**MEDIATION GUIDE**

**Buprenorphine and Naloxone**

(“sublingual tablet” or “nasal spray”)

**Sublingual Film for sublingual or buccal administration**

**IMPORTANT:**

Do not use buprenorphine and naloxone sublingual film if you are pregnant or breastfeeding. See Boxed Warning.

**How should you take buprenorphine and naloxone sublingual film?**

- **Do not split** buprenorphine and naloxone sublingual film into 2 or more parts. Each film contains buprenorphine and naloxone.
- **Do not take** buprenorphine and naloxone sublingual film more than prescribed by your doctor.
- **Do not take** buprenorphine and naloxone sublingual film for more than one patient.
- **Do not take** buprenorphine and naloxone sublingual film if you are allergic to any of the ingredients in the film.
- **Do not take** buprenorphine and naloxone sublingual film if you have had an allergic reaction to buprenorphine or naloxone.
- **Do not take** buprenorphine and naloxone sublingual film if you are pregnant or breastfeeding.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any other medications in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for psychiatric disorders in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for mood disorders in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for sexual disorders in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for substance use disorders in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for weight loss in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for chronic pain in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for hypertension in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for angina in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for diabetes in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for hyperlipidemia in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for tuberculosis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for HIV/AIDS in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for-resistant to treatment in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for immunosuppression in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for anti-tuberculosis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for anti-HIV/AIDS in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for cancer in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for hepatitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for autoimmune diseases in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for sarcoidosis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for myasthenia gravis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for encephalitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for myasthenia gravis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for encephalitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for myasthenia gravis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for encephalitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for myasthenia gravis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for encephalitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for myasthenia gravis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for encephalitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for myasthenia gravis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
- **Do not take** buprenorphine and naloxone sublingual film if you have taken any medications for encephalitis in the past 2 weeks that may cause serious withdrawal symptoms such as anxiety, tremors, hallucinations, and seizures.
General information about the safe and effective use of buprenorphine and naloxone sublingual film. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take buprenorphine and naloxone sublingual film for a condition for which it was not prescribed. Do not give buprenorphine and naloxone sublingual film 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 film. 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 1-888-345-7747.

What are the ingredients in buprenorphine and naloxone sublingual film?
Active ingredient: Buprenorphine hydrochloride and naloxone hydrochloride.

The inactive ingredients in buprenorphine and naloxone sublingual film include: sodium chloride, lactose monohydrate, cellulose, glycerin, and purified water.

What should I tell my doctor before taking buprenorphine and naloxone sublingual film?

Tell your doctor about all the medicines you take. This includes prescription and non-prescription medicines, vitamins, and herbal products. Tell your doctor about all your medical and drug allergies. Some medicines may interact with buprenorphine and naloxone sublingual film. 

What are the possible side effects of buprenorphine and naloxone sublingual film?

Buprenorphine and naloxone sublingual film can cause serious side effects, including:

- Respiratory problems. You have a higher risk of death and coma if you take buprenorphine and naloxone sublingual film with other medicines, such as benzodiazepines.
- Sleepiness, dizziness, and problems with coordination.
- Dependence or abuse. If you take buprenorphine and naloxone sublingual film for a long time, you may develop physical dependence. Physical dependence means that you need to take this medicine constantly to avoid withdrawal symptoms. If you stop taking this medicine suddenly or take too small a dose, you may experience withdrawal symptoms such as irritability, sweating, yawning, and vomiting.

Common side effects of buprenorphine and naloxone sublingual film include:

- Nausea
- Vomiting
- Drug withdrawal syndrome
- Headache
- Sweating
- Nausea
- Constipation
- Urine changes and/or painful urination
- The inside of your mouth may be more red than normal
- Incontinence (urinating when you are not expecting)
- Chills and fever
- Impaired heart beat (palpitations)
- Decrease in sleep (somnolence)
- Blurred vision
- Rash
- Fainting
- Clammy skin

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 film. For more information, ask your doctor or pharmacist.

How should I store buprenorphine and naloxone sublingual film?

Store at room temperature between 59°F and 86°F (15°C and 30°C).

Keep buprenorphine and naloxone sublingual film in a safe place, out of the sight and reach of children.

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

Do not flush the buprenorphine and naloxone sublingual film down the toilet. Follow any guidelines your pharmacist may have given you for disposal of unused medicine.