

PATIENT INFORMATION LEAFLET
INFORMATION FOR THE PATIENT ABOUT INEGY™

Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription.

- Some of the information in the previous leaflet may have changed.
- You should also read any information provided with other medicines you are currently taking.
- Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

INEGY™ 10/10 Tablet

INEGY™ 10/20 Tablet

INEGY™ 10/40 Tablet

INEGY™ 10/80 Tablet

COMPOSITION

What INEGY contains

Each INEGY 10/10 tablet contains 10 mg ezetimibe and 10 mg simvastatin.

Each INEGY 10/20 tablet contains 10 mg ezetimibe and 20 mg simvastatin.

Each INEGY 10/40 tablet contains 10 mg ezetimibe and 40 mg simvastatin.

Each INEGY 10/80 tablet contains 10 mg ezetimibe and 80 mg simvastatin.

INEGY contains 0,02 % m/m butylated hydroxyanisole and 0,005 % m/m propyl gallate as anti-oxidants.

In addition, INEGY contains the following inactive ingredients:

Butylated Hydroxyanisole, Citric Acid Monohydrate, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose and Propyl Gallate.

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INDICATIONS AND USE OF INEGY

INEGY is a medicine used to lower levels of total cholesterol, LDL cholesterol, and fatty substances called triglycerides in the blood. In addition, INEGY raises levels of HDL cholesterol. It is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

How does INEGY work?

INEGY works to reduce your cholesterol in two ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself. INEGY does not help you lose weight.

Why has my doctor prescribed INEGY?

Your doctor has prescribed INEGY to reduce the amount of cholesterol and triglycerides in your blood. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

How can high cholesterol be treated?

High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed INEGY to help lower your cholesterol.

BEFORE TAKING THIS MEDICINE

What should I know before and while taking INEGY?

It is important that you continue taking INEGY daily as prescribed by your doctor.

Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Use in elderly

No special precautions.

Use in children

INEGY is not recommended in children.

Who should not take INEGY?

Patients who:

- are hypersensitive (allergic) to ezetimibe, simvastatin, or any of the other ingredients of INEGY tablets
- have active liver disease
- are pregnant or breastfeeding
- are children as safety and efficacy have not been demonstrated

What should I tell my doctor [or pharmacist] before and while taking INEGY?

Tell your doctor about:

Pregnancy: Do not use INEGY if you are pregnant, trying to become pregnant or suspect that you are pregnant. If you become pregnant while taking INEGY, stop taking it and contact your physician immediately.

Breastfeeding: Do not use INEGY if you are breast-feeding.

Other Medicines: Talk about any other medicines that you are taking or plan to take. Include those you can get without a prescription.

Medical problems or allergies: Talk about any medical problems (including liver disease or liver problems) or allergies you have now or have had in the past. Tell your doctor if you consume substantial quantities of alcohol or have a past history of liver disease.

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

The risk of muscle breakdown is greater at higher doses of INEGY.

The risk of muscle breakdown is greater in patients with kidney problems.

Can I take INEGY with other medicines?

Because taking INEGY with any of the following medicines can increase the risk of muscle problems (see **What undesirable effects may INEGY have?**), it is particularly important to tell your doctor if you are taking:

- cyclosporin
- danazol
- antifungal agents (such as itraconazole or ketoconazole)
- fibric acid derivatives (such as gemfibrozil and bezafibrate)
- the antibiotics erythromycin, clarithromycin, telithromycin and fusidic acid
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir, and saquinavir)
- the antidepressant nefazodone
- amiodarone (a drug used to treat an irregular heartbeat)
- verapamil or diltiazem (drugs used to treat high blood pressure, angina, or other heart conditions)
- large doses (greater than or equal to 1 g/day) of niacin or nicotinic acid.

It is also important to tell your doctor if you are taking anticoagulants (medicines that prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol) or fenofibrate, another fibric acid derivative.

You should always tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription.

Can I drive or operate machinery while using INEGY?

There have been side effects reported with INEGY that may affect your ability to drive or operate machinery. Individual responses to INEGY may vary (see What undesirable effects may INEGY have?).

IF YOU ARE TAKING MEDICINES ON A REGULAR BASIS, CONCOMITANT USE OF THE MEDICINE MAY CAUSE UNDESIRABLE INTERACTIONS. PLEASE CONSULT YOUR DOCTOR, PHARMACIST OR OTHER HEALTH CARE PROFESSIONAL FOR ADVICE.

IF YOU ARE PREGNANT OR BREAST FEEDING YOUR BABY WHILE TAKING THIS MEDICINE PLEASE CONSULT YOUR DOCTOR, PHARMACIST OR OTHER HEALTH CARE PROFESSIONAL FOR ADVICE.

HOW TO TAKE THIS MEDICINE

How should I take INEGY?

- take one INEGY 10/10, 10/20, 10/40 or 10/80 tablet by mouth each day, in the evening
- take INEGY with or without food
- if your doctor has prescribed INEGY along with cholestyramine (a bile acid sequestrant) or any other bile acid sequestrant, INEGY should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant
- INEGY should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop

Do not share medicines prescribed for you with others.

What should I do if I take more INEGY than I should?

Take INEGY only as prescribed for you. If you take more INEGY than you were prescribed consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

What should I do if I miss a dose?

Try to take INEGY as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

SIDE EFFECTS

What undesirable effects may INEGY have?

In clinical studies, INEGY was generally well tolerated. The side effects were usually mild, temporary, and similar in type and frequency to side effects in patients who were given ezetimibe alone or simvastatin alone.

The following common side effects were reported: headache and muscle aches (see **What should I tell my doctor [or pharmacist] before and while taking [or using] INEGY?**).

Additionally, the following side effects have been reported in general use with either ezetimibe or simvastatin tablets (tablets that contain the active ingredients of INEGY):

- allergic reactions including swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (which may require treatment right away), rash and hives, raised red rash, sometimes with target-shaped lesions, joint pain, alterations in some laboratory blood tests, liver problems (sometimes serious), inflammation of the pancreas, nausea, dizziness, tingling sensation, depression, gallstones, inflammation of the gallbladder, trouble sleeping, poor memory.

Talk to your doctor anytime you have a medical problem you think may be related to INEGY.

If you are prescribed INEGY, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment.

Not all side-effects reported for this medicine are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

HOW CAN I LEARN MORE ABOUT INEGY AND THE CONDITIONS FOR WHICH IT IS PRESCRIBED?

You may obtain further information from your doctor or pharmacist.

STORAGE AND DISPOSAL INFORMATION

How long should I keep INEGY?

Do not use this medicine after the month and year following EXPIRES/VERVAL on the carton.

How should I store INEGY?

Store below 30 °C.

Keep INEGY and all medications away from children.

PRESENTATION

INEGY 10/10: Aluminium blister with push-through aluminium lidding; pack of 30 tablets.

INEGY 10/20: White opaque PVC/Aclar blister with push-through aluminium lidding; pack of 30 tablets.

INEGY 10/40: White opaque PVC/Aclar blister with push-through aluminium lidding; pack of 30 tablets.

INEGY 10/80: White opaque PVC/Aclar blister with push-through aluminium lidding; pack of 30 tablets.

IDENTIFICATION

INEGY 10/10 is a white to off-white, capsule shaped, biconvex compressed tablet debossed with 311 on one side and plain on the other side

INEGY 10/20 is a white to off-white, capsule shaped, biconvex compressed tablet debossed with 312 on one side and plain on the other side.

INEGY 10/40 is a white to off-white, capsule shaped, biconvex compressed tablet debossed with 313 on one side and plain on the other side.

INEGY 10/80 is a white to off-white, capsule shaped, biconvex compressed tablet debossed with 315 on one side and plain on the other side.

REGISTRATION NUMBERS

INEGY 10/10: A39/7.5/0031

INEGY 10/20: A39/7.5/0032

INEGY 10/40: A39/7.5/0033

INEGY 10/80: A39/7.5/0034

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

MSD (Pty) Ltd

16th Road

Halfway House

1685

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Co-promoted by:

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