INEGY® 10mg/40mg Tablets
(ezetimibe and simvastatin)

Read all of this leaflet carefully before you start taking this medicine.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
4. If you notice any side effects, consult your doctor or pharmacist.

The name of your medicine is INEGY 10mg/40mg Tablets, but will be referred to as INEGY throughout this leaflet. Please note that this leaflet also contains information about other strengths INEGY 20mg/20mg Tablets and INEGY 10mg/80mg Tablets.

In this leaflet:
1. What INEGY is and what it is used for
2. How to take INEGY
3. Possible side effects
4. How to store INEGY
5. Further information

1. WHAT INEGY IS AND WHAT IT IS USED FOR

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

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. INEGY is used in addition to diet if you have:
- a raised cholesterol level in your blood (primary hypercholesterolaemia (heterozygous familial and non-familial)) or elevated fat levels in your blood (mixed hyperlipidaemia):
  - that is not well controlled with a statin alone
  - for which you have used a statin and ezetimibe as separate tablets
- a hereditary illness (familial homozgyous hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.

2. BEFORE YOU TAKE INEGY

Do not take INEGY if:
- you are allergic (hypersensitive) to ezetimibe, simvastatin, or any of the other ingredients of INEGY Tablets (see Section 6: FURTHER INFORMATION)
- you currently have liver problems
- you are pregnant or breast-feeding
- you are taking one or more than one of the following drugs at the same time:
  - iraconazole, ketoconazole, or posaconazole (medicines for fungal infections)
  - erythromycin, clarithromycin, or telithromycin (antibiotics for infections)
  - HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (HIV protease inhibitors are used for HIV infections)
  - ciclosporin or tacrolimus (medicines for hepatitis C virus infection)
  - nefazodone (a medicine for depression)
  - valsartan, losartan, or olmesartan (medicines for blood pressure, chest pain associated with heart disease, or other heart conditions)
  - large amounts (1 gram or more each day) of niacin or nicotinic acid (medicines for lowering cholesterol)
- if you are having any of the following conditions:
  - a niacin-containing product and are Chinese.
- as well as the medicines listed above, tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without prescription. In particular, tell your doctor if you are taking any of the following:
  - medicines to prevent blood clots, such as warfarin, fluindione, phenprocoumon or acenocoumarol (anticoagulants)
  - colchyzymine (a medicine for lowering cholesterol), because it affects the way INEGY works
  - fenofibrate (another fibrac acid derivative)
  - ritonavir (a medicine used to treat tuberculosis).

You should also tell any doctor who is prescribing a new medicine for you that you are taking INEGY.

Taking INEGY with food and drink

Grapefruit juice contains one or more components that alter the metabolism of some medications, including INEGY. Consuming grapefruit juice should be avoided as it may increase your risk of muscle problems.

Pregnancy and Breast-feeding

Do not take INEGY if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while you are taking INEGY, stop taking it immediately and tell your doctor. Do not take INEGY if you are breast-feeding, because it is not known if the medicine is passed into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

Children

INEGY is not recommended for children under age 10.

Driving and using machines

INEGY is not expected to interfere with your ability to drive or to use machinery. However, you should take into account that some people get dizzy after taking INEGY.

Important information about some of the ingredients of INEGY

INEGY tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Always take INEGY exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Before starting INEGY, you should be on a diet to lower your cholesterol.
- You should keep on this diet while taking INEGY.

For adults the dose is 1 tablet (1 INEGY 10mg/10mg, 10mg/20mg, 10mg/40mg, or 10mg/80mg tablet) by mouth once a day. For adolescents (10 to 17 Years of age), the dose is 1 tablet (1 INEGY 10mg/10mg, 10mg/20mg or 10mg/40mg tablet) by mouth once a day. The tablets are not scored and should not be divided.

The 10mg/80mg dose is only recommended for adult patients with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.

Your doctor will determine the appropriate tablet strength for you, depending on your current treatment and your personal risk status.

Take INEGY in the evening. You can take it with or without food.

If your doctor has prescribed INEGY along withcolestipramine or any other bile acid sequestrant (medicines for lowering cholesterol), you should take INEGY at least 2 hours before or 4 hours after taking the bile acid sequestrant.

If you take more INEGY than you should:
- please contact your doctor or pharmacist

If you forget to take INEGY:
- do not take an extra dose, just take your normal amount of INEGY at the usual time the next day

If you stop taking INEGY:
- your cholesterol may rise again.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, INEGY can cause side effects, although not everybody gets them (see BEFORE YOU TAKE INEGY).

The following common side effects were reported (observed in 1 or more in 100 and less than 1 in 10 patients treated):
- muscle aches
- elevations in laboratory blood tests of liver (transaminases) and/or muscle (CK) function

The following uncommon side effects were reported (observed in 1 or more in 1000 and less than 1 in 100 patients treated):
- elevations in blood tests of liver function; elevations in blood uric acid; elevations in the time it takes for blood to clot; protein in urine; weight decreased
- dizziness; headache; tingling sensation
- abdominal pain; indigestion; fatigue; nausea; vomiting; abdominal bloating; diarrhoea; dry mouth; heartburn
- rash; itching; hives
- joint pain, muscle pain, tenderness, weakness or spasms; neck pain; pain in arms and legs; back pain
- unusual tiredness or weakness; feeling tired; chest pain; swelling, especially in the hands and feet
- sleep disorder; trouble sleeping

Additionally, the following side effects have been reported in people taking either INEGY or ezetimibe or simvastatin tablets:
- low red blood cell count (anaemia); reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia)
- numbness or weakness of the arms and legs; poor memory
- breathing problems including persistent cough and/or shortness of breath or fever
- constipation; inflammation of the pancreas often with severe abdominal pain
- inflammation of the liver or yellowing of the skin and eyes; liver failure; gallstones or inflammation of the gallbladder (which may cause abdominal pain, nausea, vomiting)
- hair loss; raised red rash, sometimes with target-shaped lesions
- a hypersensitivity reaction including some of the following: hypersensitivity (allergic reactions including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing and requires treatment immediately, pain or inflammation of the joints, inflammation of blood vessels, unusual bruising, skin rashes and swelling, hives, skin sensitivity to the sun, fever, flushing, shortness of breath and feeling unwell, lupus-like disease picture (including rash, joint disorders, and effects on white blood cells)); muscle pain, tenderness, weakness or cramps; muscle breakdown; tendon problems, sometimes complicated by rupture of the tendon.
- decreased appetite
- hot flush; high blood pressure
- pain
- erectile dysfunction
- depression
- alterations in some laboratory blood tests for liver function

Additional possible side effects reported with some statins:
- sleep disturbances, including nightmares
- memory loss
- sexual difficulties
- diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Contact your doctor immediately 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; and very rare deaths have occurred.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE INEGY

- Keep out of the reach and sight of children.
- Do not use INEGY after the expiry date which is stated on the carton and blister label after ‘Exp’.
- Do not store above 30°C. Store in the original pack in order to protect from light and moisture
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What INEGY contains
The active substances are ezetimibe and simvastatin.
Each tablet contains 10mg ezetimibe and 40mg simvastatin.
The other ingredients are: butylated hydroxyanisole, citric acid, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and propyl gallate.

What INEGY looks like and contents of the pack
INEGY Tablets are capsule-shaped, white to off-white with code “313” on one side. The tablets are not scored and should not be divided.

INEGY tablets are available in pack size of 28 Tablets.

Manufactured by: Merck Sharp & Dohme (Italia) S.p.A., Via Emilia, 21, 27010 – Pavia, Italy

Procured from within the EU and repackaged by the PPA holder
B&G Healthcare, Unit 4, Bradford Road, Ruislip, Middlesex, HA4 0NU, UK.

INEGY® 10mg/40mg Tablets, PPA No – 1328/203/001

Leaflet date: 25.01.2013

This medicinal product is authorised in the member states of the EEA under the following name: INEGY in Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom.

INEGY is a registered trademark of MSD-SP Limited.