

Informed Consent for a Low Calorie Diet/Appetite Suppressant

We want you to know... The calorie deficit and portion-controlled diets are used with patients who are overweight. These methods of weight reduction have been described and evaluated in many professional medical journals since 1974.

Your role... Your success depends upon your commitment to fulfilling your obligations during treatment. You should be willing to:

- Provide honest and complete answers to questions about your health, weight, eating and lifestyle patterns.
- Devote the time needed to complete and comply with the course of treatment as prescribed.
- Attend your appointments regularly and follow your diet and exercise prescription.
- Allow your health care professional to share information with your personal physician.
- Obtain blood/diagnostic tests which your physician may deem necessary during your treatment.
- Advise the clinic staff of ANY concerns, problems, complaints, symptoms, or questions even if you may think it is not terribly important, so the physician can determine if you should be seen more often. This affords the best chance of intervening before a problem becomes serious.

Risks Associated with Being Overweight... People who are overweight or obese have greater tendencies toward:

- High blood pressure, Diabetes/Metabolic Syndrome, High Cholesterol, Asthma, Esophageal Reflux, Heart Attack, Stroke, Peripheral Vascular Disease, Obstructive Sleep Apnea, Arthritis, and various types of cancer.

These risks/conditions can be reduced or eliminated with weight loss (starting around 10 percent of initial weight).

Medications... If you are taking medications for one or more of these conditions, dosages will be adjusted as your diet progresses.

Unknown Side Effects... The possibility always exists in medicine that the combination of any disease with methods employed for its treatment may lead to previously unobserved or unexpected ill effects, including death. Should one or more of these conditions occur, additional medical or surgical treatment may be necessary.

Common Side Effects... During a low calorie diet, common side effects can be: *a reduced metabolic rate, increased urination, dizziness, sensitivity to cold, a slower heart rate, dry skin, fatigue, diarrhea, constipation, bad breath, dry or brittle hair, hair loss, muscle cramps, or menstrual changes.* These responses are temporary and resolve when calories are increased after the period of weight loss.

Reduced Potassium Levels... It is important to consume all of the food that has been prescribed in your diet. Failure to do so may cause low blood potassium levels or deficiencies in other key nutrients. Low potassium levels can cause serious heart irregularities.

Gallstones... Overweight people develop gallstones at a rate higher than normal weight individuals. It is possible to have gallstones and not know it. As body weight and age increase, so do the chances of developing gallstones. These chances double for women, women using estrogen, and smokers. Losing weight, especially rapidly, may increase the chance of developing stones or sludge and increase the size of existing stones within the gallbladder. Should symptoms develop (commonly fever, nausea and a cramping right upper abdominal pain) or if you know or suspect that you already have gallstones, let your physician know immediately. Gallbladder problems may need medication or surgery to remove the gallbladder, and less commonly, may be associated with more serious complications or even death.

Pancreatitis, or an inflammation/infection of the pancreas, may be associated with the presence of gallstones and the development of sludge or obstruction in the bile ducts. The symptoms of pancreatitis include pain in the left upper abdominal area, nausea, and fever. Pancreatitis may be precipitated by binge-eating or consuming a large meal after a period of dieting. Also associated with pancreatitis are long term abuse of alcohol and the use of certain medications and increased age. Pancreatitis may require surgery and may be associated with more serious complications or even death.

Pregnancy... If you become pregnant, report this to your health care professional and physician immediately. Your calorie restricted diet must be stopped promptly to avoid further weight loss and potential damage to a developing fetus. ***You must take precautions to avoid becoming pregnant during the course of weight loss.***

The risk of weight regain... Obesity is a chronic condition, and the majority of overweight individuals who lose weight have a tendency to regain all or some of it over time. Factors which favor maintaining a reduced body weight include regular exercise, adherence to a diet, and having a coping strategy for weight regain before it occurs. Successful treatment may take months or years.

Sudden Death... Patients with morbid obesity and serious health problems such as severe hypertension, heart disease, or diabetes, have a statistically higher chance of suffering sudden death when compared to normal weight people without these problems. **Rare instances of sudden death have occurred while obese patients were undergoing medically supervised weight reduction, though no cause and effect relationship with the diet has been established.** Other rare risks are primary pulmonary hypertension and valvular heart disease.

Your Rights and Responsibility... You may leave treatment at any time. You have a responsibility to notify the physician that you are discontinuing treatment and to find another physician who is able to assume medical care for you after you leave treatment.

No Guarantees... I understand that much of the success of the program will depend on my efforts and that there are no guarantees that the program will be successful. I also understand that I will have to continue watching my weight all of my life if I am to be successful.

Appetite Suppressants

FDA Labeling...Appetite suppressants, have labeling that suggests using the medications for obese individuals, for short time periods (usually up to 12 weeks), and for dosages indicated in the labeling.

ASBP Guidelines for Anorectic Usage: We adhere to the guidelines for anorectic usage as laid out in the American Society of Bariatric Physicians (ASBP) Overweight and Obesity Evaluation and Management guidelines. Indications for anorectic usage laid out by these guidelines include:

- ☐ BMI > 30 in normal healthy individuals
- ☐ BMI > 27 in individuals with comorbidities (DM, HTN, insulin resistance, vascular disease, hyperlipidemia, asthma, OSA, GERD, cancer, osteoarthritis, gall bladder disease, and other associated conditions)
- ☐ Current weight > 120% of a long standing healthy weight maintained after the age of 18.
- ☐ Body fat >30% in females and >25% in males
- ☐ Waist-hip ratio > 0.8 in women or > 0.95 in men
- ☐ Waist circumference > 35" in women and > 40" in men
- ☐ Any comorbid condition that is aggravated by weight
- ☐ Prevention of weight regain in a person who has previously lost weight
- ☐ Weight loss for occupational needs
- ☐ Prevention of weight gain in a person who has a familial/genetic predisposition

Physician Statement..."I am not required to use the medication as the labeling suggests. This is called off label prescribing and is specifically allowed by the FDA. I have found appetite suppressants helpful for periods exceeding 12 weeks and at doses larger than those suggested in the labeling. The indications for these usages are based on my experience, the experience of my colleagues, and guidelines from the ASBP. Such usage has not been as systematically studied as that suggested in the labeling and it is possible, as with most other medications, that there could be serious side effects. I believe the probability of such side effects is outweighed by the benefit of the appetite suppressant for the given dose and indication. However, you must decide if you are willing to accept the risks of side effects, even if they might be serious, for the possible help the appetite suppressants may give."

Responsibility...I understand it is my responsibility to follow the instructions carefully and to report to the doctor treating me for my weight any significant medical problems that I think may be related to my weight control program as soon as possible.

Purpose...I understand the purpose of this treatment is to assist me in my desire to decrease my body weight and to maintain this weight loss. My continuing to receive appetite suppressants will be dependent on my progress in weight reduction and weight maintenance.

Drug Testing...If you are drug tested as part of your employment or for another purpose, you may register as positive for methamphetamines. If needed, you may be given a doctor's note to state that you are taking a medication to aid in weight loss.

Alternatives...I understand there are other ways that can assist me in my desire to decrease my body weight and to maintain this weight loss. In particular, a balanced calorie counting program or an exchange eating program without the use of appetite suppressants would likely prove successful if followed, even though I would probably be hungrier without the appetite suppressants.

Risks of Proposed Treatment...I understand this authorization is given with the knowledge that the use of the appetite suppressants, especially for more than 12 weeks and at equal or higher doses than the dose indicated in the labeling, involves some risks and hazards. Risks are higher for dosages that exceed the recommended labeling. Common side effects include: **insomnia, palpitations, dry mouth, headaches, psychological problems, medication allergies, and short term high blood pressure, and dependence** (rarely at the recommended dosage). Less common, but more serious, risks are **primary pulmonary hypertension and valvular heart disease**. These side effects were observed rarely with fenfluramine and have a very rare occurrence with other appetite suppressants and have not been found to have a direct association. These and other possible risks could, on rare occasion, be serious or fatal.

Patient's Consent – Low Calorie Diet...I, the undersigned, have reviewed the above information with my health care professional, regarding low calorie diets and understand and agree with the risks and benefits of the proposed therapy. I have had an opportunity to ask questions and have them answered to my satisfaction.

Patient's Consent – Appetite Suppressants...I, the undersigned, have reviewed the above information with my health care professional, regarding the use of appetite suppressants for the purpose of weight loss and understand and agree with the risks and benefits of the proposed therapy. I have had an opportunity to ask questions and have them answered to my satisfaction.

Participant Signature

Date

Participant Signature

Date

I hereby certify that I have explained the nature, purpose, benefits, risks of, and alternatives to, the proposed program and have answered any questions posed by the patient. I believe the patient/relative/guardian fully understands what I have explained and answered.

Physician Signature

Date