

Patient Informed Consent for Weight-Management Medications

I. Procedure & Alternatives

I, _____ authorize Dr. _____ to assist me in my weight-reduction efforts. I understand my treatment may involve, but is not necessarily limited to, the use of weight management medications for more than 12 weeks and when indicated in higher doses than the dosage indicated in the medication's labeling.

I have read and understand my doctor's statements that follow:

"All prescription medication has labeling determined between its manufacturer and the U. S. Food and Drug Administration. This labeling contains among other things suggestions for use. Weight-management medication labeling suggestions are generally based on shorter term studies (up to 12 weeks) using the dosage indicated on the label.

"As an obesity medicine specialist, I have found the weight-management medication helpful for periods much longer than 12 weeks and when indicated at an increased dosages than those suggested on the labeling. As a physician, I am not required to use the medication as the labeling suggests, but I do use the labeling as a source of information along with my own experience, the experience of my colleagues, recent longer-term studies and recommendations of university based investigators. Based on these, I have chosen, when indicated, to use the weight-management medications for longer periods of time and at times and when indicated at increased dosages. 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 (as noted below).

"As an obesity medicine specialist, I believe that the probability of such side effects is outweighed by the benefit of the weight-management medication being used for longer periods of time and when indicated at increased dosages. 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 that the medication used in this manner may give."

I understand it is my responsibility to follow the instructions carefully and to report to the physician treating me for my weight any significant medical problems that I think may be related to my weight-control program, as soon as reasonably possible. Also, I will notify the physician of all medication I am taking, including anti-depressant medications and herbal supplements.

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. I understand that my continuing to receive the weight-management medication will be dependent on my progress in weight reduction and weight maintenance.

I understand there are other programs 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 the weight-management medication likely may prove successful if followed, even though I probably will be hungrier without the use of a weight-management medication.

II. Risks of Proposed Treatment

I understand this authorization is given with the knowledge that the use of the weight-management medication for more than 12 weeks and in higher dosages than those indicated on the label involves some risk and hazard. The more common include: nervousness, sleeplessness, headaches, dry mouth, weakness, tiredness, psychological problems, medication allergies, high blood pressure, rapid heart beat and heart irregularities. Less common but more serious

risks are primary pulmonary hypertension and valvular heart disease. These and other possible risks could on occasion be serious or fatal.

III. Risks Associated with Obesity

I am aware that there are certain risks associated with remaining overweight or obese. Among them are tendencies for high blood pressure; diabetes; heart attack and heart disease; and arthritis of the joints, hips, knees and feet. I understand these risks may be modest, however, these risks can increase significantly the more overweight I am.

IV. No Guarantees

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

V. Consent

I have read and fully understand this consent form and I realize I should not sign this form if all items have not been explained, or any questions have not been answered to my complete satisfaction. I acknowledge that I have been given time to completely read and understand this form, as well as discuss with my physician the risks associated with the proposed treatment and other treatments not involving weight-management medications.

Patient Warning

If you have any questions as to the risks or hazards of the proposed treatment, or any questions concerning the proposed treatment or other possible treatments, please ask your provider now before signing this consent form.

Patient's Name (print)

Signature (or person with authority to consent for patient)

Date

Witness: _____

VI. Physician Declaration:

I have explained the contents of this document to the patient and have answered all the patient's related questions, and, to the best of my knowledge, I feel the patient has been adequately informed concerning the benefits and risks associated with the use of the weight-management medications, the benefits and risks associated with alternative therapies, and the risks of obesity. After being adequately informed, the patient has consented to therapy involving the weight-management medications, if indicated, in the aforementioned manner.

Physician's Signature