



2053 02 DEC 16 P3:31

NOV 25 2002

David R. Morrison, Esq.
Director, Scientific Affairs
Pharmaton Natural Health Products
Division of Boehringer Ingelheim Pharmaceuticals
900 Ridgebury Road
Ridgefield, Connecticut 06877

Dear Mr. Morrison:

This is in response to your letters of November 7, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Pharmaton Natural Health Products is making the claims identified below for the products **Flexium™ Joint Comfort & Cartilage Renewal** and **Flexium™ Joint Comfort**.

The products **Flexium™ Joint Comfort & Cartilage Renewal** and **Flexium™ Joint Comfort** use the claim "...ease the pain from everyday activities." This claim is a disease claim because it suggests that the products are intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

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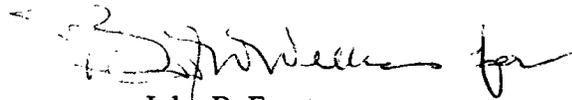
Page 2 - Mr. David R. Morrison

Neither of the claims contained in your notifications refer to pain associated with a non-disease state. Although "everyday activities are not themselves diseases, they would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such pain.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

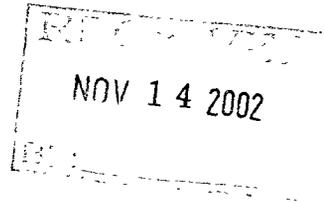
FDA, New England District Office, Office of Compliance, HFR-NE240



Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Boehringer Ingelheim
Pharmaceuticals Inc.

Pharmaton Natural
Health Products



November 07, 2002

Dear Sir/Madam:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products (Pharmaton), Division of Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, wishes to notify the Food and Drug Administration that Pharmaton has begun marketing a dietary supplement with a label which bears statements of nutritional support. Pharmaton is the distributor of the product.

David R. Morrison
Director, Scientific Affairs
Telephone (203) 778-7826
Telefax (203) 791-6733

900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

The dietary supplement for which the statements are made is **Flexium™ Joint Comfort & Cartilage Renewal**, which consists of S-adenosylmethionine (SAME) an amino acid in combination with glucosamine a nutritional dietary supplement. The statements of nutritional support for this ingredient read as follows:

- Naturally helps to renew cartilage and ease the pain from everyday activities,
- Flexium with glucosamine and SAME, helps to renew cartilage and ease the pain from everyday activities,
- Clinically proven to help promote joint comfort and improve flexibility,
- Flexium naturally helps renew cartilage and promote joint comfort as part of your daily health regimen.

A copy of the package for each size of the product is attached.



These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by the FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease.

Pharmaton certifies that it possesses adequate substantiation for these statements of nutritional support which render the statements truthful and non-misleading, and thus permissible under the Federal Food, Drug and Cosmetic Act, and that the information contained in this notice is complete and accurate.

Sincerely,

A handwritten signature in cursive script that reads "David R. Morrison" followed by a horizontal line.

David R. Morrison, Esq.
Director, Scientific Affairs

Enclosures

Original plus two copies enclosed

Glue

Store in a cool, dry place.



PHARMATON Quality Guarantee:

This product has been proven safe and effective and is manufactured according to rigorous quality standards. With a more than 40-year heritage of dedication to your wellness, PHARMATON stands behind its products and guarantees satisfaction or your money back.

FLEXIUM™ - Make Every Day a Good Day™

Flexium™, with glucosamine and SAM-e, helps to renew cartilage and ease the pain from everyday activities. These compounds occur naturally in your body but, as you age, the levels can decrease and you may need to supplement them. Flexium combines glucosamine - a natural building block for the cartilage that cushions your joints - and SAM-e, clinically proven to help promote joint comfort and improve flexibility.

Flexium provides you with the original, patented form of SAM-e, called SD-4. This form of SAM-e has been extensively tested to assure that it is both safe and effective. And Flexium is the only brand available at major retailers* that offers this patented form of SAM-e for joint comfort.

Flexium naturally helps renew cartilage and promote joint comfort as part of your daily health regimen. And specially coated Flexium tablets are gentle enough on your stomach to take every day, as shown in over 20 years of use.

Feel the freedom to do the things you want to do. Let Flexium help make every day a good day.

Recommended Adult Intake: Adults should take one tablet two or three times a day, as desired, before meals. Do not use within one hour of taking an antacid or milk; do not chew or crush tablet. Clinical research has shown SAM-e to be effective in as little as two weeks - and glucosamine as early as four weeks - with continuous, daily use.

Precautions: Consult a physician if you are allergic to shellfish, are taking prescription medication (particularly an antidepressant), are pregnant or nursing. Individuals with bipolar disorder should not use this product. In case of accidental ingestion/overdose, seek the advice of a healthcare professional immediately. As with other vitamins and supplements, please keep this product out of the reach of children.

SUPPLEMENT FACTS:
Daily Serving Size 2 to 3 tablets

Amount per tablet:	
SAM-e (as S-adenosylmethionine 1,4-butanedisulfonate)	200mg**
Glucosamine HCl	500mg**

**Daily Value not established.

Ingredients: Glucosamine hydrochloride, S-adenosylmethionine 1,4-butanedisulfonate, microcrystalline cellulose, sodium starch glycolate, povidone, methacrylic acid copolymer, talc, polyethylene glycol 6000, magnesium stearate, colloidal silica, polysorbate 80, sodium hydroxide, iron oxide, simethicone

*Major retailers only; excludes health food stores and natural food distributors.

Questions about Flexium?
Call toll-free 1-800-451-8688
Or visit our Web site at www.Pharmaton.com

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.

Glue

Glue

Visit www.Pharmaton.com

Flex
Glucosamine & SAM-e

PHARMATON
NATURAL HEALTH PRODUCTS

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Glue

Flex

NEW!



PHARMATON
NATURAL HEALTH PRODUCTS

Flexium™

Glucosamine & SAM-e

JOINT COMFORT & CARTILAGE RENEWAL



Naturally Helps to Renew Cartilage & Ease the Pain from Everyday Activities*

Original, Patented Form of SAM-e Plus Glucosamine - Proven Safe & Non-Habit Forming

Feel Results in as Little as Two Weeks

500 mg Glucosamine

200 mg SAM-e SD-4†

†See back panel

20

Enteric Coated
Tablets

DIETARY SUPPLEMENT

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.

Flex
Glucosamine & SAM-e

PHARMATON
NATURAL HEALTH PRODUCTS

Visit www.Pharmaton.com

Glue

FLEXIUM™ is a trademark of Boehringer Ingelheim Pharmaceuticals, Inc.
Distributed by: **PHARMATON**
NATURAL HEALTH PRODUCTS

Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
Product of Italy.

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Store in a cool, dry place.



PHARMATON Quality Guarantee:

This product has been proven safe and effective and is manufactured according to rigorous quality standards. With a more than 40-year heritage of dedication to your wellness, PHARMATON stands behind its products and guarantees satisfaction or your money back.

FLEXIUM™ - Make Every Day a Good Day™

Flexium™, with glucosamine and SAM-e, helps to renew cartilage and ease the pain from everyday activities. These compounds occur naturally in your body but, as you age, the levels can decrease and you may need to supplement them. Flexium combines glucosamine – a natural building block for the cartilage that cushions your joints – and SAM-e, clinically proven to help promote joint comfort and improve flexibility.

Flexium provides you with the original, patented form of SAM-e, called SD-4. This form of SAM-e has been extensively tested to assure that it is both safe and effective. And Flexium is the only brand available at major retailers* that offers this patented form of SAM-e for joint comfort.

Flexium naturally helps renew cartilage and promote joint comfort as part of your daily health regimen. And specially coated Flexium tablets are gentle enough on your stomach to take every day, as shown in over 20 years of use.

Feel the freedom to do the things you want to do. Let Flexium help make every day a good day.

Recommended Adult Intake: Adults should take one tablet two or three times a day, as desired, before meals. Do not use within one hour of taking an antacid or milk; do not chew or crush tablet. Clinical research has shown SAM-e to be effective in as little as two weeks – and glucosamine as early as four weeks – with continuous, daily use.

Precautions: Consult a physician if you are allergic to shellfish, are taking prescription medication (particularly an antidepressant), are pregnant or nursing. Individuals with bipolar disorder should not use this product. In case of accidental ingestion/overdose, seek the advice of a healthcare professional immediately. As with other vitamins and supplements, please keep this product out of the reach of children.

SUPPLEMENT FACTS:

Daily Serving Size 2 to 3 tablets

Amount per tablet:

SAM-e (as S-adenosylmethionine 1,4-butanedisulfonate)	200mg**
Glucosamine HCl	500mg**

** Daily Value not established.

Ingredients: Glucosamine hydrochloride, S-adenosylmethionine 1,4-butanedisulfonate, microcrystalline cellulose, sodium starch glycolate, povidone, methacrylic acid copolymer, talc, polyethylene glycol 6000, magnesium stearate, colloidal silica, polysorbate 80, sodium hydroxide, iron oxide, simethicone

*Major retailers only; excludes health food stores and natural food distributors

Questions about Flexium?

Call toll-free 1-800-451-6688

Or visit our Web site at www.Pharmaton.com

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Visit www.Pharmaton.com

Flex
Glucosamine & SAM-e

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NATURAL HEALTH PRODUCTS

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Flex

NEW!



PHARMATON
NATURAL HEALTH PRODUCTS

Flexium™
Glucosamine & SAM-e

JOINT COMFORT & CARTILAGE RENEWAL



Naturally Helps to Renew Cartilage & Ease the Pain from Everyday Activities*

Original, Patented Form of SAM-e Plus Glucosamine – Proven Safe & Non-Habit Forming

Feel Results in as Little as Two Weeks

500mg Glucosamine
200mg SAM-e SD-4†

†See back panel

40
Enteric Coated
Tablets

DIETARY SUPPLEMENT

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.

FLEXIUM™ is a trademark of Boehringer Ingelheim Pharmaceuticals, Inc. Distributed by:

PHARMATON
NATURAL HEALTH PRODUCTS

Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
Product of Italy.

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NATURAL HEALTH PRODUCTS

Flex
Glucosamine & SAM-e

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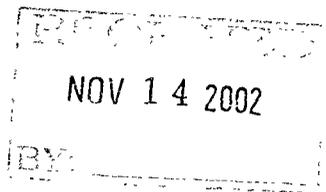


Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Boehringer Ingelheim
Pharmaceuticals Inc.

Pharmaton Natural
Health Products

November 07, 2002



David R. Morrison
Director, Scientific Affairs
Telephone (203) 778-7826
Telefax (203) 791-6733

900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

Dear Sir/Madam:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products (Pharmaton), Division of Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Road, Ridgefield, Connecticut 06877, wishes to notify the Food and Drug Administration that Pharmaton has begun marketing a dietary supplement with a label which bears statements of nutritional support. Pharmaton is the distributor of the product.

The dietary supplement for which the statements are made is **Flexium™ Joint Comfort**, which consists of S-adenosylmethionine (SAME) an amino acid and a nutritional dietary supplement. The statements of nutritional support for this ingredient read as follows:

- Naturally helps to renew cartilage and ease the pain from everyday activities,
- Flexium naturally helps ease the pain and stiffness that can come from physical exertion or everyday activities,
- Flexium is clinically proven to help improve flexibility and ease the pain from daily activities in as little as two weeks,
- Flexium naturally helps promote joint health and comfort as part of your daily health regimen.

A copy of the package for each size of the product is attached.

Store in a cool, dry place.



PHARMATON Quality Guarantee:

This product has been proven safe and effective and is manufactured according to rigorous quality standards. With a more than 40-year heritage of dedication to your wellness, PHARMATON stands behind its products and guarantees satisfaction or your money back.

FLEXIUM™ - Make Every Day a Good Day™

Flexium™, with the original, patented form of SAM-e, naturally helps ease the pain and stiffness that can come from physical exertion or everyday activities. SAM-e (short for S-adenosylmethionine) is a natural compound that your body produces. But as you age, the levels of SAM-e in your body can decrease and you may need to supplement them.

Flexium provides you with the patented form of SAM-e that is clinically proven to help improve flexibility and ease the pain from daily activities in as little as two weeks. This form of SAM-e is called SD-4, and has been extensively tested to assure that it is both safe and effective. And Flexium is the only brand available at major retailers* that offers this patented form of SAM-e for joint comfort.

Flexium naturally helps promote joint health and comfort as part of your daily health regimen. And specially coated Flexium tablets are gentle enough on your stomach to take every day, as shown in over 20 years of use.

Feel the freedom to do the things you want to do. Let Flexium help make every day a good day.

Recommended Adult Intake: Adults should take one tablet per day before a meal. Do not use within one hour of taking an antacid or milk; do not chew or crush tablet. Clinical research has shown effectiveness in as little as two weeks with continuous, daily use.

Precautions: Consult a physician if you are taking prescription medication (particularly an antidepressant), are pregnant or nursing. Individuals with bipolar disorder should not use this product. In case of accidental ingestion/overdose, seek the advice of a healthcare professional immediately. As with other vitamins and supplements, please keep this product out of the reach of children.

SUPPLEMENT FACTS:

Daily Serving Size 1 tablet

Amount per daily serving.

SAM-e (as S-adenosylmethionine 1,4-butanedisulfonate) 400mg**

**Daily Value not established.

Ingredients: S-adenosylmethionine 1,4-butanedisulfonate, microcrystalline cellulose, methacrylic acid copolymer, sodium starch glycolate, talc, polyethylene glycol 6000, colloidal silica, magnesium stearate, polyorbate 80, sodium hydroxide, iron oxide, simethicone.

*Major retailers only, excludes health food stores and natural food distributors

Questions about Flexium?

Call toll-free 1-800-451-6688
Or visit our Web site at www.Pharmaton.com

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.

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Flexium
Double Strength SAM-e

PHARMATON
NATURAL HEALTH PRODUCTS

Flexium

NEW!



PHARMATON
NATURAL HEALTH PRODUCTS

Flexium™
Double Strength SAM-e
JOINT COMFORT



**Naturally Helps Ease Pain & Stiffness
from Everyday Activities***

**Original, Patented Form of SAM-e
Proven Safe & Non-Habit Forming**

Feel Results in as Little as Two Weeks

400mg

SAM-e SD-4†

†See back panel

10

Enteric Coated
Tablets

DIETARY SUPPLEMENT

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.

FLEXIUM™ is a trademark of Boehringer Ingelheim Pharmaceuticals, Inc.

Distributed by: **PHARMATON**

NATURAL HEALTH PRODUCTS
Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877

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Flexium
Double Strength SAM-e

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PHARMATON Quality Guarantee
 This product has been proven safe and effective and is manufactured according to rigorous quality standards. With a more than 40 year heritage of dedication to your wellness, PHARMATON stands behind its products and guarantees satisfaction of your money back.

FLEXIUM™ – Make Every Day a Good Day™

Flexium™, with the original, patented form of SAM-e, naturally helps ease the pain and stiffness that can come from physical exertion or everyday activities. SAM-e (short for S-adenosylmethionine) is a natural compound that your body produces. But as you age, the levels of SAM-e in your body can decrease and you may need to supplement them.

Flexium provides you with the patented form of SAM-e that is clinically proven to help improve flexibility and ease the pain from daily activities in as little as two weeks. This form of SAM-e is called SD-4, and has been extensively tested to assure that it is both safe and effective. And Flexium is the only brand available at major retailers* that offers this patented form of SAM-e for joint comfort.

Flexium naturally helps promote joint health and comfort as part of your daily health regimen. And specially coated Flexium tablets are gentle enough on your stomach to take every day, as shown in over 20 years of use.

Feel the freedom to do the things you want to do. Let Flexium help make every day a good day.

Recommended Adult Intake: Adults should take one tablet twice a day before meals. Do not use within one hour of taking an antacid or milk; do not chew or crush tablet. Clinical research has shown effectiveness in as little as two weeks with continuous, daily use.

Precautions: Consult a physician if you are taking prescription medication (particularly an antidepressant), are pregnant or nursing. Individuals with bipolar disorder should not use this product. In case of accidental ingestion/overdose, seek the advice of a healthcare professional immediately. **As with other vitamins and supplements, please keep this product out of the reach of children.**

SUPPLEMENT FACTS:

Daily Serving Size 2 tablets
Amount per daily serving:
SAM-e (as S-adenosylmethionine 1,4-butanedisulfonate) 400mg**
**Daily Value not established

Ingredients: S-adenosylmethionine 1,4-butanedisulfonate, microcrystalline cellulose, sodium starch glycolate, methacrylic acid copolymer, talc, polyethylene glycol 6000, colloidal silica, magnesium stearate, polysorbate 80, sodium hydroxide, iron oxide, simethicone

*Major retailers only, excludes health food stores and natural food distributors

Questions about Flexium?

Call toll-free 1-800-451-6688
Or visit our Web site at www.Pharmlaton.com

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.

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NEW!



PHARMATON
NATURAL HEALTH PRODUCTS

Flexium™

SAM-e

JOINT COMFORT



**Naturally Helps Ease Pain & Stiffness
from Everyday Activities***

**Original, Patented Form of SAM-e
Proven Safe & Non-Habit Forming**

Feel Results in as Little as Two Weeks

200 mg
SAM-e SD-4†
†See back panel

20
Enteric Coated
Tablets

DIETARY SUPPLEMENT

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.

FLEXIUM™ is a trademark of Boehringer Ingelheim Pharmaceuticals, Inc.
Distributed by **PHARMATON**
NATURAL HEALTH PRODUCTS
Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
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Visit www.Pharmlaton.com

Flexium SAM-e

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Flexium SAM-e

Visit www.Pharmlaton.com

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Store in a cool, dry place.

40 YEARS
PHARMATON Quality Guarantee
 This product has been proven safe and effective and is manufactured according to rigorous quality standards. With a more than 40 year heritage of dedication to your wellness, PHARMATON stands behind its products and guarantees satisfaction or your money back.

FLEXIUM™ - Make Every Day a Good Day™

Flexium™, with the original, patented form of SAM-e, naturally helps ease the pain and stiffness that can come from physical exertion or everyday activities. SAM-e (short for S-adenosylmethionine) is a natural compound that your body produces. But as you age, the levels of SAM-e in your body can decrease and you may need to supplement them.

Flexium provides you with the patented form of SAM-e that is clinically proven to help improve flexibility and ease the pain from daily activities in as little as two weeks. This form of SAM-e is called SD-4, and has been extensively tested to assure that it is both safe and effective. And Flexium is the only brand available at major retailers* that offers this patented form of SAM-e for joint comfort.

Flexium naturally helps promote joint health and comfort as part of your daily health regimen. And specially coated Flexium tablets are gentle enough on your stomach to take every day, as shown in over 20 years of use.

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Precautions: Consult a physician if you are taking prescription medication (particularly an antidepressant), are pregnant or nursing. Individuals with bipolar disorder should not use this product. In case of accidental ingestion/overdose, seek the advice of a healthcare professional immediately. As with other vitamins and supplements, please keep this product out of the reach of children.

SUPPLEMENT FACTS:

Daily Serving Size 1 tablet
Amount per daily serving:
SAM-e (as S-adenosylmethionine 1,4-butanedisulfonate) 400mg**
**Daily Value not established.

Ingredients: S-adenosylmethionine 1,4-butanedisulfonate, microcrystalline cellulose, methacrylic acid copolymer, sodium starch glycolate, talc, polyethylene glycol 6000, colloidal silica, magnesium stearate, polysorbate 80, sodium hydroxide, iron oxide, simethicone

* Major retailers only, excludes health food stores and natural food distributors

Questions about Flexium?

Call toll-free 1-800-451-6688
Or visit our Web site at www.Pharmaton.com

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NEW!



PHARMATON
NATURAL HEALTH PRODUCTS

Flexium™
Double Strength SAM-e
JOINT COMFORT



Naturally Helps Ease Pain & Stiffness
from Everyday Activities*

Original, Patented Form of SAM-e
Proven Safe & Non-Habit Forming

Feel Results in as Little as Two Weeks

400mg

SAM-e SD-4†
†See back panel

30

Enteric Coated
Tablets

DIETARY SUPPLEMENT

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.

FLEXIUM™ is a trademark of Boehringer Ingelheim Pharmaceuticals, Inc.
Distributed by

PHARMATON
NATURAL HEALTH PRODUCTS

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Flexium
Double Strength SAM-e

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Flexium
Double Strength SAM-e

Visit www.Pharmaton.com

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