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PATIENT CONSENT AND RELEASE FORM FOR

BUPRENORPHINE TREATMENT DURING PREGNANCY

I, _____, am currently receiving prenatal care from _____ . Because I am currently prescribed buprenorphine combined with naloxone (Suboxone®) for treatment of my _____ and do not wish to take methadone, my doctor has offered to treat my condition with buprenorphine during my pregnancy. During my pregnancy, I agree to be switched from the combination tablet of buprenorphine with naloxone (Suboxone®) to the non-combination buprenorphine tablet (Subutex®) as recommended by national addiction treatment guidelines. _____ will continue to provide my pre-natal care and Dr Edrich for my opioid dependency condition.

I have met with Dr Edrich he has discussed with me and I understand the risks and benefits of taking buprenorphine and those associated with taking methadone during my pregnancy.

I have been informed that the federal Food and Drug Administration (FDA) has not approved the use of either methadone nor buprenorphine for the treatment of opioid addiction/dependency in pregnant women. The FDA has, in fact, stated that methadone was “preferred” over suboxone. Based on data from the American Academy of Addiciton Medicine (ASAM) either medication can be used and buprenorphine is actually preferred by many addiction specialists. Studies have shown that there is less neonatal abstinence with buprenorphine and of shorter duration. There have been studies of the effects of buprenorphine on laboratory animals. Buprenorphine has caused some bone problems in laboratory animal embryos and fetuses after injections of buprenorphine but not when the same amount of buprenorphine was given by mouth. A possible problem of taking any opioid (heroin, methadone or buprenorphine) during pregnancy is that after birth the child may suffer a withdrawal syndrome called Neonatal Abstinence Syndrome. Babies with Neonatal Abstinence Syndrome may suffer from sleep disturbances, feeding difficulties, tremor, sneezing, irritability, vomiting, weigh loss, and seizures. A large proportion of these children will require hospitalization, often for long periods of time. I understand these risks and benefits and have decided to take buprenorphine (Subutex®) rather than methadone. I understand that medical knowledge on the actual or potential risks of buprenorphine on pregnant women and unborn children is not at all certain. I accept responsibility for this decision. On behalf of myself and my unborn child, I hereby release and agree to hold harmless, the program, the prescribing doctor, and the hospital’s officers, directors, agents and employees from any liability of any kind which may arise in connection with my taking buprenorphine (Subutex®) during the duration of my pregnancy.

Buprenorphine with or without naloxone is an FDA approved medication for treatment of people with heroin or other opioid addiction. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary. There are other treatments for opiate addiction, including methadone, naltrexone, and some treatments without medications that include counseling, groups and meetings. Buprenorphine sometimes used “off label” for pain. If you are dependent on opiates - any opiates - you should be in as much withdrawal as possible when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine can cause severe opiate withdrawal. We recommend that you arrange not to drive after your first dose, because some patients get drowsy until the correct dose is determined for them. Some patients find that it takes several days to get used to the transition from the opiate they had been using to buprenorphine. During that time, any use of other opiates may cause worsened symptoms. Attempts to override the buprenorphine by taking more opiates could result in an opiate overdose. You should not take any other medication without discussing it with the physician first. Combining buprenorphine with alcohol or other sedating medications is dangerous. The combination of buprenorphine with benzodiazepines (such as Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) has resulted in deaths. Although sublingual (under the tongue) buprenorphine is very unlikely to be liver-damaging, your doctor may monitor your liver tests while you are taking buprenorphine. (This is a blood test.) The form of buprenorphine you may be taking could be a combination of buprenorphine with a short-acting opiate blocker (naloxone). It will maintain physical dependence, and if you discontinue it suddenly, you will likely experience withdrawal. If the Suboxone tablet were dissolved and injected by someone taking heroin or another strong opioid, it could cause severe opiate withdrawal. Buprenorphine tablets must be held under the tongue until they dissolve completely. It is important not to talk or swallow until the tablet dissolves. This takes up to ten minutes. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed. If you swallow the tablet, you will not have the important benefits of the medication, and it may not relieve your withdrawal. Most patients end up at a daily dose of 16 mg to 24mg of buprenorphine. (This is roughly equivalent to 60mg of methadone maintenance). Beyond that dose, the effects of buprenorphine plateau, so there may not be any more benefit to increase in dose. It may take several weeks to determine just the right dose for you. The first dose is usually 2mg to 4mg. If you are transferring to buprenorphine from methadone maintenance, your dose should ideally be tapered until you have been below 30mg, preferably for at least a week. There must be at least 24 hours (preferably longer) between the time you take your last methadone dose and the time you are given your first dose of buprenorphine. You should not begin buprenorphine until you are in withdrawal.

Patient Date/Time

MD PRESCRIBER Date/Time

Witness Date/Time