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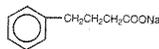
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**BUPHENYL®**  
[bu'fen-ah]  
(sodium phenylbutyrate)  
Tablets

**BUPHENYL®**  
(sodium phenylbutyrate)  
Powder  
Rx Only

**DESCRIPTION**

Buphenyl® (sodium phenylbutyrate) Tablets for oral administration and Buphenyl® (sodium phenylbutyrate) Powder for oral, nasogastric, or gastrostomy tube administration contain sodium phenylbutyrate. Sodium phenylbutyrate is an off-white crystalline substance which is soluble in water and has a strong salty taste. Sodium phenylbutyrate also is freely soluble in methanol and practically insoluble in acetone and diethyl ether. It is known chemically as 4-phenylbutyric acid, sodium salt with a molecular weight of 186 and the molecular formula  $C_{11}H_{11}O_2Na$ .  
Chemical Structure:



Each tablet of BUPHENYL contains 500 mg of sodium phenylbutyrate and the inactive ingredients microcrystalline cellulose, magnesium stearate, and colloidal silicon dioxide. Each gram of BUPHENYL Powder contains 0.94 grams of sodium phenylbutyrate and the inactive ingredients calcium stearate, and colloidal silicon dioxide.

**CLINICAL PHARMACOLOGY**

Sodium phenylbutyrate is a pro-drug and is rapidly metabolized to phenylacetate. Phenylacetate is a metabolically-active compound that conjugates with glutamine via acetylation to form phenylacetylglutamine. Phenylacetylglutamine then is excreted by the kidneys. On a molar basis, it is comparable to urea (each containing two moles of nitrogen). Therefore, phenylacetylglutamine provides an alternate vehicle for waste nitrogen excretion.

**PHARMACOKINETICS**

**General:** Pharmacokinetic studies have not been conducted in the primary patient population (neonates, infants, and children), but pharmacokinetic data were obtained from normal adult subjects.

**Absorption:**

Peak plasma levels of phenylbutyrate occur within 1 hour after a single dose of 5 grams of sodium phenylbutyrate tablet with a  $C_{max}$  of 218  $\mu$ g/mL under fasting conditions; peak plasma levels of phenylbutyrate occur within 1 hour after a single dose of 5 grams of sodium phenylbutyrate powder with a  $C_{max}$  of 195  $\mu$ g/mL under fasting conditions. The effect of food on phenylbutyrate's absorption is unknown.

**Disposition:**

The overall disposition of sodium phenylbutyrate and its metabolites has not been characterized fully. However, the drug is known to be metabolized to phenylacetate and subsequently to phenylacetylglutamine. Following oral administration of 5 grams (tablets), measurable plasma levels of phenylbutyrate and phenylacetate were detected 15 and 30 minutes after dosing, respectively, and phenylacetylglutamine was detected shortly thereafter. The pharmacokinetic parameters for phenylbutyrate for  $C_{max}$  ( $\mu$ g/mL),  $T_{max}$  (hours), and elimination half-life (hours) were 218, 1.35, and 0.77, respectively, and for phenylacetate were 48.5, 3.74, and 1.15, respectively.

Following oral administration of 5 grams of the powder, measurable plasma levels of phenylbutyrate and phenylacetate were detected 15 and 30 minutes after dosing, respectively, and phenylacetylglutamine was detected shortly thereafter. The pharmacokinetic parameters for phenylbutyrate for  $C_{max}$  ( $\mu$ g/mL),  $T_{max}$  (hours), and elimination half-life (hours) were 195, 1.00, and 0.76, respectively, and for phenylacetate were 45.3, 3.55, and 1.29, respectively.

The major sites for metabolism of sodium phenylbutyrate are the liver and kidney.

**Excretion:**

A majority of the administered compound (approximately 80 - 100%) was excreted by the kidneys within 24 hours as the conjugation product, phenylacetylglutamine. For each gram of sodium phenylbutyrate administered, it is estimated that between 0.12 - 0.15 grams of phenylacetylglutamine nitrogen are produced.

**Pharmacodynamics:**

In patients with urea cycle disorders, BUPHENYL decreases elevated plasma ammonia glutamine levels. It increases waste nitrogen excretion in the form of phenylacetylglutamine.

**Special Populations:**

**Gender:**

Significant gender differences were found in the pharmacokinetics of phenylbutyrate and phenylacetate but not for phenylacetylglutamine. The pharmacokinetic parameters, (AUC and  $C_{max}$ ), for both plasma phenylbutyrate and phenylacetate were about 30 to 50 percent greater in females than in males.

**Hepatic insufficiency:**

In patients who did not have urea cycle disorders but had impaired hepatic function, the metabolism and excretion of

sodium phenylbutyrate were not affected. However, this information was obtained from unvalidated, uncontrolled case studies.

**INDICATIONS AND USAGE**

BUPHENYL is indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. It is important that the diagnosis be made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a life-threatening emergency.

BUPHENYL must be combined with dietary protein restriction and, in some cases, essential amino acid supplementation. (See Nutritional Supplementation subsection of the DOSAGE AND ADMINISTRATION section.)

Previously, neonatal-onset disease was almost universally fatal within the first year of life, even when treated with peritoneal dialysis and essential amino acids or their nitrogen-free analogs. However, with hemodialysis, use of alternative waste nitrogen excretion pathways (sodium phenylbutyrate, sodium benzoate, and sodium phenylacetate), dietary protein restriction, and, in some cases, essential amino acid supplementation, the survival rate in newborns diagnosed after birth but within the first month of life is almost 80%. Most deaths have occurred during an episode of acute hyperammonemic encephalopathy. Patients with neonatal-onset disease have a high incidence of mental retardation. Those who had IQ tests administered had an incidence of mental retardation as follows: ornithine transcarbamylase deficiency, 100% (14/14 patients tested); argininosuccinic acid synthetase deficiency, 88% (15/17 patients tested); and carbamyl phosphate synthetase deficiency, 57% (4/7 patients tested). Retardation was severe in the majority of the retarded patients.

In patients diagnosed during gestation and treated prior to any episode of hyperammonemic encephalopathy, survival is 100%, but even in these patients, most subsequently demonstrate cognitive impairment or other neurologic deficits. In late-onset deficiency patients, including females heterozygous for ornithine transcarbamylase deficiency, who recover from hyperammonemic encephalopathy and are then treated chronically with sodium phenylbutyrate and dietary protein restriction, the survival rate is 98%. The two deaths in this group of patients occurred during episodes of hyperammonemic encephalopathy. However, compliance with the therapeutic regimen has not been adequately documented to allow evaluation of the potential for BUPHENYL and dietary protein restriction to prevent mental deterioration and recurrence of hyperammonemic encephalopathy if carefully adhered to. The majority of these patients tested (30/46 or 65%) have IQ's in the average to low average/borderline mentally retarded range. Reversal of pre-existing neurologic impairment is not likely to occur with treatment and neurologic deterioration may continue in some patients. Even on therapy, acute hyperammonemic encephalopathy recurred in the majority of patients for whom the drug is indicated.

BUPHENYL may be required life-long unless orthotopic liver transplantation is elected. (See CLINICAL PHARMACOLOGY, Pharmacodynamics subsection for the biochemical effects of BUPHENYL).

**CONTRAINDICATIONS**

BUPHENYL should not be used to manage acute hyperammonemia, which is a medical emergency.

**WARNINGS**

Each BUPHENYL Tablet contains 62 mg of sodium (9.2% w/w) (corresponding to 124 mg of sodium per gram of sodium phenylbutyrate (12.4% w/w)) and BUPHENYL Powder contains 11.7 grams of sodium per 100 grams of powder, corresponding to 125 mg of sodium per gram of sodium phenylbutyrate (12.4% w/w). BUPHENYL should be used with great care, if at all, in patients with congestive heart failure or severe renal insufficiency, and in clinical states in which there is sodium retention with edema.

Because BUPHENYL is metabolized in the liver and kidney, and phenylacetylglutamine is primarily excreted by the kidney, use caution when administering the drug to patients with hepatic or renal insufficiency or inborn errors of beta oxidation. Probenecid is known to inhibit the renal transport of many organic compounds, including hippuric acid, and may affect renal excretion of the conjugated product of BUPHENYL as well as its metabolite.

Use of corticosteroids may cause the breakdown of body protein and increase plasma ammonia levels.

**PRECAUTIONS**

**General:**

BUPHENYL should not be administered to patients with known hypersensitivity to sodium phenylbutyrate or any component of this preparation.

There have been published reports of hyperammonemia being induced by haloperidol and valproate.

**Neurotoxicity of phenylacetate in animals:**

When given subcutaneously to rat pups, 190-474 mg/kg phenylacetate caused decreased proliferation and increased loss of neurons, and it reduced CNS myelin. Cerebral syn-

apse maturation was retarded, and the number of functioning nerve terminals in the cerebrum was reduced, which resulted in impaired brain growth. Prenatal exposure of rat pups to phenylacetate produced lesions in layer 5 of the cortical pyramidal cells; dendritic spines were longer and thinner than normal and reduced in number.

**Information for the Patients:**

The full text of the separate insert of information for patients is reprinted at the end of the labeling.

**Laboratory Tests:**

Plasma levels of ammonia, arginine, branched-chain amino acids, and serum proteins should be maintained within normal limits, and plasma glutamine should be maintained at levels less than 1,000  $\mu$ mol/L. Serum drug levels of phenylbutyrate and its metabolites, phenylacetate and phenylacetylglutamine, should be monitored periodically.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Carcinogenicity, mutagenicity, and fertility studies of sodium phenylbutyrate have not been conducted.

**Pregnancy:**

**Pregnancy Category C.** Animal reproduction studies have not been conducted with BUPHENYL. It is also not known whether BUPHENYL can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

BUPHENYL should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BUPHENYL is administered to a nursing woman.

**Pediatric Use:**

The use of tablets for neonates, infants and children under the weight of 20 kg is not recommended. (See DOSAGE AND ADMINISTRATION).

**ADVERSE REACTIONS**

The assessment of clinical adverse events came from 206 patients treated with sodium phenylbutyrate. Adverse events (both clinical and laboratory) were not collected systematically in these patients, but were obtained from patient-visit reports by the 65 co-investigators. Causality of adverse effects is sometimes difficult to determine in this patient population because they may result from either the underlying disease, the patient's restricted diet, intercurrent illness, or BUPHENYL. Furthermore, the rates may be under-estimated because they were reported primarily by parent or guardian and not the patient.

**Clinical Adverse Events**

In female patients, the most common clinical adverse event reported was amenorrhea/menstrual dysfunction (irregular menstrual cycles), which occurred in 23% of the menstruating patients.

Decreased appetite occurred in 4% of all patients. Body odor (probably caused by the metabolite, phenylacetate) and bad taste or taste aversion were each reported in 3% of patients. Other adverse events reported in 2% or fewer patients were: **Gastrointestinal:** abdominal pain, gastritis, nausea and vomiting; constipation, rectal bleeding, peptic ulcer disease, and pancreatitis each occurred in one patient.

**Hematologic:** aplastic anemia and ecchymoses each occurred in one patient.

**Cardiovascular:** arrhythmia and edema each occurred in one patient.

**Renal:** renal tubular acidosis

**Psychiatric:** depression

**Skin:** rash

**Miscellaneous:** headache, syncope, and weight gain

Neurotoxicity was reported in cancer patients receiving intravenous phenylacetate, 250-300 mg/kg/day for 14 days, repeated at 4-week intervals. Manifestations were predominantly somnolence, fatigue, and lightheadedness; with less frequent headache, dysgeusia, hypospousis, disorientation, impaired memory, and exacerbation of a pre-existing neuropathy. These adverse events were mainly mild in severity. The acute onset and reversibility when the phenylacetate infusion was discontinued suggest a drug effect.

**Laboratory Adverse Events**

In patients with urea cycle disorders, the frequency of laboratory adverse events by body system were:

**Metabolic:** acidosis (14%), alkalosis and hyperchloremia (each 7%), hypophosphatemia (6%), hyperuricemia and hyperphosphatemia (each 2%), and hypernatremia and hypokalemia (each 1%).

**Nutritional:** hypoalbuminemia (11%) and decreased total protein (3%).

**Hepatic:** increased alkaline phosphatase (6%), increased liver transaminases (4%), and hyperbilirubinemia (1%).

**Hematologic:** anemia (9%), leukopenia and leukocytosis (each 4%), thrombocytopenia (3%), and thrombocytosis (1%). The clinician is advised to routinely perform urinalysis, blood chemistry profiles, and hematologic tests.

**OVERDOSAGE**

No adverse experiences have been reported involving overdoses of sodium phenylbutyrate in patients with urea cycle disorders.

In the event of an overdose, discontinue the drug and institute supportive measures.

Hemodialysis or peritoneal dialysis may be beneficial.

*Continued on next page*

**Buphenyl—Cont.****DOSAGE AND ADMINISTRATION**

For oral use only.

The use of BUPHENYL Tablets is indicated for children weighing more than 20 kg and for adults. The usual total daily dose of BUPHENYL Tablets and Powder for patients with urea cycle disorders is 450–600 mg/kg/day in patients weighing less than 20 kg, or 9.9–13.0 g/m<sup>2</sup>/day in larger patients. The tablets and powder are to be taken in equally divided amounts with each meal or feeding (i.e., three to six times per day).

BUPHENYL Powder is indicated for oral use (via mouth, gastrostomy, or nasogastric tube) only. The powder is to be mixed with food (solid or liquid). Sodium phenylbutyrate is very soluble in water (5 grams per 10 mL). When BUPHENYL Powder is added to a liquid, only sodium phenylbutyrate will dissolve, the excipients will not. The effect of food on sodium phenylbutyrate has not been determined. Each level teaspoon (enclosed) dispenses 3.2 grams of powder and 3.0 grams of sodium phenylbutyrate. Each level tablespoon (enclosed) dispenses 9.1 grams of powder and 8.6 grams of sodium phenylbutyrate.

Shake lightly before use. The safety or efficacy of doses in excess of 20 grams (40 Tablets) per day has not been established.

**NUTRITIONAL MANAGEMENT**

To promote growth and development, plasma levels of ammonia, arginine, branched-chain amino acids, and serum protein should be maintained within normal limits while plasma glutamine is maintained at levels less than 1,000 µmol/L. Minimum daily protein intake for a patient of a particular age should be taken from, for example, "Recommended Dietary Allowances", 10th ed., Food and Nutrition Board, National Academy of Sciences, 1989. The allocation of dietary nitrogen into natural protein and essential amino acids is a function of age, residual urea-cycle enzyme activity, and the dose of sodium phenylbutyrate.

At the recommended dose of sodium phenylbutyrate, it is suggested that infants with neonatal-onset CPS and OTC deficiencies initially receive a daily dietary protein intake limited to approximately 1.6 g/kg/day for the first 4 months of life. If tolerated, the daily protein intake may be increased to 1.9 g/kg/day during this period. Protein tolerance will decrease as the growth rate decreases, requiring a reduction in dietary nitrogen intake. From 4 months to 1 year of age, it is recommended that the infant receive at least 1.4 g/kg/day, but 1.7 g/kg/day is advisable. From 1 to 3 years of age, the protein intake should not be less than 1.2 g/kg/day; 1.4 g/kg/day is advisable during this period. For neonatal-onset patients with carbamylphosphate synthetase deficiency or ornithine transcarbamylase deficiency who are at least 6 months of age, it is recommended that the daily protein intake be equally divided between natural protein and supplemental essential amino acids.

Patients with argininosuccinic acid synthetase deficiency and those with late-onset disease (partial deficiencies, including females heterozygous for ornithine transcarbamylase), initially may receive a diet containing the age-determined minimal daily natural protein allowance. The protein intake may be increased as tolerated and determined by plasma glutamine and other amino acid levels. However, many patients with partial deficiencies avoid dietary protein.

Citrulline supplementation is required and recommended for patients diagnosed with neonatal-onset deficiency of carbamylphosphate synthetase or ornithine transcarbamylase; citrulline daily intake is recommended at 0.17 g/kg/day or 3.8 g/m<sup>2</sup>/day.

The free-base form of arginine may be used instead of citrulline in patients with milder forms of carbamylphosphate synthetase and ornithine transcarbamylase deficiency (daily intake is recommended at 0.17 g/kg/day or 3.8 g/m<sup>2</sup>/day).

Arginine supplementation is needed for patients diagnosed with deficiency of argininosuccinic acid synthetase; arginine (free base) daily intake is recommended at 0.4–0.7 g/kg/day or 8.8–15.4 g/m<sup>2</sup>/day.

If caloric supplementation is indicated, a protein-free product is recommended. Caloric intake should be based upon the "Recommended Dietary Allowances", 10th ed., Food and Nutrition Board, National Research Council, National Academy of Sciences, 1989.

**HOW SUPPLIED**

BUPHENYL Tablets are available in 250 cc bottles, which contain 250 sodium phenylbutyrate tablets (NDC 62592-496-03). The bottles are equipped with child-resistant caps. Each tablet is off-white, oval, and embossed with "UCY 500". Each tablet contains 500 mg of sodium phenylbutyrate. **STORE AT ROOM TEMPERATURE 15°C–30°C (59°F–86°F). AFTER OPENING, KEEP BOTTLE TIGHTLY CLOSED.**

BUPHENYL Powder is available in 500 cc bottles, which hold 266 grams of powder, containing 250 grams of sodium phenylbutyrate (NDC 62592-188-64). The bottles are equipped with child-resistant caps. Measurers are provided. Each level teaspoon (enclosed) dispenses 3.2 grams of powder and 3.0 grams of sodium phenylbutyrate. Each level tablespoon (enclosed) dispenses 9.1 grams of powder and 8.6 grams of sodium phenylbutyrate. **STORE AT 15°C–30°C (59°F–86°F). AFTER OPENING, KEEP BOTTLE TIGHTLY CLOSED.**

US Patent number 4,457,942.

Manufactured for: Ucyclid Pharma, Inc., Scottsdale, AZ 85258  
By: Pharmaceutics International, Inc. Hunt Valley, MD 21031  
NDC 62592-496-03 bottle of 500 mg tablets.  
NDC 62592-188-64 bottle containing 250g of sodium phenylbutyrate powder.  
Prescribing Information as of August 2003

49603-06A

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**THE MAKE LIFE BETTER COMPANY**  
**1201 NORTH 800 EAST**  
**OREM, UT 84097**

**Direct Inquiries to:**

(801) 226 2600  
www.makelifebetter.com  
science@unicity.net

Products of Unicity International, The Make Life Better Company are distributed through independent distributors.

**BIOSLIFE 2®**

[bi-ös lif 2]

**Advanced Fiber and Nutrient Drink****OTC****DESCRIPTION**

BioLife 2 is a nutrient-rich fiber drink mix that contains a patented complex of soluble and insoluble fibers, vitamins, and minerals.

**BENEFITS AND RESEARCH**

BioLife 2 — a good source of dietary fiber— when included as part of a healthy diet, may help lower your blood cholesterol levels and reduce your risk of heart disease. Eight weeks of BioLife 2 showed a significant reduction in LDL-c compared to placebo. The mechanism of BioLife 2 in cholesterol reduction is through bile-acid sequestration.

**SUGGESTED USE**

First users: dissolve the contents of one packet into 8 to 10 fl. oz. of liquid (water or juice), stir vigorously and drink immediately 5 to 10 minutes before the main meals. After fiber adjustment use as directed above up to three times daily before every meal.

**CONTENTS**

One packet of BioLife 2 contains 4.5 gram fiber, comprising of 4 grams of soluble fiber. Added to this fiber mix are optimal daily levels and bio-available forms of several vitamins, and chromium (as ChromeMate™). BioLife 2 is available in Natural, Original, and Tropical Fruit flavors. For detailed dietary information, please see www.unicity.net

**SAFETY AND WARNINGS**

BioLife 2 is well accepted. Some users report mild gastrointestinal discomfort after first use. This is a normal effect of increased fiber intake and normally disappears within 30 days. Taking this product without adequate liquid can result in complications. If you are a diabetic, consult a physician for proper use of this product, as the chromium may reduce the need for medication.

**HOW SUPPLIED**

Conveniently packaged in single-serving packets or bulk canisters.

**REFERENCES**

Sprecher, DL and Pearce GL (2002), *Metabolism* 51: 1166–70.

Verdegem, PJE, Freed, S and Joffe D (2005), American Diabetes Association 65<sup>th</sup> Scientific Sessions, San Diego.

US Patent 4,883,788 and US Patent 4,824,672.

\*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT CURE, OR PREVENT ANY DISEASE.

**CARDIOESSENTIALS®****Caring for your heart****OTC****DESCRIPTION**

CardioEssentials is Unicity's superior heart product.

**Benefits and research**

CardioEssentials provides nutrients for the heart muscle, and supports healthy heart function. The combination of L-carnitine, L-taurine, and Coenzyme Q10 has been shown to help congestive heart failure patients in a clinical study. In this study, left ventricular size was reduced in CHF patients, giving them a better prognosis. These ingredients are known to be important in providing adequate energy for the heart muscle. CardioEssentials provides adequate amounts of these ingredients, i.e. 100 mg of CoQ10. Hawthorn extract is traditionally used in supporting the heart function.

**SUGGESTED USE**

Take six capsules daily with food.

**Contents**

CardioEssentials features a proprietary blend of L-carnitine, L-taurine, and Hawthorn, combined with 100 mg of Coenzyme Q10.  
For detailed dietary information, please see www.makelifebetter.com

**SAFETY AND WARNINGS**

CardioEssentials is well accepted. Some gastrointestinal discomfort may be experienced as with any dietary supplement.

**HOW SUPPLIED**

Available in bottles of 180 tablets.

\*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT CURE, OR PREVENT ANY DISEASE.

**REFERENCES**

Jeejeebhoy, F *et al* (2002), *American Heart Journal* 143: 1092–1100.

**CM PLEX™ AND CM PLEX™ CREAM**

[CM plëks]

**Proprietary fatty acid blend to help alleviate symptoms of osteo arthritis\*****OTC****DESCRIPTION**

CM Plex and CM Plex Cream are a softgel, and topical cream product respectively, combining fatty acids, in a proprietary blend of cetyl myristate, cetyl myristoleate, and other cetyl esters.

**Benefits and research**

Cetyl myristoleate and related fatty acids have been proven to improve joint health, through their anti-inflammatory effects. A clinical study indicated that subjects exhibited improvements in knee flexion compared to placebo. A second study indicated the cream is effective for improving knee range of motion, improving ability to climb stairs, rise from a chair, and walk, and improving balance, strength, and endurance.\*

**SUGGESTED USE**

Softgels: Take one or two softgels three times daily with meals. Cream: Apply generously onto clean skin and gently massage until the cream disappears. Repeat 3 to 4 times daily as necessary. For maximum results combine both products.

**Contents**

CM Plex contains a proprietary blend of cetyl myristate, cetyl myristoleate, and other cetyl esters. For detailed dietary information, please see www.unicity.net.

**Safety and Warnings**

CM Plex Softgels and Cream are well accepted. Some gastrointestinal discomfort may be experienced with CM Plex Softgels as with any dietary supplement.

**HOW SUPPLIED**

CM Plex is available in both cream and soft gels.

**REFERENCES**

Hesslink, R *et al* (2002), *Journal of Rheumatology* 29: 1708–1712.

Kraemer, WJ *et al* (2004), *Journal of Rheumatology* 31: 767–774.

\*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT CURE, OR PREVENT ANY DISEASE.

**VISUTEIN®**

[vis-u-tēn]

**Clinically proven to support healthy eyes and vision.\*****OTC****DESCRIPTION**

VISUTEIN is Unicity's product providing key nutrients for the eye.

**Benefits and research**

The carotenoids lutein and zeaxanthin play an important role in eye health. Low concentrations of these phytonutrients in the retina have been associated with age-related macula degeneration (AMD). Studies have shown, that supplementation with high levels of lutein, as present in VISUTEIN, can restore the lutein concentration in the retina. The product further features important vitamins, and carotenoids that are important in preserving overall eye health and supporting clear vision. N-acetyl cysteine is added to boost the glutathione levels in the retina. Low glutathione levels have been shown to reduce protection of the eye against oxidative stress. A recent clinical study with VISUTEIN has shown that AMD patients experience clear improvements in visual acuity, contrast sensitivity, and recovery from a flash.\*

**SUGGESTED USE**

Take two capsules per day with a meal.

**Contents**

VISUTEIN provides 18 mg of lutein, along with 200 mg of N-acetyl cysteine, and 60 mg anthocyanidins from bilberry.