

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

INEGY® 10/10 Tablet

INEGY® 10/20 Tablet

INEGY® 10/40 Tablet

INEGY® 10/80 Tablet

- ezetimibe and simvastatin

INEGY contains sugar (lactose monohydrate):

Each 10/10 mg Tablet contains 58,2 mg of lactose monohydrate.

Each 10/20 mg Tablet contains 126,5 mg of lactose monohydrate.

Each 10/40 mg Tablet contains 262,9 mg of lactose monohydrate.

Each 10/80 mg Tablet contains 535,8 mg of lactose monohydrate.

Read all of this leaflet carefully before you start taking INEGY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- You should also read any information provided with other medicines you are currently taking.
- INEGY has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

What is in this leaflet

1. What INEGY is and what it is used for

2. What you need to know before you take INEGY
3. How to take INEGY
4. Possible side effects
5. How to store INEGY
6. Contents of the pack and other information

1. What INEGY is and what it is used for

What INEGY is used for

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 INEGY.

If you have heart disease, INEGY reduces the risk of heart attack, stroke, surgery to increase heart blood flow or hospitalisation for chest pain.

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.

Your doctor has prescribed INEGY to reduce the amount of cholesterol and triglycerides in your blood.

2. What you need to know before you take INEGY

Do not take INEGY:

If you:

- are hypersensitive (allergic) to ezetimibe, simvastatin, or any of the other ingredients

of INEGY Tablets (listed in Section 6)

- have active liver disease
- are pregnant or breastfeeding
- are a child less than 10 years old
- are taking any of the following medicines:
 - certain antifungal medicines (such as itraconazole, ketoconazole, posaconazole or voriconazole)
 - HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir and saquinavir)
 - certain hepatitis C virus protease inhibitors (such as boceprevir or telaprevir)
 - certain antibiotics (such as erythromycin, clarithromycin or telithromycin)
 - the antidepressant nefazodone
 - gemfibrozil (a fibric acid medicine for lowering cholesterol)
 - ciclosporin
 - danazol.

Ask your doctor if you are not sure if your medicine is listed above.

Warnings and precautions

Take special care with 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.

Medical problems or allergies: Talk about any medical problems (including liver disease or kidney disease) 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 doctor promptly if you experience unexplained muscle pain, tenderness or weakness. This is because muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

The risk of muscle breakdown is greater at higher doses of INEGY particularly the 10/80 mg dose.

The risk of muscle breakdown is also greater for older patients (65 years of age and older), female patients, patients with kidney problems, and patients with thyroid problems.

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

Use in elderly

No special precautions.

Use in children

INEGY is not recommended in children under 10 years of age.

Other medicines and INEGY

Because taking INEGY with any of the following medicines or substances can increase the risk of muscle problems (see Section 4), it is particularly important to tell your doctor if you are taking:

- antifungal agents (such as itraconazole, posaconazole, ketoconazole or voriconazole)
- HIV protease inhibitors (such as indinavir, nelfinavir, ritonavir or saquinavir)

- hepatitis C antiviral agents (such as boceprevir, telaprevir, elbasvir or grazoprevir)
- the antibiotics erythromycin, clarithromycin, telithromycin and fusidic acid
- the antidepressant nefazodone
- ciclosporin
- danazol
- fibric acid derivatives (such as gemfibrozil and bezafibrate)
- amiodarone (a medicine used to treat an irregular heartbeat)
- verapamil, diltiazem or amlodipine (medicines used to treat high blood pressure, angina or other heart conditions)
- large doses ($\geq 1\text{g/day}$) of niacin or nicotinic acid
- rifampicin
- daptomycin (a medicine used to treat complicated skin and skin structure infections and bacteraemia)
- grapefruit juice (which should be avoided while taking INEGY).

It is also important to tell your doctor if you are taking anticoagulants (medicines that prevent blood clots, such as warfarin, phenprocoumon or acenocoumarol), colchicine (a medication used for gout), niacin or fenofibrate, another fibric acid derivative. Also tell your doctor if you are taking niacin or a niacin-containing product. If you are of Chinese ethnicity, you should inform your doctor, as you may be at a higher risk when taking INEGY with niacin containing medicines.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy and Breastfeeding

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 doctor immediately.

Breastfeeding

Women who are taking INEGY should not breastfeed their infants.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking INEGY.

Driving and using machines

Dizziness has been reported with the use of INEGY. You should therefore not drive or operate machinery if you are affected (see Section 4).

It is not always possible to predict to what extent INEGY may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which INEGY affects you.

INEGY with food, drink and alcohol

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. Tell your doctor if you drink large quantities of alcohol; INEGY may not be right for you.

INEGY contains lactose

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 INEGY.

3. How to take INEGY

Always take INEGY exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- **The dose for adults:** Take one INEGY 10/10, 10/20, 10/40 or 10/80 Tablet by mouth each day, in the evening.
- Because of the increased risk of muscle problems, INEGY 10/80 Tablet is only for patients at high risk of heart disease problems who have not reached their cholesterol goal on lower doses.
- **Adolescents (10 to 17 years of age):** Take one INEGY 10/10, 10/20 or 10/40 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 healthcare provider.
- Your doctor will tell you how long your treatment with INEGY will last. Do not stop treatment early. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

Do not share medicines prescribed for you with others.

If you have the impression that the effect of INEGY is too strong or too weak, tell your doctor or pharmacist.

If you take more INEGY than you 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 to the nearest hospital or poison control centre.

If you forget to take INEGY

Try to take INEGY as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily. Do not take a double dose to make up for the missed dose.

4. Possible side effects

INEGY can have side effects.

Not all side effects reported for INEGY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking INEGY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions including swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing (which may require urgent treatment right away); rash and hives; raised red rash, sometimes with target-shaped lesions.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to INEGY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the nearest casualty department at you nearest hospital if you notice any of the following: unexplained muscle pain, tenderness or weakness while taking INEGY. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects: muscle aches and muscle pain (see Other medicines and INEGY).

Less frequent side effects: elevations in the time it takes for blood to clot; weight decreased; dizziness; headache; tingling sensation; abdominal pain; indigestion; flatulence; 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 general use with either INEGY, ezetimibe or simvastatin tablets (tablets that contain the active ingredients of INEGY):

- inflammation of the pancreas often with severe abdominal pain
- constipation
- depression
- gallstones
- inflammation of the gallbladder which may cause abdominal pain, nausea, vomiting
- poor memory
- memory loss
- confusion
- erectile dysfunction
- breathing problems including persistent cough and/or shortness of breath or fever.

Tell your doctor if you have a medical problem that 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 and if you have any symptoms of liver problems while you take INEGY. Call your doctor right away if you have the following symptoms of liver problems:

- feel tired or weak
- loss of appetite
- upper belly pain
- dark urine
- yellowing of your skin or the whites of your eyes.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of INEGY.

5. How to store INEGY

Do not use INEGY after the month and year following EXP.: on the carton.

Store at or below 30 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What INEGY contains

The active substances are ezetimibe and simvastatin.

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

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

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

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

INEGY contains butylated hydroxyanisole 0,02 % *m/m* and propyl gallate 0,005 % *m/m* as antioxidants.

The other ingredients are: citric acid monohydrate, croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

What INEGY looks like and contents of the pack

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

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.

Holder of Certificate of Registration

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