

SLENTROL® dirlotapide

Oral solution for use in dogs only.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS: SLENTROL (dirlotapide) Oral Solution is indicated for the management of obesity in dogs.

CONTRAINDICATIONS: SLENTROL should not be used in cats. SLENTROL increases the risk of producing hepatic lipidoses during weight loss in obese cats. SLENTROL is not recommended for use in dogs currently receiving long-term corticosteroid therapy. Do not use in dogs with liver disease.

WARNINGS: Not for use in humans. Keep this and all drugs out of reach of children. Adverse reactions associated with humans ingesting dirlotapide include: abdominal distention, abdominal pain, diarrhea, flatulence, headache, increased serum transaminases, nausea, and vomiting.

SLENTROL may cause eye-irritation. If accidental eye exposure occurs, flush the eyes immediately with clean water.

PRECAUTIONS: Safety in breeding, pregnant, or lactating dogs has not been established. Caution should be taken when considering any weight loss program in growing dogs, including treatment with SLENTROL. SLENTROL has not been evaluated in dogs less than 1 year of age.

All dogs should undergo a thorough history and physical examination that includes laboratory tests to screen for underlying conditions. Pre-existing endocrine disease, including hyperadrenocorticism (Cushing's disease), should be managed prior to use of SLENTROL.

SLENTROL may produce a mild to moderate elevation in serum hepatic transaminase activity. If the elevation in alanine aminotransferase (ALT) activity is mild, continue SLENTROL, and monitor as needed. If there is a marked elevation in ALT activity above the normal reference range or there is a simultaneous increase in aspartate aminotransferase (AST), alkaline phosphatase (ALP), γ -glutamyl transferase (GGT), or total bilirubin, discontinue treatment with SLENTROL. Elevations in hepatic transaminase activity usually decrease when SLENTROL is discontinued.

The safety of SLENTROL use in dogs has not been evaluated beyond 1 year.

ADVERSE REACTIONS:

The adverse reactions associated with treatment with SLENTROL include vomiting, loose stools/diarrhea, lethargy, and anorexia. These adverse reactions were mainly observed during the first month of treatment or during the week after a dose increase. Vomiting was usually mild in severity, of short duration, and resolved with continued SLENTROL treatment. The SLENTROL-treated dogs generally had an increased frequency and duration of vomiting and diarrhea compared to the control dogs. The control dogs received corn oil.

Adverse Reactions During Weight Loss:

Treatment	Percentage of Patients with Reported Signs	
	Control n = 88	SLENTROL n = 170
Vomiting	21.6%	24.7%
Diarrhea	6.8%	12.4%
Lethargy	3.4%	9.4%
Anorexia	2.3%	7.6%
Constipation	1.1%	2.4%
Dehydration	0%	1.2%

In addition to the adverse reactions listed above, there were other abnormal findings. Many control and SLENTROL-treated dogs had dental disease, abnormal skin and ear findings, and lameness/arthritis. The incidence of these findings were similar in both control and SLENTROL-treated groups and most dogs had similar lesions noted pre-treatment. Two dogs in the SLENTROL treatment group developed corneal ulcers. One SLENTROL-treated and one control dog developed signs consistent with pancreatitis. One treated dog developed inappropriate urination and defecation and another treated dog developed polyuria and polydipsia.

A 5-year-old Beagle with no medical history of seizures in the SLENTROL treatment group had a seizure on Day 52 of the study. The dog continued to receive SLENTROL until additional seizures occurred 11 and 12 days later. The investigator referred the case to a neurologist and the seizures continued approximately twice weekly. The neurologist found no lesions that support the causality of the seizures.

A 5-year-old Dachshund developed a hepatopathy after 82 days of treatment and was withdrawn from the study for vomiting, increased hepatic enzymes, and anorexia. Vomiting continued for a few days after stopping treatment and the dog was hospitalized due to the anorexia. ALT activity levels continued to rise after all clinical observations resolved.

During weight stabilization, vomiting (16.1%) and lethargy (4.8%) were the most frequent adverse reactions associated with treatment with SLENTROL. Other adverse reactions included diarrhea (1.6%), anorexia (1.6%), and ataxia (1.6%).

In the post-treatment period, a 6-year-old spayed female Chihuahua, was found dead by the owner 7 days after stopping dirlotapide therapy. The cause of death was not conclusive but did not appear to be related to the dirlotapide therapy.

Some dogs treated with SLENTROL displayed a mild to moderate elevation in serum hepatic transaminase activity early in treatment that decreased over time while treatment continued. Hepatic transaminases generally returned to normal when treatment was discontinued (See Precautions for further information).

Serum Chemistry Results:

Serum Analyte	Percentage of Dogs			
	Control n = 88		SLENTROL n = 170	
	Pre ^a	Post ^b	Pre ^d	Post ^e
ALT ^a > 120 IU/L	3.4%	6.0%	4.7%	9.9%
AST ^b > 60 IU/L	0%	4.8%	3.5%	9.2%
ALP ^c > 125 IU/L	11.4%	16.9%	17.6%	9.9%
Cholesterol > 320 mg/dL	14.8%	9.6%	14.7%	4.6%

^a ALT = serum alanine aminotransferase activity.

^b AST = serum aspartate aminotransferase activity.

^c ALP = serum alkaline phosphatase activity. Dogs with ALP activity > 325 IU/L were excluded from the study.

^d Pre = % of dogs with values above the laboratory reference range at pre-treatment.

^e Post = % of dogs with values above the laboratory reference range after 4 months of treatment.

To report a suspected adverse reaction call Pfizer Animal Health at 1-800-366-5288.

For a copy of the Material Safety Data Sheet (MSDS) for SLENTROL oral solution call 1-800-753-5500.

STORAGE INFORMATION:

Store in original container at room temperature 15° to 30° C (59° to 86° F).

HOW SUPPLIED:

SLENTROL is available in 20, 50 and 150 mL bottles containing 5 mg/mL of dirlotapide in solution.

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Humor

REALITY CHECKS

HEAR anything about the economy not doing so well?

Those of you regularly checking Craigslist for deals on mildly expired food products surely have. And so has the government. It turns out Uncle Sam noticed that the economy is so feeble it would have to strain its neck to see above an ant's kneecap, so he's getting out his checkbook. When the going gets tough ... the tough cut rebate checks.

Starting this month, the government hopes to stimulate the economy by sending up to \$600 to single tax filers, \$1,200 to married couples, plus \$300 per dependent child.

Free money? Pretty awesome, right?

Not really, according to a random sampling of my fellow Americans (who are also friends of mine). The consensus: The rebate money is about as stimulating as seeing your ex-girlfriend walk into a bar with George Clooney. Flashing an engagement ring. This is, after all, a country where game show contestants routinely act insulted to receive an offer of \$100,000, gleefully screaming "No deal!" in response to such a paltry sum. The nerve!

It turns out we don't mind free money, but we prefer to get a whole lot of it. "I wouldn't send it back, but it isn't exactly life-altering money," offers Jon S., a New Yorker who works in marketing and didn't want to reveal his full name for fear of sounding like an ingrate.

A less-than-scientific look at what American taxpayers plan to do with their sudden windfall from Uncle Sam

BY JAY DYCKMAN



But, like it or not, this isn't *Deal or No Deal*. Dick Cheney isn't standing on a stage in a sequined gown, tempting us with promises of greater sums in his numbered briefcase.

The question is, what are people going to do with the money? The financial experts recommend that Americans use the check to pay down debt. The government, however, wants us to spend it to boost the economy.

New York writer Robin Epstein's idea might at least lift the spirit. "That sum will cover two rounds of martinis in Manhattan," she says. "Cheers, U.S. government!" Hey, it's ladies' night, America, and Uncle Sam is buying!

"I'd spend it," declares Scott Ehrlich, a mid-30s brand manager, adding that "conspicuous consumption is second only to baseball as the national pastime." Thirty-something Marco Madero adds that he'll probably "spend it on something stupid." Now that's music to the government's ears. The Medal of Freedom for both of you!

One person even tried to spend it long before the check arrived, which, when you think about it, is pretty much how we got into this mess in the first place. "I tried to buy a pair of jeans on credit after assuring the clerk that I would be getting the rebate," says Ed Thomas, a Boston lawyer.

To anyone considering this approach, please note that it was, in fact, highly unsuccessful.

Others are certain that paying down debt is, indeed, the way to go. "I'd reduce my debt," confirms Scott Corrigan, another New Yorker who works in

marketing. "After that, I'll make a rabbit jump out of this hat." A good point, actually. What good is David Copperfield if he can't make our national debt disappear? How about it, David Blaine?

Some people see wisdom in both approaches. "I'd pay bills," says artist Michael Mut. Upon reflection, however, he adds, "Or maybe I'll buy lottery tickets." Now that's sound financial planning.

Still, others find the whole rebate scheme entirely counterproductive. "The government has probably spent more money debating, legislating, implementing, mailing and overseeing the program per person than the amount of the rebates being offered,"

It's ladies' night in America, and Uncle Sam is buying!

suggests Joe S. of Tampa, another dear friend who requested anonymity. No wonder: With that kind of sober analysis, he clearly couldn't land a job in government service.

To me, the kicker is that the patriotic thing to do is to buy something "fun" with the rebate money. Inexplicably, the whimsical item the experts refer to most is a plasma TV. A tank of gas and the asthma medication that would really come in handy this spring rarely make that list. Apparently, those items aren't particularly fun.

The problem is that most of us aren't feeling very fun these days. It isn't that the money isn't appreciated, but it is sort of like being offered a free oil change on the same day your car got totaled. On the way to putting your cat to sleep. Right after getting fired. **W**

JAY DYCKMAN last wrote about the classic Gen-X movies of 1983.

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