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SUBOXONE - INITIAL INFORMATION

There is a new medication out called Suboxone, which is what we call a partial opiate agonist. Now it is an opiate, just like morphine etc., but it is very different. As a partial agonist, there are two things you do not get with Suboxone that you get with other opiates. The first is that you do not get an addiction and the second is that you do not get a tolerance.

The addiction means there is no way to over-use the Suboxone. The over-use of medications can come through tolerance. Tolerance occurs when it takes an ever-increasing amount of a pain medication to achieve the last effect. The problem with tolerance is that there will come a time when you need to take more medication to ward off the withdrawal effects, although you are not really receiving relief from pain.

What happens with Suboxone is that as a partial agonist it binds completely to all the new receptors in the brain, so you get complete coverage. As a partial agonist, you will not get the full intensity but all the receptor sites are bound. Once they are bound there is no withdrawal. So, taking the medications once a day, with a maximum of twice a day when I am treating pain, there is no withdrawal or discomfort from being on medication. If what Suboxone offers in pain relief is sufficient to block the pain, there is no tolerance. It does not require an ever-increasing amount to get the same effect. That is probably due to the fact it is a partial agonist, but they don't know for certain.

What Suboxone has the potential of offering is 24 [hour] coverage with no withdrawal and no tolerance, which causes you to take increasing amounts of medication. I have looked at the issue of tolerance in the literature, I have talked to the manufacturers of the medication and I have talked to people who are using it, to see if their experience has been what mine has been. Over the past year I have been using this medication for pain. For the people in which it works, it is an outstanding pain medication. I have a number of young men who are working on the

oil rigs and were injured fairly severely, who have been treated and although they were somewhat improved, they could not get off the Vicodin or other pain medication, who then switched to Suboxone and now come in telling me they have their lives back. They are no longer having a roller-coaster effect during the day, their pain has been covered and, in 1-year, they haven't required additional amounts of Suboxone

I do want to emphasize the fact it is an opiate. At one level you are treating one form of opiate with another. The difference, however, is that there has been no tolerance issues thus far and there is no abuse potential. The reason for this is that once the receptor sites are bound, taking more medication does not help. The receptor sites are blocked and anything above the blocking dose is a waste of medication. When people have taken more, and I have had some patients double the medicine they were on, they receive absolutely no effect. When they reduce it back down to the level they should be taking, there is no withdrawal. Once the sites are bound, they remain bound. The real issue is that once the sites are bound, does a person get the level of pain control that is better than whatever medication they were on before?

Suboxone is also a more powerful binding molecule than most other opiates. It is a very powerful opiate. I describe it like them being a 200-pound guy who knocks a 50-pound guy off the receptor site. Once they bind to the receptor site, if someone were to take another opiate, it doesn't bind and is a waste of money. This is important because the medication is only FDA approved for treating people who have an opiate dependency. It is important to know that an FDA indication only dictates how a drug can be marketed. It says nothing about how a medication can be used. Any medication can be used "off label" as long as there is enough research to support it. For this reason, most doctors are unaware of Suboxone because they don't want to be treating opiate dependency and that is the only way the medication is marketed.

I am giving this information now for you to think about. There is always a risk and going from a patient's current medication to Suboxone may not give as good coverage. In order to make it as comfortable as possible, a patient has to be in mild to moderate withdrawal before taking Suboxone. The reason for that is that if a person really isn't in withdrawal, Suboxone will put them into withdrawal. It will knock the other opiates off the receptor sites and initially, because of the withdrawal factor, there may not be enough Suboxone on board to block the withdrawal. If a person is in withdrawal, Suboxone blocks the withdrawal and provides pain relief.

I am giving you this information to think about, Suboxone is an option, and I am always guided by the great psychiatrist Yogi Berra who said, "Predictions are difficult, particularly when they involve the future." There is no way to know for certain that the medicine will work, but I am presenting this information as it may be something you want to think about and something I would be willing to discuss with you in the future.



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Here's a list of doctors in your area who have experience treating opioid dependence. If you're having trouble finding a doctor or making an appointment, give us a call at 866-973-4373 to see how we can help.

Map	Name	Address	Phone	Distance
	Gregory Baca	1120 Industrial Park Rd Suite 401, Espanola, NM 87532	(505) 795-5217	12.16 miles
	Barbara Troy	El Centro Family Health, 2010 Industrial Park, Espanola, NM 87532	(505) 753-7395	12.16 miles
A	Jodi Casados	Presbyterian/family Practice, 1010 Spruce St., Espanola, NM 87532	(505) 367-0340	13.27 miles
B	Mark Bjorklund	El Centro Family Health, 620 Coronado St., Espanola, NM 87532	(505) 753-7395	13.34 miles
B	Leslie Hayes	620 Coronado St., Espanola, NM 87532	(505) 753-7395	13.34 miles
C	Gregory Baca	464 Central Ave Suite 405, Los Alamos, NM 87544	(505) 747-9696	15.9 miles

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Indication:

SUBOXONE® (buprenorphine and naloxone) Sublingual Film (CIII) is a prescription medicine used for maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and behavioral therapy.

Important Safety Information:

Do not take SUBOXONE® (buprenorphine and naloxone) Sublingual Film if you are allergic to buprenorphine or naloxone as serious negative effects, including anaphylactic shock, have been reported.

SUBOXONE Sublingual Film can be abused in a manner similar to other opioids, legal or illicit.

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

SUBOXONE Sublingual Film can cause serious life-threatening breathing problems, overdose and death, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other medications that act on the nervous system (ie, sedatives, tranquilizers, or alcohol). It is extremely dangerous to take nonprescribed benzodiazepines or other medications that act on the nervous system while taking SUBOXONE Sublingual Film.

You should not drink alcohol while taking SUBOXONE, as this can lead to loss of consciousness or even death.

Death has been reported in those who are not opioid dependent.

Your doctor may monitor liver function before and during treatment.

Keep SUBOXONE Sublingual Film out of the sight and reach of children. Accidental or deliberate ingestion of SUBOXONE Sublingual Film by a child can cause severe breathing problems and death.

Do not take SUBOXONE Sublingual Film before the effects of other opioids (eg, heroin, hydrocodone, methadone, morphine, oxycodone) have subsided as you may experience withdrawal symptoms.

Injecting SUBOXONE may cause serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Before taking SUBOXONE, tell your doctor if you are pregnant or plan to become pregnant. If you become pregnant while taking SUBOXONE, alert your doctor immediately as there may be significant risks to you and your baby; your baby may have symptoms of withdrawal at birth. If you are pregnant or become pregnant while taking SUBOXONE, you should report it using the contact information provided below.*

Before taking SUBOXONE, talk to your doctor if you are breast-feeding or plan to breast-feed. SUBOXONE can pass into your milk and may harm the baby. Talk to your doctor about the best way to feed your baby if you take SUBOXONE. Breast-feeding is not recommended while taking SUBOXONE.

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE affects you. Buprenorphine in SUBOXONE can cause drowsiness and slow reaction times during dose-adjustment periods.

Common side effects of SUBOXONE Sublingual Film include nausea, vomiting, drug withdrawal syndrome, headache, sweating, numb mouth, constipation, painful tongue, redness of the mouth, intoxication (feeling lightheaded or drunk), disturbance in attention, irregular heartbeat, decrease in sleep, blurred vision, back pain, fainting, dizziness, and sleepiness.

This is not a complete list of potential adverse events associated with SUBOXONE Sublingual Film. Please see full Product Information for a complete list.

*To report negative side effects associated with taking SUBOXONE Sublingual Film, please call 1-877-782-6966. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see [full US Product Information](#) and [Medication Guide](#) for SUBOXONE Sublingual Film.

For more information about SUBOXONE® (buprenorphine and naloxone) Sublingual Tablets (CIII), please see [full US Product Information](#) and Medication

Clinical Opiate Withdrawal Scale (COWS)

Flow-sheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name: _____ Date: _____ Buprenorphine induction: Enter scores at time zero, 30m in after first dose, 2 h after first dose, etc. Times: _ _ _ _ _ _ _ _ _ _ _ _				
Resting Pulse Rate: (record beats per minute) Measured after patient is sitting or lying for one minute 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120				
Sweating: over past hour not accounted for by room temperature or patient activity. 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face				
Restlessness Observation during assessment 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds				
Pupil size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible				
Bone or Joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort				
Runny nose or tearing Not accounted for by cold symptoms or allergies 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks				

COWS I Flow-sheet format for measuring symptoms over a period of time during buprenorphine induction

<p>GI Upset: over last hour</p> <p>0 no GI symptoms</p> <p>1 stomach cramps</p> <p>2 nausea or loose stool</p> <p>3 vomiting or diarrhea</p> <p>5 Multiple episodes of diarrhea or vomiting</p>
<p>Tremor observation of outstretched hands</p> <p>0 No tremor</p> <p>1 tremor can be felt, but not observed</p> <p>2 slight tremor observable</p> <p>4 gross tremor or muscle twitching</p>
<p>Yawning Observation during assessment</p> <p>0 no yawning</p> <p>1 yawning once or twice during assessment</p> <p>2 yawning three or more times during assessment</p> <p>4 yawning several times/minute</p>
<p>Anxiety or Irritability</p> <p>0 none</p> <p>1 patient reports increasing irritability or anxiousness</p> <p>2 patient obviously irritable anxious</p> <p>4 patient so irritable or anxious that participation in the assessment is difficult</p>
<p>Gooseflesh skin</p> <p>0 skin is smooth</p> <p>3 piloerection of skin can be felt or hairs standing up on arms</p> <p>5 prominent piloerection</p>
<p style="text-align: right;">Total scores</p> <p style="text-align: center;">with observer's initials</p>

Score:

5-12 =mild;

13-24 =moderate;

25-36 = moderately severe;

more than 36 =severe withdrawal