

Weight-loss drug: Worth the risks?

She has tried numerous other boxes on this shelf the green tea supplements, the 10-day Hoodia diet. And now it's time for something new.

I'm very interested in this, the 65-year-old said, unhappy that the drug couldn't be purchased until that Friday. You reach a plateau, and then you have to try something else.

As Alli, the first FDA-approved diet drug cleared for over-the-counter sale, arrived recently in drugstores nationwide, doctors and nutritionists have been trying to counter the intense consumer interest and a marketing juggernaut with spin of their own, arguing that the drug's high cost and limited effectiveness may not be worth its notably unpleasant side effects.

Alli (pronounced ally), sold by GlaxoSmithKline, is a half-dose of the prescription drug orlistat. The drug has been marketed in prescription form by Roche Holding AG under the brand name Xenical since 1999, but it was not a blockbuster.

GlaxoSmithKline, however, expects Alli to ultimately rake in at least \$1.5 billion in annual sales, and the company is expected to spend \$150 million on marketing the drug in its first year. Television and magazine ads already are running. E-tailers Amazon.com and Drugstore.com report that the drug, which some customers ordered in advance of availability, already is a top seller even at a cost of \$50 to \$60 for a month's supply.

Alli blocks enzymes that digest fat, preventing the body from absorbing about a quarter of the fat eaten. The undigested fat is then excreted. One study of Alli showed that dieters who took the drug along with diet and exercise over a year lost about 3 pounds more than people who only dieted and exercised.

The company's message is that the pills, typically taken three times a day, are not a magic bullet, and officials urge purchasers to use Alli only along with exercise and a reduced-calorie, low-fat diet.

Because Alli can interfere with vitamin absorption, it can affect how medications act in the body, and users are advised to take a multivitamin supplement. The drug is not recommended for anyone younger than 18, people with kidney disease, patients on blood thinners and certain other medications, and pregnant or breast-feeding women.

Then there are the side effects, which can include oily discharge, diarrhea and uncontrollable bowel movements significant enough for the company to recommend carrying an extra pair of pants until users have accommodated to the drug. The side effects alone can force users to eat less.

The drug's backers say that the embarrassment is exaggerated and that the effects can be managed by a low-fat diet.

Only half of all users had fecal urgency or related effects in clinical trials, and just 5 percent quit for those reasons, said Vidhu Bansal, director of medical affairs for GlaxoSmithKline's consumer health division.

They actually served as a positive feedback tool, she said. It reminded them that they cheated on their diet.

As the American population grows fatter about 65 percent of adults are overweight or obese pharmaceutical companies have tried to create a diet pill that is safe and effective, with minimal success. A previous drug combination popularly known as fen-phen was pulled from the market in 1997 after reports of heart-valve damage.

Earlier this month, an advisory committee to the U.S. Food and Drug Administration recommended against approval of the diet drug Acomplia, which has been approved in Europe but increases the risk of suicidal thoughts.

At a recent Weight Watchers meeting in San Jose, Stephanie Vose, 23, said that she and her friends had tried numerous diet fads over the years, only to experience strange side effects like shaking or bursts of energy.

It's not like it taught you how to eat right, Ms. Vose said. So it all comes right back.

Was Alli worth a try, given its unpleasant side effects? No way, Ms. Vose said. That's disgusting, she said. I would not take that.

Doctors and nutritionists wish more of their patients shared Ms. Vose's attitude and willingness to try dieting the hard way: The Weight Watchers program emphasizes portion control, exercise and slow, long-term weight loss.

Alli is not the solution to the obesity epidemic, said Christopher Gardner, a Stanford University Medical School nutrition researcher.

He painted a glum picture of how a stint with Alli might go:

The dieter starts out taking the drug but doesn't change her diet. Gradually, she begins to lose weight, because her body isn't absorbing all of the fat she eats. Eventually, she achieves her goal and stops taking the drug.

But she's in for a surprise. Since she did not change her diet, her body now will absorb the fat that Alli helped reject, and the weight will return to where it was before.

This trap looks a lot like the ones from previous drugs, which often have worked for a small group of people and failed for everybody else, he said.

If we had a great way for everybody to lose weight, we wouldn't need to have any of these discussions, Dr. Gardner said.

His suggestion? The usual: Just eat less and exercise more.

McClatchy-Tribune Information Services contributed to this report.

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