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Suboxone Film, Medicated

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Description

Side Effects Nausea, vomiting, drowsiness, dizziness, constipation, or headache may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To prevent constipation, eat dietary fiber, drink enough water, and exercise. You may also need to take a laxative. Ask your pharmacist which type of laxative is right for you. To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Although this medication is used to prevent withdrawal reactions, it may rarely cause opioid withdrawal symptoms. This is more likely to happen when you first start treatment or if you have been using long-acting opioids such as methadone. If such symptoms occur, tell your doctor or pharmacist right away. Severe (possibly fatal) breathing problems can occur, especially if this medication is abused, injected, or mixed with other depressants (such as alcohol, benzodiazepines including diazepam, other opioids). Tell your doctor right away if you have any serious side effects, including: interrupted breathing during sleep (sleep apnea), tooth/gum pain, signs of your adrenal glands not working well (such as unusual tiredness, weight loss). Get medical help right away if you have any very serious side effects, including: fainting, fast/irregular heartbeat, severe dizziness, mental/mood changes (such as agitation, confusion, hallucinations), slow/shallow breathing, unusual drowsiness/difficulty waking up. This drug may rarely cause serious (possibly fatal) liver disease. Get medical help right away if you have any symptoms of liver damage, including: nausea/vomiting that doesn't stop, loss of appetite, dark urine, severe stomach/abdominal pain, yellowing eyes/skin. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses This medication contains 2 medicines: buprenorphine and naloxone. It is used to treat opioid use disorder. Buprenorphine belongs to a class of drugs called mixed opioid agonist-antagonists. Buprenorphine helps prevent withdrawal symptoms caused by stopping other opioids. Naloxone is an opioid antagonist that blocks the effect of opioids and can cause severe opioid withdrawal when injected. Withdrawal is less likely when naloxone is taken by

mouth, dissolved under the tongue, or dissolved on the inside of the cheek. It is combined with buprenorphine to prevent abuse and misuse (injection) of this medication. This combination medication is used as part of a complete treatment program for opioid use disorder (such as compliance monitoring, counseling, behavioral contract, lifestyle changes). Ask your doctor or pharmacist if you should have naloxone available to treat opioid overdose. Teach your family or household members about the signs of an opioid overdose and how to treat it. How to use Suboxone sublingual Read the Medication Guide provided by your pharmacist before you start using this medication and each time you get a refill. This medication can either be dissolved under the tongue or dissolved on the inside of the cheek. Follow your doctor's directions. Learn how to correctly use this medication. If you have any questions, ask your doctor or pharmacist. Use this medication as directed by your doctor, usually once daily. Drink some water to moisten your mouth before use. This helps the film dissolve. With dry hands, open the foil packet just before use and place the medication film under your tongue or inside your cheek. Keep the film in place until it completely dissolves. Do not talk, swallow, chew, or move the film after placing it under your tongue or on the inside of your cheek, or it will not work as well. If you are prescribed more than one film each day, place the second film under your tongue on the opposite side of the mouth or on the inside of the other cheek. Try not to have the films touch each other. If your doctor has prescribed a third film, place it under your tongue or on the inside of either cheek after the first 2 films have completely dissolved. After the medication is fully dissolved, take a large sip of water and swish gently around your teeth and gums, and then swallow the water. This will help to prevent problems with your teeth. Do not brush your teeth for at least one hour after using this medication. Buprenorphine alone may be used instead of this medication for the first 2 days after you have stopped all other opioids. It is usually given in your doctor's office. Your doctor will then switch you to this combination buprenorphine/naloxone medication for maintenance treatment. The dosage is based on your medical condition and response to treatment. Your doctor will adjust the dose until there are no symptoms of withdrawal. Do not switch between sublingual tablets and film, because you may need a different dose if you switch. Do not increase your dose or use this drug more often or for longer than prescribed. Properly stop the medication when directed. Use this medication regularly to get the most benefit from it. To help you remember, use it at the same time each day. If you suddenly stop using this medication, you may have withdrawal symptoms (such as restlessness, watering eyes, runny nose, nausea, sweating, muscle aches). To help prevent withdrawal, your doctor may lower your dose slowly. Withdrawal is more likely if you have used this medication for a long time or in high doses. Tell your doctor or pharmacist right away if you have withdrawal. Do not inject ("shoot up") buprenorphine/naloxone. Injecting it is dangerous, and will likely cause severe withdrawal symptoms due to the naloxone in this medication, especially if you have been using opioids such as heroin, morphine or methadone. Keep this medicine in a safe place to prevent theft, misuse, or abuse. If a child accidentally swallows this drug, get medical help right away. Precautions Before taking this medication, tell your doctor or pharmacist if you are allergic to buprenorphine or naloxone; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain disorders (such as head injury, tumor, seizures), breathing problems (such as asthma, sleep apnea, chronic obstructive pulmonary disease-COPD), liver disease, mental/mood disorders (such as confusion, depression, thoughts of suicide), stomach/intestinal problems (such as blockage, constipation, diarrhea due to infection, paralytic ileus), difficulty urinating (such as due to enlarged prostate). This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Alcohol increases your risk for serious, possibly fatal, breathing problems. Buprenorphine may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can rarely cause serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that need medical attention right away. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may cause QT prolongation. Before using buprenorphine, tell your doctor or pharmacist of all the drugs you take and if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as

diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using buprenorphine safely. Some people using this medication may have dental problems (such as tooth decay/loss, cavities, infection). Schedule a visit to the dentist soon after starting this medication and tell your dentist that you are using this medication. To help prevent dental problems, have regular dental exams and learn how to keep your teeth and gums healthy. If you have tooth or gum pain, tell your doctor and dentist right away. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Older adults may be more sensitive to the side effects of this drug, especially drowsiness, slow/shallow breathing, and QT prolongation (see above). Before using this medication, women of childbearing age should talk with their doctor(s) about the risks and benefits. Tell your doctor if you are pregnant or if you plan to become pregnant. During pregnancy, this medication should be used only when clearly needed. It may slightly increase the risk of birth defects if used during the first two months of pregnancy. Also, using it for a long time or in high doses near the expected delivery date may harm the unborn baby. To lessen the risk, use the smallest effective dose for the shortest possible time. Tell the doctor right away if you notice any symptoms in your newborn baby such as abnormal/nonstop crying, slow/shallow breathing, irritability, vomiting, or diarrhea. Buprenorphine passes into breast milk. It is unknown if naloxone passes into breast milk. This product may rarely have undesirable effects on a nursing infant. Tell the doctor right away if your baby develops unusual sleepiness, difficulty feeding, or trouble breathing. Consult your doctor before breast-feeding.

Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, give them naloxone if available, then call 911. If the person is awake and has no symptoms, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: slow/shallow breathing, slow heartbeat, coma. Do not share this medication with others. Sharing it is against the law. Tell all of your doctors that you use this medication and have regularly used opioids, especially in cases of emergency treatment. Lab and/or medical tests (such as liver function, urine drug screening) should be done while you are using this medication. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store in a secure place at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. For more details, read the Medication Guide, or consult your pharmacist or local waste disposal company.

Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this medication include: certain pain medications (mixed opioid agonist-antagonists such as butorphanol, nalbuphine, pentazocine), naltrexone, samidorphan. The risk of serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is used with other products that may also affect breathing or cause drowsiness. Tell your doctor or pharmacist if you are taking other products such as alcohol, marijuana (cannabis), antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), and other opioid pain relievers (such as codeine, hydrocodone). Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely. Deaths have occurred when this medication has been misused by injecting it ("shooting up"), especially when used in combination with benzodiazepines (such as diazepam) or other depressants such as alcohol or additional opioids.

Side Effects

Uses

Interactions

Other Details
