Here’s how to take BUNAVAIL®
(buprenorphine and naloxone buccal film), CIII

Once you apply the practice films to the inside of your cheek a few times, it will become second nature. Take BUNAVAIL once a day, always exactly the way your doctor tells you. Do not take it more or less often than prescribed by your doctor. The dose of BUNAVAIL varies from one person to another and may change over time.

1. 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.

2. Hold the BUNAVAIL buccal film with clean, dry fingers with the text (BN2, BN4, or BN6) facing up.

3. Place the BUNAVAIL buccal film inside your mouth with the text (BN2, BN4, or BN6) against the inside of your moistened cheek.

4. With your finger, press the BUNAVAIL buccal film against your cheek. Hold it there for 5 seconds as it adheres.

5. Take your finger away from the BUNAVAIL buccal film. It will stick to the inside of your cheek.

6. Leave the film in place until it completely dissolves.

7. 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.

For more information, please see full Prescribing Information and Medication Guide at BUNAVAIL.com.
INDICATION

BUNAVAIL® (buprenorphine and naloxone buccal film), CIII, is indicated for the treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

IMPORTANT SAFETY INFORMATION

Keep BUNAVAIL (buprenorphine and naloxone buccal film), CIII, out of the sight and reach of children. Ingestion of BUNAVAIL by a child may cause severe breathing problems and death. If a child takes BUNAVAIL, get emergency help right away.

Do not take BUNAVAIL if you are allergic to buprenorphine or naloxone, as serious negative effects including anaphylactic shock, have been reported.

Do not take BUNAVAIL before the effects of other opioids (e.g., heroin, methadone, oxycodone, morphine) have lessened as you may experience withdrawal symptoms.

BUNAVAIL is not appropriate as an analgesic. There have been reported deaths of opioid naïve individuals who received a buprenorphine dose smaller than the lowest available BUNAVAIL strength.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how BUNAVAIL affects you.

BUNAVAIL contains buprenorphine, an opioid that can cause physical dependence. Your doctor can tell you more about the difference between physical dependence and drug addiction. Do not stop taking BUNAVAIL without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to this medicine.

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. Your doctor will prescribe a dose of BUNAVAIL that may be different than other buprenorphine-containing medicines you may have been taking.

BUNAVAIL can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines, sedatives, tranquilizers or alcohol. You should not drink alcohol while taking BUNAVAIL, as this can lead to loss of consciousness or even death.

If BUNAVAIL is used with benzodiazepines or other CNS depressants, including alcohol, potentially fatal additive effects may occur. You should not take these medications together unless supervised by a healthcare provider.

Like other opioids (e.g., heroin, methadone, oxycodone, morphine), BUNAVAIL may produce orthostatic hypotension (‘dizzy spells’) in ambulatory individuals.

Common side effects of BUNAVAIL include headache, drug withdrawal syndrome, lethargy (lack of energy), sweating, constipation, decrease in sleep (insomnia), fatigue and sleepiness.

Cases of adrenal insufficiency, a potentially-life threatening condition, have been reported with opioid use, more often following greater than one month of treatment.

Your doctor may monitor your liver function tests prior to and during your treatment with BUNAVAIL.

Because BUNAVAIL contains naloxone, injecting BUNAVAIL may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

BUNAVAIL can be abused in a manner similar to other opioids, legal or illicit. Keep BUNAVAIL in a safe place. Do not give your BUNAVAIL to other people, it can cause them harm or even death. Selling or giving away this medicine is against the law.

BUNAVAIL is not recommended in patients with severe hepatic impairment. BUNAVAIL may be used with caution for maintenance treatment in patients with moderate hepatic impairment.

Before taking BUNAVAIL, tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking BUNAVAIL, tell your doctor immediately as there may be significant risks to you and your baby; your baby may have symptoms of withdrawal at birth.

Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy, whether that use is medically-authorized or illicit.

Before taking BUNAVAIL, talk to your doctor if you are breastfeeding or plan to breastfeed your baby. BUNAVAIL can pass into your breast milk and may harm your baby. Monitor your baby for increased sleepiness and breathing problems. Your doctor should tell you about the best way to feed your baby if you are taking BUNAVAIL.

This is not a complete list of potential adverse events associated with BUNAVAIL. Please see full Prescribing Information for a complete list.

Call your doctor for medical advice about side effects. You may also report side effects by calling 1 800-469-0261 or to FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

For more information, please see full Prescribing Information and Medication Guide at BUNAVAIL.com.