Axona (caprylidene) is a medical food (see Section 11 “Description” below) consisting of a 60% caprylic triglyceride (MCT) formulation specifically caprylic triglyceride, for the clinical dietary management of the diet-induced metabolic syndrome: elevated waist circumference (≥40 inches in men, ≥35 inches in women), BP ≥130/80 mm Hg, TG ≥150 mg/dL, reduced fasting HLD <40 mg/dL, and fasting glucose ≥100 mg/dL. 

5. Warnings and Precautions

Axona is designed to safely elevate serum ketone levels to assist with the clinical management of the diet-induced metabolic syndrome. Subjects within each cohort contained different ratios of proteins to carbohydrates. Subjects within each cohort contained different ratios of proteins to carbohydrates. 

6. Contraindications

Axona is designed to safely elevate serum ketone levels to assist with the clinical dietary management of the diet-induced metabolic syndrome. 

7. Drug Interactions

Axona cannot be entirely ruled out. Healthcare providers should discuss the importance of routine renal function test monitoring with their patients who have a history of renal dysfunction. 

8. Use in Specific Populations

Ketone bodies provide a safer alternative is required. Ketone bodies provide metabolic and nutritional requirements. 

9. Drug Abuse and Dependence

Ketone bodies are naturally produced from fat stores as an alternative to glucose as an energy source for the brain. 

10. Overuse

During periods of sustained hypoglycemia, such as during fasting or very low carbohydrate intake. In a controlled clinical study in human subjects experiencing hypoglycemia, the infusion of ketones was shown to improve cognitive function compared to glucose. Ketone bodies have been shown to be effective at reducing ketosis, especially for patients who may be at risk for development of these symptoms. 

11. Description

It was found that the severity of AEs could be reduced if Axona was taken with food. In the DB AD study, the incidence of severe GI events in Axona patients included diarrhea (5.8%), dyspepsia (2.3%), and flatulence (2.3%), and it was found that the severity of AEs could be reduced if Axona was taken with food. In the DB AD study, the incidence of severe GI events in Axona patients included diarrhea (5.8%), dyspepsia (2.3%), and flatulence (2.3%).

1. Axona (caprylidene) is a medical food (see Section 11 “Description” below) containing a 60% caprylic triglyceride (MCT) formulation specifically caprylic triglyceride, for the clinical dietary management of the diet-induced metabolic syndrome: elevated waist circumference (≥40 inches in men, ≥35 inches in women), BP ≥130/80 mm Hg, TG ≥150 mg/dL, reduced fasting HLD <40 mg/dL, and fasting glucose ≥100 mg/dL. 

2. Axona is designed to safely elevate serum ketone levels to assist with the clinical dietary management of the diet-induced metabolic syndrome. 

3. Axona cannot be entirely ruled out. Healthcare providers should discuss the importance of routine renal function test monitoring with their patients who have a history of renal dysfunction. 

4. Elevated triglyceride values were observed in some subjects who presented with probable metabolic syndrome. 

5. Elevated triglyceride values were observed in some subjects who presented with probable metabolic syndrome. Ketone bodies are naturally produced from fat stores as an alternative to glucose as an energy source for the brain. 

6. It was found that the severity of AEs could be reduced if Axona was taken with food. In the DB AD study, the incidence of severe GI events in Axona patients included diarrhea (5.8%), dyspepsia (2.3%), and flatulence (2.3%).

7. The incidence of severe GI events in Axona patients included diarrhea (5.8%), dyspepsia (2.3%), and flatulence (2.3%).

8. Treatment of Metabolic Syndrome

In a controlled clinical study in human subjects experiencing hypoglycemia, the infusion of ketones was shown to improve cognitive function compared to glucose. Ketone bodies have been shown to be effective at reducing ketosis, especially for patients who may be at risk for development of these symptoms.

9. Adverse Events Reported in ≥3% of Axona Patients* 

Reported more frequently in Axona than in placebo patients: Bridging Study: The first clinical trial was a 14-day, open-label, randomized trial performed at 4 U.S. clinical centers in 66 normal elderly volunteers. Three formulations of Axona were administered for 14 days either with a 7-day titration (14 days at 15 grams caprylic triglyceride) or without titration (14 days at 20 grams caprylic triglyceride). The original formulation of Axona (33% caprylic triglyceride) contained different ratios of proteins to carbohydrates. Subjects within each cohort contained different ratios of proteins to carbohydrates. Six of these 7 subjects were identified as having probable metabolic syndrome. Of note, dietary restrictions were not imposed during this study, and the quantity of food and other sources of carbohydrate consumption was monitored. Therefore, although a causal relationship to Axona was not determined, triglyceride levels should be periodically monitored in patients receiving Axona who meet criteria indicative of metabolic syndrome. 

10. Administration

Axona is designed to safely elevate serum ketone levels to assist with the clinical dietary management of the diet-induced metabolic syndrome. 

11. Warnings and Precautions

Ketone bodies are naturally produced from fat stores as an alternative to glucose as an energy source for the brain. 

12. Adverse Reactions

Counseling Information” for graduated dosing instructions). Axona should be used with caution in patients with a history of alcohol abuse and poorly controlled diabetes. 

13. Contraindications

In general, adverse events associated with MCTs include gastrointestinal symptoms (e.g., abdominal pain, gas, and flatulence) due to rapid hydrolysis of MCTs in the gut and the resultant accretion of high concentration of medium-chain fatty acids in the small intestine. For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition. 

14. Contraindications

Axona contains casein (milk-derived), whey (milk), and lactose (isom). Do not use in patients with a history of galactosemia. Axona contains casein (milk-derived), whey (milk), and lactose (isom). Do not use in patients with a history of galactosemia. 

15. Adverse Events

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition. 

16. Adverse Events

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition. 

17. Patient Counseling Information

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

18. Precautions

It was found that the severity of AEs could be reduced if Axona was taken with food. In the DB AD study, the incidence of severe GI events in Axona patients included diarrhea (5.8%), dyspepsia (2.3%), and flatulence (2.3%).

19. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

20. Precautions

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

21. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

22. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

23. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

24. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

25. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

26. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

27. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

28. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

29. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.

30. Dosage and Administration

For a substance to be GRAS, the Food and Drug Administration (FDA) requires that the substance be Generally recognized as Safe (GRAS) and which is intended for the specific dietary management of a disease or condition.
12. Clinical Pharmacology — Mechanism of Action/ Metabolism

Axona is a medical food designed to supplement the diet of Alzheimer’s disease patients. Typically, individuals with Alzheimer’s disease have a lower ability to utilize ketone bodies than healthy humans, leading to a reduced generation of ATP and reduced cognitive function. Therefore, Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.

Axona, a medium-chain triglyceride (MCT) emulsion, is intended to provide a concentrated source of ketone bodies to the brain. Axona is composed of medium-chain triglycerides (MCTs) and additional minor ingredients. Metabolism of MCTs is similar to that of long-chain triglycerides (LCTs). Approximately 50% of MCTs are oxidized in the mitochondrial matrix of the liver to produce acetoacetate and acetone. The remaining 50% are synthesized into ketone bodies, which are subsequently transported to the brain, where they are metabolized to induce a ketosis-like state and provide an alternative energy source for the brain.

Dosing: Axona dosage is intended as an adjunctive treatment for Alzheimer’s disease and is not intended to be used as the sole source of nutrition. In a double-blind, placebo-controlled, randomized clinical trial, 76 patients were randomized to receive Axona or placebo. The primary outcome, measured by the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog), was a composite measure of cognitive performance and did not change significantly over the study period. No statistically significant differences were observed in the change from baseline ADAS-Cog scores between those administered Axona and placebo. The placebo group still demonstrated a decline, whereas the Axona group showed no significant improvement compared with placebo. In a 16-week, open-label study with Axona, no clinically significant changes in amyloid load were observed in the cohort of subjects receiving the full dose of Axona (20 grams MCTs/kg/day). Axona was found to be generally well-tolerated. No significant adverse events were observed in the Axona group compared with the placebo group.