



**CHOLESTEROL, PRAVACHOL 10 & YOU BOOKLET**  
**(PREDICT BUSINESS REPLY CARD PB1004-96-00)**  
**(OPTIONS BUSINESS REPLY CARD PB1033-96-00)**

**Cholesterol,  
Pravachol 10  
& You**

(pravastatin sodium)



*How to lower your cholesterol level and  
reduce your risk of coronary heart disease*



**PRAVACARE**

## **Table of Contents**

*Here's to Health*

*Cholesterol and What it Does*

*Page 3*

How Cholesterol Levels Are Measured and Classified

*Page 9*

LDL Cholesterol

HDL Cholesterol

Triglycerides

*Managing Your Other Risk Factors*

Talk to Your Doctor

Smoking

Hypertension and Diabetes

Exercise

Weight Loss

*Page 14*

*Lowering Your Cholesterol With Diet and Exercise*

Page 19

- Diet Can Make a Difference
- Why Saturated Fat is Important
- Shopping
- Adjusting Favorite Recipes
- Cooking

*When Diet Alone Isn't Enough*

Page 25

- Why Drug Therapy is Helpful
- How Pravachol 10 Works
- How Safe is Pravachol 10?
- Taking Pravachol 10
- Minor Side Effects
- Follow-up Exams
- Beyond Pravachol 10

*For More Information*

Page 31

## Here's To Health!

The habits and lifestyles we enjoy in the U.S. come with a price tag, and for many of us that price is a cholesterol level that is higher than it should be. A low-fat diet and exercise plan is the place to start. But some people need more help to get their cholesterol level down. If your cholesterol is still high after trying a diet and exercise plan, Pravachol 10 may be the help you need. To find out... **See your doctor.** You may think it's okay to start taking Pravachol 10 on your own, but it is really important to start by seeing your doctor.

*The habits and lifestyles we enjoy in the U.S. come with a price tag*

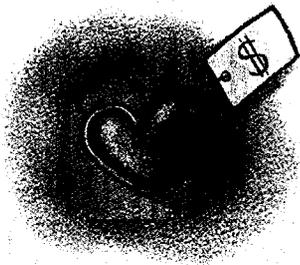
3

*There are two important things you need to do when you see your doctor:*

• **Find out your Total Cholesterol and LDL Cholesterol levels.**

Pravachol 10 is only meant for people who have a mildly elevated cholesterol (a Total Cholesterol between 200-240mg/dL and an LDL Cholesterol of more than 130mg/dL).

• **Discuss your risk factors for heart disease.** In addition to lowering your cholesterol, there are other health changes you may need to make to reduce your risk for heart disease.



4

If you have heart disease (angina, heart attack, etc.) or diabetes or if you have more than one of the following risk factors:

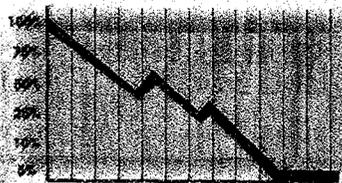
- smoking
- high blood pressure
- a close relative with a heart attack before age 60
- total cholesterol too high (more than 240mg/dL)
- "good" cholesterol too low (less than 35mg/dL)

you should not use Pravachol 10 unless told to do so by a doctor.



5

Treatments to lower cholesterol can make a great deal of difference. Even if you are in good health and have cholesterol that is only slightly elevated, you can reduce your risk of heart disease by



lowering your cholesterol to a healthy level.

Lowering cholesterol is relatively painless. There's no surgery, no shots. And the changes you need to make aren't really as difficult as you might think. Each small step you take adds up. Just one Pravachol 10 tablet daily, added to your diet and exercise program, can really make a difference.

6



# PRAVACARE

This booklet is part of the PravaCare program whose aim is to help you understand what you can do to lower your cholesterol. Call 1-888-200-4758 today to enroll.

You will receive additional information about healthy foods and cooking methods, about cholesterol and what it does, and how Pravachol 10 can help.

7



Success can be yours! Just be sure you take that critical first step of seeing your doctor. With your doctor's advice, you can quickly make Pravachol 10 part of a cholesterol-lowering program.

8

*You can quickly make Pravachol 10 part of a cholesterol-lowering program*

## Cholesterol and What it Does

Cholesterol isn't all bad. It's present everywhere in your body including your skin, muscles, organs, and nervous system. Your body needs a supply of cholesterol to make hormones, vitamin D and to build cell walls. In fact, to make sure your body has enough cholesterol, your liver manufactures it. Under normal circumstances, your liver makes just enough cholesterol to meet all your body's needs.

9

*Over time, these fatty deposits can block an artery, cutting off blood flow*

But when we eat a diet high in cholesterol or high in saturated fat, the body may take in or make too much cholesterol. In some people, the liver simply makes too much to begin with. Extra cholesterol isn't used up. Instead, it floats through the bloodstream and

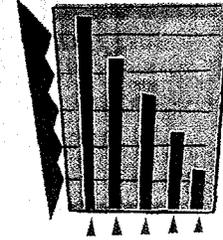
sticks to artery walls. This build-up is known as the disease

atherosclerosis. Over time, these fatty deposits can block an artery, cutting off blood flow. If that happens to the narrow arteries bringing blood to the heart muscle, the result is a heart attack.



### *How Cholesterol Levels Are Measured and Classified*

Your cholesterol level tells you how much cholesterol you have in your blood (called serum cholesterol). A small blood sample taken from your finger or arm is analyzed to find the amount of total cholesterol, LDL and HDL cholesterol and triglycerides present in your blood stream.





LDL cholesterol is often called the “bad” cholesterol, because it tends to stick to artery walls. The first goal of cholesterol therapy is to **lower LDL cholesterol**.

HDL cholesterol is often called the “good” cholesterol because it doesn’t stick to artery walls and seems to remove some bad cholesterol from the bloodstream. If your level of “good” cholesterol is too low (less than 35mg/dL) you may be at greater risk for heart disease. The second goal of cholesterol therapy is to **raise HDL cholesterol**.



12

Triglycerides are a type of fat made by your body from the carbohydrates you eat. Your triglycerides are high if they are over 200 mg/dL. High triglycerides increase the risk of heart disease only in some people. But in general, the third goal of cholesterol therapy is to **lower triglycerides**.



13

## Managing Other Risk Factors

### *Talk to Your Doctor About Risk Factors and Heart Disease*

There are several risk factors (health problems) that have been shown to increase the risk of heart disease. High cholesterol is only one risk factor. There are other risk factors as well. Some of these you cannot help (age, family history of heart disease). But there are five other factors you can do something about.

14

If you have any of these factors, ask your doctor for a plan to get them under control.

### *Risk Factors You Can Change:*

Cigarette smoking

High blood pressure

Diabetes

Lack of physical activity

Excess weight

Don't be discouraged. You don't have to make these changes overnight.

15

*There are five other important factors you can do something about:*

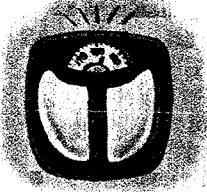
### *Exercise for Energy and Lower Cholesterol*

Exercise not only burns off extra body fat and increases your endurance, it also improves your cholesterol levels. Regular physical activity increases the amount of high-density lipoprotein or HDL cholesterol, the "good" type of cholesterol. It also reduces levels of low-density lipoprotein, or LDL cholesterol, the "bad" type. High levels of LDL cholesterol are linked to heart disease.



### *Maintain an Appropriate Weight*

Excess weight is another risk factor for coronary disease. It is also linked to other conditions such as high blood pressure, high cholesterol, and diabetes. A healthy low-fat eating plan coupled with moderate exercise can result in weight loss as well as lower cholesterol.

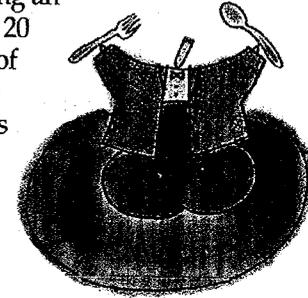


18

## **Lowering Your Cholesterol With Diet and Exercise**

### *Diet Can Make a Difference*

Limit your intake of saturated fat to 8% - 10% of total calories, limit total fat to 30% or less of calories, and less than 2 grams of saturated fat per serving. Thus, a man eating an average 2,500 calorie-a-day diet is allowed 20 to 25 grams of saturated fat and 75 grams of total fat. A woman eating an average 2,000 calorie-a-day diet is allowed 16 to 20 grams of saturated fat and 60 grams of total fat.



19

### *Why Saturated Fat is Important*

Experts say that saturated fat raises your blood cholesterol level more than anything else in your diet. Saturated fat is found mostly in foods from animals such as meat, poultry, and dairy products.

A few vegetable oils – mainly coconut and palm oil – are also high in saturated fat. These are found mainly in pre-made cakes and cookies.

Polyunsaturated fats are healthier alternatives taken from vegetables in the form of oils.

Monounsaturated fats, such as olive oil, are also better for you than saturated fats. A good rule of thumb: Saturated fats are usually solid at room temperature, while monounsaturated and polyunsaturated fats are usually liquid at room temperature.



20

Reducing the amount of total fat you eat is the most effective way to make improvements in your diet.

A diet low in saturated fat and cholesterol doesn't have to be boring. In fact,

this is an opportunity to

try tasty recipes and cooking styles you might not have considered before. The many new low-fat and fat-free products make it easier than ever to keep to the plan. But when reading food labels remember, "Cholesterol-Free" on a package is good, but it still may contain more fat than is good for you.



*A low-saturated fat, low-cholesterol diet doesn't have to be boring.*

21

## Shopping

- Pick up more fresh fruit & vegetables (or canned or frozen ones packed in water or their own juices).
- Choose breads and cereals that are whole-grain varieties.
- Plan to eat red meat less often and substitute leaner cuts such as bottom round, top round, sirloin tip, and tenderloin.
- Choose low-fat dairy products. Cheese, sour cream, yogurt and milk are all available in low-fat or fat-free varieties.
- Check the grams of fat and saturated fat per serving on food labels. A rule of thumb: Try to stay below 2 grams of saturated fat per serving.

22

*Try to stay  
below 2 grams  
of saturated  
fat per  
serving*

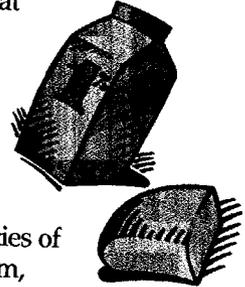
## Adjusting Favorite Recipes

Low-fat alternatives can often be switched for high-fat ingredients in your favorite recipes – and you'll hardly notice the difference. Try these lower fat alternatives:

- Use low-fat spreads - mustard or non-fat mayonnaise - on sandwiches.
- Use low - or non-fat salad dressings and sauces.
- Substitute ingredients - use low - or non-fat varieties of any dairy item in a recipe (milk, cheese, sour cream, cottage cheese).
- Always use olive or sunflower oil instead of butter or margarine.

Small changes like these add up quickly to big differences in the amount of fat in your diet.

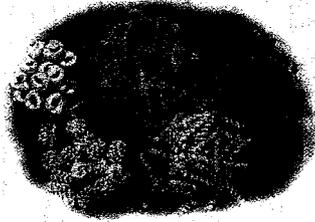
23



## When Diet Alone Isn't Enough

### Cooking

- Trim off all visible fat from meat and remove skin from poultry before cooking.
- Steam, broil, poach, boil, bake, microwave or roast (on a roasting rack) your foods. Avoid deep-frying or frying with butter or lard.
- Cook more pasta. Pasta makes an extremely versatile, inexpensive, and delicious high-carbohydrate, low-fat meal. Avoid cream and cheese sauces.
- Use lemon juice, low-fat sauces, and fat-free salad dressings to add that satisfying zip instead of butter or margarine, gravy, cream sauces, and oil-based salad dressings.



24

### Why Drug Therapy is Helpful

Your doctor knows Pravachol 10 is effective in improving your overall cholesterol profile in three important ways:

- lowering your LDL ("bad") cholesterol level
- raising your HDL ("good") cholesterol level
- lowering your triglycerides

Pravachol 10 has an impressive proven record of safety. Pravachol 10 is a low-dose version of the popular prescription drug, Pravachol, which has been prescribed by doctors over 30 million times.

This section of the booklet explains exactly how Pravachol 10 works, how it complements the healthy steps you've taken in your lifestyle, and how to take the drug so you can lower your cholesterol effectively.

25

### *How Pravachol 10 Works*

Pravachol 10 works to effectively improve your cholesterol by preventing the body from making too much "bad" cholesterol. In addition, Pravachol 10 helps your body make more of the "good" cholesterol and reduces triglycerides.

### *How Safe Is Pravachol 10?*

Pravachol 10 has been taken by millions of patients for many years as a prescription medication. Most doctors are very familiar with this medication and recognize its long record of safety. In fact, the medication in Pravachol 10 has been studied in more patients than any other medication of its kind.

26

*Pravachol 10  
has been taken  
by millions of  
patients for  
many years...*

### *Taking Pravachol 10*

Pravachol 10 is easy to take. Just one tablet a day, at bedtime. Do not take more than one tablet a day. If you miss or forget a dose, skip it. Do not try to "catch up" with doses you missed. Just start again the next day with one tablet. Taking Pravachol 10 at bedtime helps make it more effective. This is because your body makes most of its cholesterol while you sleep. But if bedtime is not convenient for you, take it once a day at some other time that works for your schedule.

### *Minor Side Effects*

Pravachol 10 is generally well tolerated. Side effects are usually mild and last only a short time. Some mild side effects, such as a slight rash or stomach upset, occur in about 2 - 4% of people.

27

But if symptoms persist, contact your doctor. It is especially important to contact your doctor if these side effects include any unusual muscle pain or tenderness (especially if you also feel weak and have a fever) or if you have any unusual loss of appetite along with stomach pains.

*See Your Doctor for Follow-Up Exams*

Along with your initial doctor visit, it is important that you have some regular follow-up visits. This will help you and your doctor track your progress. Your first follow-up exam should occur about six to eight weeks after you first start taking Pravachol 10. If Pravachol 10 has lowered your cholesterol to a healthy level, keep taking it daily. It is preventing the damage that may lead to a heart attack. Don't stop taking Pravachol 10 once your cholesterol is under control. For most people, cholesterol will go back up if left untreated. To be sure your cholesterol remains under control, have your cholesterol checked once a year, or as directed by your doctor.

Use this handy schedule to call your doctor and plan your follow-up visits now. You can tear this page out of the booklet and put it on your refrigerator to help you remember your appointment times and dates.

|   | Date: | Cholesterol Test Results |           | Healthy Cholesterol Level |           |
|---|-------|--------------------------|-----------|---------------------------|-----------|
|   |       | Total Chol.              | LDL Chol. | Total Chol.               | LDL Chol. |
| Baseline (when I started to take Pravachol 10)            |       |                          |           |                           |           |
| Follow-Up Visit (after taking Pravachol 10 for 6-8 weeks) |       |                          |           |                           |           |
| My One-Year Follow-Up Visit                               |       |                          |           |                           |           |

### *Beyond Pravachol 10*

For many people, Pravachol 10 will lower cholesterol to a healthy level and help keep it there as long as you continue to take it. Some people are at increased risk of cholesterol damage. This includes people who have heart disease or diabetes. If you're one of these people or if your risk factors change, you may need a prescription-strength product.

Ask your doctor if you feel you need a prescription-strength medication.

30

### *For More Information...*

If you would like more information about high cholesterol and how to lower it, there are many sources you can turn to. Ask at your local library for books about cholesterol or for heart-healthy cookbooks. Other centers for information include:

American Heart Association  
7272 Greenville Avenue  
Dallas, TX 75231  
(800) 242-8721

Citizens for Public Action Against Cholesterol  
P.O. Box 30374  
Bethesda, MD 20824  
(301) 770-1711

31

*Questions to ask your doctor*

- What is my current total cholesterol level?
- What is my current LDL or "bad" cholesterol level?
- What is my current HDL or "good" cholesterol level?
- Do I have other cardiovascular risk factors?
- What is a healthy cholesterol level for me?
- What diet and exercise program is right for me?
- Is Pravachol 10 right for me?

Free Enrollment in



Name \_\_\_\_\_  
please print

Address \_\_\_\_\_

Apt. \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_ Zip \_\_\_\_\_

Subject # (See package) \_\_\_\_\_

Yes!

Please enroll me today in the FREE PravaCare Patient Newsletter Program. I understand that my name and address will be kept confidential by the Bristol-Myers Squibb Company.

There are two easy ways to enroll:

1. Mail this postcard today or
2. Call 1-888-200-4758

You will receive a series of four newsletters designed just for Pravachol 10 users. Articles include additional tips on how to get the most out of your diet, exercise and medication program.

PB1004-96-00

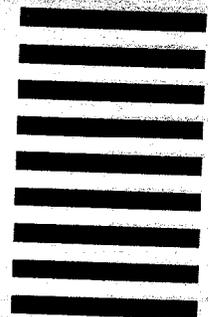


NO POSTAGE  
NECESSARY  
IF MAILED IN THE  
UNITED STATES

**BUSINESS REPLY MAIL**  
FIRST-CLASS MAIL PERMIT NO 4519 ELIZABETH, NJ

POSTAGE WILL BE PAID BY ADDRESSEE

PravaCare Enrollment Center  
Bristol-Myers Products  
1350 Liberty Avenue  
Hillside, NJ 07205-9889



Free Enrollment in



Name \_\_\_\_\_  
please print

Address \_\_\_\_\_

Apt. \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_ Zip \_\_\_\_\_

Subject # (See package) \_\_\_\_\_

Yes!

Please enroll me today in the FREE PravaCare Patient Newsletter Program. I understand that my name and address will be kept confidential by the Bristol-Myers Squibb Company.

There are two easy ways to enroll:

1. Mail this postcard today *or*
2. Call 1-800-814-8392

You will receive newsletters designed just for Pravachol 10 users. Articles include additional tips on how to get the most out of your diet, exercise and medication program.

PB1033-96-00

Enroll in the PravaCare,  
Patient Support Program and  
you will receive



1 year subscription to



Good on your  
next purchase



Subscription to  
PravaCare Program  
Newsletter

NO POSTAGE  
NECESSARY  
IF MAILED IN THE  
UNITED STATES



**BUSINESS REPLY MAIL**

FIRST-CLASS MAIL PERMIT NO 4519 ELIZABETH, NJ

POSTAGE WILL BE PAID BY ADDRESSEE

PravaCare Enrollment Center  
Bristol-Myers Products  
1350 Liberty Avenue  
Hillside, NJ 07205-9889



**Enroll in the PravaCare,  
Patient Support Program**

Call now, toll free at **1-800-814-8392** or  
mail the attached reply card to enroll.  
It's **100% FREE**, and your address will  
be kept **100% CONFIDENTIAL**

You will receive:

- A one year (10 issues) subscription to full of great ideas and delicious, low-fat recipes for healthy living.
- A \_\_\_\_\_ on your next purchase of Pravachol 10.
- Subscription to the \_\_\_\_\_

with tips on getting the most out of your program of exercise, diet and medication.

**PREDICT  
PACKAGE INSERT**

CHOLESTEROL REDUCER

**PRAVACHOL<sup>®</sup> 10**  
Pravastatin sodium, 10mg tablets

Only certain information is printed on the package label.  
Please read this leaflet thoroughly.

**KEEP ENTIRE LEAFLET FOR FUTURE USE**

**FREE ENROLLMENT  
IN  
PRAVA CARE  
1-888-200-4758**

An information and support newsletter  
program for Pravachol 10 users.

PB1015-38-00

**How Pravachol 10 Works  
To Improve Cholesterol.**

Pravachol 10 works three ways to improve your cholesterol profile. First, it reduces the "bad cholesterol" (LDL cholesterol) by blocking a step the body takes in making cholesterol. Second, Pravachol 10 helps your body make more of the "good cholesterol" (HDL cholesterol). Third, Pravachol 10 reduces your triglycerides.

**What is in Pravachol 10?**

The active ingredient in Pravachol 10 is called pravastatin sodium. This ingredient has been proven to lower cholesterol for millions of patients in prescription form. Doctors have written over 30 million prescriptions for the ingredient in Pravachol 10.

**How do I know if I need Pravachol 10?**

Start out by getting your cholesterol level tested and talking to your doctor about it as well as other risk factors for heart disease. Most people get their cholesterol tested by their doctor, but you can often go to your company health office, local clinic, hospital or pharmacy.

than one of the following risk factors for heart disease:

- Smoking
- High Blood Pressure
- Family History of Heart Disease (a close relative had a heart attack before age 60)
- Total Cholesterol that is more than 240 mg/dL and/or your good cholesterol (HDL) is very low.

These conditions and risk factors put you at greater risk from cholesterol damage. You may need prescription treatment. Lastly, if you drink 3 or more alcoholic beverages daily, you may have liver disease and not know about it. People known to have liver disease, should not take Pravachol 10. Be sure to ask your doctor before using Pravachol 10, if any of the above conditions apply to you.

**What about side effects?**

Over a billion doses of the ingredient in Pravachol 10 have been taken by millions of patients in the U.S. alone. During this time, it has been generally well tolerated. But talk to your doctor about any side effect that does not go away, or comes and goes. This is very important if it includes certain "flu like" symptoms (muscle pain or tenderness with fever) that don't seem to have any other explanation such as a cold, recent injury or sprain.

**Before You Start... See Your Doctor**

You need to find out your Total and LDL Cholesterol levels. It is important to know both these levels to determine if Pravachol 10 is right for you. You also need to discuss other risk factors you may have for heart disease. People with too many risk factors are at greater risk from cholesterol damage and should seek prescription treatment. If you have heart disease or diabetes, you should not use this product, unless told to do so by a doctor.

**What Causes Elevated Cholesterol?**

Cholesterol is important to your body for normal structure and function. Under most circumstances, your body makes just enough cholesterol to meet all your body's needs. When we eat a diet high in cholesterol or high in saturated fat, the body may take in too much cholesterol. In this case, reducing the amount of cholesterol and saturated fat in your diet is the best way to lower your cholesterol. But in some people, the body simply makes too much to begin with. In that case, controlling your diet will help, but it will take medication to get and keep your cholesterol at a healthy level.

Just be sure it's a test that gives the following results:

- Your Total Cholesterol number
- The amount of the total that is "bad" cholesterol (your LDL Cholesterol).
- The amount of the total that is "good" cholesterol (your HDL Cholesterol).

If your Total Cholesterol number is between 200 and 240 mg/dL and your LDL Cholesterol ("bad cholesterol" portion) is more than 130 mg/dL, a program of a low-fat diet, exercise and Pravachol 10 can help.

**Who should not use Pravachol 10?**

Certain people should not take Pravachol 10. This includes people already taking cholesterol lowering medicines (including niacin) or the antibiotic erythromycin. Also, women who are pregnant, can become pregnant or are nursing. Lastly, anyone with liver disease, anyone under the age of 18 or people with allergies to any of the ingredients in Pravachol 10, should not take it.

**Pravachol 10 may not be right for you if...**

You have heart disease, diabetes, any ongoing condition that needs a doctor's care, or if you have more

**TAKING Pravachol 10 FOR BEST RESULTS**

**Take Pravachol 10 on a regular basis.** To get the best effects from Pravachol 10, it is very important to take your dose each day. Do not take more or less of it during any one day. If you should forget a dose until the next day, skip it; do not try to catch up with the dose you missed a day before.

**Take Pravachol 10 at bed time.** Because your body makes most of its cholesterol at night, the best time to take Pravachol 10 is at bed time. But any time of day is alright, just pick a time that is easy for you to remember and stick to it.

**While you are taking Pravachol 10** it is important to continue to do all of the things that improve your chance of preventing a heart attack, including eating a low-fat diet, maintaining normal weight, exercising regularly, stopping smoking, and taking your Pravachol 10 daily.

**Continue to take Pravachol 10** even after your cholesterol level goes down. In general, any treatment of high cholesterol must be continued in order to keep cholesterol levels down. If you stop taking Pravachol 10, your cholesterol level will go back up.

**Active Ingredient:** Pravastatin sodium, 10mg per tablet

**Purpose:** Cholesterol reducer

**Use:** To lower LDL cholesterol if it is still high after a program of diet and exercise AND

- Your Total Cholesterol number is between 200 - 240 mg/dL AND
- Your LDL Cholesterol ("bad cholesterol" portion) is more than 130 mg/dL.

*Before you start it is important to talk with your doctor about both your Total and LDL Cholesterol numbers and your risk factors for heart disease.*

**WARNINGS:**

**Do Not Use if You Are:**

- Already taking cholesterol medication (including niacin) or are taking erythromycin (an antibiotic).
- Pregnant, can become pregnant, or are nursing.
- Known to have liver disease.
- Under 18 years of age.
- Allergic to pravastatin or any of the inactive ingredients.

**Ask Your Doctor Before Use If:**

- You have heart disease, diabetes or any other ongoing condition that needs a doctor's care.
- You have more than one of these risk factors for heart disease:
  - Smoking,
  - High Blood Pressure,
  - Family History of Heart Disease (a close relative had a heart attack before age 60).
  - Your Total Cholesterol is more than 240 mg/dL and/or your good cholesterol (HDL) is very low.
- You drink 3 or more alcoholic beverages daily.

**When Using This Product**

**See Your Doctor:**

- If you have any unusual muscle pain or tenderness. This is very important if you also feel weak or have a fever.
- If the number of risk factors you have for heart disease changes.

**Keep this and all other drugs out of reach of children.** In case of accidental overdose, get medical help right away or contact a poison control center immediately.

**Directions:**

- Take 1 tablet every day, at bedtime.
- 8 weeks later, consult your doctor once more to find out if you have reached a healthy cholesterol level.
  - If you *have reached* a healthy cholesterol level, keep taking Pravachol 10. This will help you stay at a healthy cholesterol level.
  - If you *haven't reached* a healthy cholesterol level, you may need a prescription dose of Pravachol. You are still at risk for heart disease.
- Once a year have your cholesterol level checked.
- Continue to exercise and stay on a low-fat diet.

**Inactive Ingredients:** Croscarmellose sodium, lactose, magnesium stearate, microcrystalline cellulose and povidone.

**DIST. BY:**  
BRISTOL-MYERS PRODUCTS  
A BRISTOL-MYERS SQUIBB CO.  
©1997, NY, NY 10154 MADE IN USA

**Where To Go For More Information**

Many sources are available for additional information on making healthy lifestyle changes, and a few sources are listed below. Limited quantities of most materials are free of charge.

**American Heart Association**  
7272 Greenville Avenue  
Dallas, TX 75231-4596  
1-800-242-8721  
[www.americanheart.org](http://www.americanheart.org)

**Citizens for Public Action Against Cholesterol**  
Box 30374  
Bethesda, MD 20824  
1-301-770-1711

**OPTIONS  
PACKAGE INSERT**

CHOLESTEROL REDUCER

**PRAVACHOL® 10**  
Pravastatin sodium, 10mg tablets

Only certain information is printed on the package label.  
Please read all of this leaflet.

**KEEP ENTIRE LEAFLET FOR FUTURE USE**

FREE ENROLLMENT IN

**PRAVACARE**

A consumer support  
and newsletter program.  
Call Toll-Free

**1-800-814-8392**

All information kept confidential

PB1035-38-00

## Before You Start... See Your Doctor

Your doctor will check your cholesterol levels to find out how high your total cholesterol is, as well as your "good" (HDL) and "bad" (LDL) cholesterol and triglycerides. You also need to find out if you have other risk factors for heart disease that you may not know about. Your doctor needs all this information to know if Pravachol 10 is right for you. People with too many risk factors are at greater risk from cholesterol damage and may need prescription treatment. If you have heart disease or diabetes, you may need extra care and should not use this product unless told to do so by a doctor.

## What Causes Elevated Cholesterol?

Cholesterol is important to your body for normal structure and function. Under most circumstances, your body makes just enough cholesterol to meet all your body's needs. When we eat a diet high in cholesterol or high in saturated fat, the body may take in too much cholesterol. In this case, reducing the amount of cholesterol and saturated fat in your diet is the best way to lower your cholesterol. But in some people, the body simply makes too much to begin with. In that case, controlling your diet will help, but it will take medication to attain and keep your cholesterol at a healthy level.

## How do I know if I need Pravachol 10?

Start out by getting your cholesterol levels checked and talking to your doctor about your test results as well as other risk factors for heart disease. If your total cholesterol level is *between 200-240 mg/dL* even after a program of diet and exercise, AND you are a *man 35 yrs. or older* OR a *woman 55 yrs. or older*, Pravachol 10 may be right for you.

## Pravachol 10 may not be right for you if..

- Your total cholesterol is below 200 mg/dL OR if you are younger in age (less than 35 for men, less than 55 for women).
- Your cholesterol is above 240 mg/dL OR if you have more than one of the following

risk factors for heart disease:

- Smoking
- High Blood Pressure
- Family History of Heart Disease (a close relative had a heart attack before age 60)

If any of these factors describe you, you are at increased risk for cholesterol damage and may need prescription-strength Pravachol.

Always talk to your doctor before using Pravachol 10, and be sure to mention the above conditions that apply to you.

## Who should not use Pravachol 10?

Certain people should not take Pravachol 10. Women who are pregnant or breast-feeding should not take any medication unless told to do so by their doctor. Because cholesterol is critical to the development of a healthy baby (fetus), Pravachol 10 should not be

taken by women who are pregnant, breast-feeding or able to become pregnant. You are able to become pregnant if you have not yet gone through menopause (periods stopped for one year) or are not surgically sterile. If you become pregnant while on Pravachol 10, stop taking it right away and consult your doctor.

Anyone with liver disease or anyone who drinks 3 or more alcoholic beverages daily should not take Pravachol 10.

Anyone with heart disease or diabetes may need prescription-strength Pravachol and should only take Pravachol 10 if told to do so by a doctor.

People with allergies to any of the ingredients in Pravachol 10, people taking prescription medicines to lower cholesterol, or people taking the antibiotic erythromycin, should

not take Pravachol 10. Pravachol 10 should not be given to children.

### What is in Pravachol 10?

The active ingredient in Pravachol 10 is called *pravastatin sodium*. In prescription form, this ingredient has been proven to lower cholesterol for millions of patients. Doctors have written over 30 million prescriptions for the ingredient in Pravachol 10. The amount of sodium contained in Pravachol 10 is so small, it is an insignificant part of daily sodium intake.

### What about side effects?

Over a billion doses of the ingredient in Pravachol 10 have been taken by millions of patients in the U.S. alone. During this time, it has been generally well-tolerated. But talk to your doctor about any side effect that does not go away, or worsens. This is

very important if it includes any unusual muscle pain or tenderness with fever, that doesn't seem to have any other explanation (such as a cold, recent injury or sprain).

### TAKING Pravachol 10 FOR BEST RESULTS

#### Take Pravachol 10 on a regular basis.

To get the best effects from Pravachol 10, it is very important to take your dose every day. Do not take more or less of it during any one day. If you should forget to take a dose, skip it; do not try to catch up with the dose you missed a day before.

**Take Pravachol 10 at bedtime.** Because your body makes most of its cholesterol at night, the best time to take Pravachol 10 is at bedtime. But any time of day is alright; just pick a time that is easy for you to remember and stick to it.

**Check back with your doctor after the first 8 weeks.** You will want to find out if you have reached a healthy cholesterol level yet.

#### Continue to take Pravachol 10

even after your cholesterol level goes down. In general, any treatment of high cholesterol must be continued in order to keep cholesterol levels down. If you stop taking Pravachol 10, your cholesterol level will go back up.

In addition, it is important to continue to do all of the other things that improve your chance of preventing a heart attack. This includes eating a low-fat diet, maintaining normal weight, exercising regularly and stopping smoking.

**Every year** make an appointment with your doctor to have your cholesterol level checked. You may need a prescription dose of Pravachol if your cholesterol levels have gone up again.

### Where To Go For More Information

Many sources are available for additional information on making healthy lifestyle changes. One source is listed below. Limited quantities of most materials are free of charge.

American Heart Association  
7272 Greenville Avenue  
Dallas, TX 75231-4596  
1-800-242-8721  
[www.americanheart.org](http://www.americanheart.org)

**ACTIVE INGREDIENT:** Pravastatin sodium, 10 mg per tablet

**PURPOSE:** Cholesterol reducer

**USE:** To lower cholesterol if it is between 200 - 240 mg/dL after a program of diet and exercise **AND**

- For **MEN:** You are 35 years of age or older.
- For **WOMEN:** You are 55 years of age or older. For women, the risk of heart disease increases after menopause.

#### WARNINGS

##### Do Not Use if You Are

- Pregnant, nursing, or still able to become pregnant.
- Known to have Heart disease, Diabetes, or Liver disease (unless told to do so by a doctor).
- Taking prescription medication to lower your cholesterol.
- Taking erythromycin (an antibiotic).
- Someone who drinks 3 or more alcoholic beverages daily.
- A man less than 35 yrs. or a woman less than 35 yrs.
- Allergic to pravastatin or any of the inactive ingredients.

**Not for use in children. Keep out of reach of children.** In case of overdose, get medical help or contact a poison control center right away.

#### Before Use Ask Your Doctor About

- Your cholesterol levels.
- These risk factors for heart disease: Smoking, High blood pressure, Family history of heart disease.

*If your cholesterol is too high, or you have too many risk factors, you are at increased risk for cholesterol damage and may need prescription strength Pravachol. See your doctor for more advice.*

#### When Using This Product See Your Doctor

- If you have any unusual muscle pain or tenderness that is not caused by a cold, flu, recent injury or sprain. This is very important if you also feel weak or have a fever.

#### DIRECTIONS:

- Take 1 tablet every day, at bedtime.
- 8 weeks later, consult your doctor once more to find out if you have reached a healthy cholesterol level.
  - If you have reached a healthy cholesterol level, keep taking Pravachol 10 to stay at a healthy level.
  - If you haven't reached a healthy cholesterol level, you may need a prescription dose of Pravachol.
- Once a year have your cholesterol level checked.
- Continue to exercise and stay on a low-fat diet.

**Inactive Ingredients:** Croscarmellose sodium, lactose, magnesium oxide, magnesium stearate, microcrystalline cellulose and povidone.

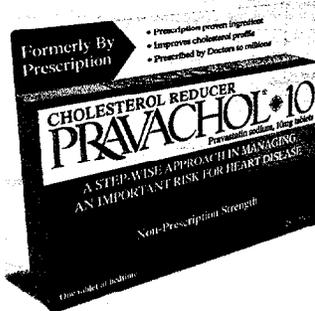
DIST. BY:  
BRISTOL-MYERS PRODUCTS  
A BRISTOL-MYERS SQUIBB CO.  
© 1998, NY, NY 10154 MADE IN USA

MANUFACTURER'S COUPON

EXPIRES 6/30/99

# SAVE \$5.00

On your next purchase of



**STUDY SUBJECT:** Only one coupon is redeemable per purchase and only on specified product. **STUDY SITE:** You are authorized to act as our agent and redeem this coupon at face value on specified product. Collect this coupon and return it with all other study materials at the end of the trial.  
**EXPIRES 6/30/99.**

PB1012-35-00