxyethyl cellulose, hydroxypropyl cellulose, methylparaben, monobasic sodium phosphate, polycarbophil, propylene glycol, propylparaben, yellow iron oxide, sodium benzoate, sodium hydroxide, sodium saccharin, vitamin E acetate, and purified water. The blue ink contains FD&C blue #1, ethanol, purified shellac, acetone, ammonium hydroxide and water.

Manufactured for:

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