

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

INECHOL 10/10 mg, tablet

Contains sugar: Lactose monohydrate 68,855 mg per tablet

INECHOL 10/20mg, tablet

Contains sugar: Lactose monohydrate 147,71 mg per tablet

INECHOL 10/40 mg, tablet

Contains sugar: Lactose monohydrate 305,42 mg per tablet

Ezetimibe and Simvastatin

Read all of this leaflet carefully before you start taking INECHOL

- 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.
- INECHOL 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 INECHOL is and what it is used for
2. What you need to know before you take INECHOL
3. How to take INECHOL
4. Possible side effects
5. How to store INECHOL
6. Contents of the pack and other information

1. What INECHOL is and what it is used for

INECHOL contains ezetimibe and simvastatin, one of a group of medicines called serum-cholesterol reducers.

INECHOL is taken by patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking INECHOL.

INECHOL is used in addition to your cholesterol-lowering 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 (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood. You may also receive other treatments.

2. What you need to know before you take INECHOL

Do not take INECHOL:

- if you are hypersensitive (allergic) to ezetimibe, simvastatin or to any of the ingredients of INECHOL (listed in section 6);
- if you have liver disease;
- if you are pregnant or breastfeeding your baby;
- if you are a child;
- if you are taking medicine(s) with one or more than one of the following active ingredients:
- itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections),
- erythromycin, clarithromycin or telithromycin (used to treat infections),
- protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (HIV protease inhibitors are

used to treat HIV infections),

- boceprevir or telaprevir (used to treat hepatitis C virus infections),
- nefazodone (used to treat depression),
- cobicistat,
- gemfibrozil (used to lower cholesterol),
- ciclosporin (often used in organ transplant patients),
- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus).
- if you are taking or have taken, in the last 7 days, a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and INECHOL can lead to serious muscle problems (rhabdomyolysis).

Do not take more than 10/40 mg INECHOL if you are taking lomitapide (used to treat a serious and rare genetic cholesterol condition).

Warnings and precautions

Take special care with INECHOL:

- if you have moderate to severe liver problems;
- if you are taking medicines containing danazol (to treat endometriosis), niacin (nicotinic acid), acipimox (also used to lower cholesterol);
- if you are taking medicine containing ciclosporin (used in organ transplant patients), as your doctor will want to monitor your progress;
- if you are taking medicine to treat fungal or bacterial infections (e.g. itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin);
- if you are taking medicine to treat HIV or medicine to treat depression (nefazodone);
- if you are taking fibrates (to lower cholesterol levels), especially gemfibrozil and bezafibrate;

- if you are taking medicines to treat a heart condition (amiodarone or verapamil);
- **if you experience any unexplained muscle pain, tenderness, or weakness, contact your doctor immediately. 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 INECHOL. The risk of muscle breakdown is also greater in certain patients:

- if you have kidney problems,
- if you have thyroid problems,
- if you are 65 years old or older,
- if you are female,
- if you have ever had muscle problems during treatment with cholesterol lowering medicines called “statins” (such as simvastatin, atorvastatin, and rosuvastatin),
- if you or close family members have a hereditary muscle disorder.
- if you drink large amounts of alcohol;
- if you are taking any medicines that may increase the risk of myopathy and rhabdomyolysis (disease of the muscle tissue);
- if you are taking medicines to thin your blood (e.g. warfarin);
- if you have diabetes or are at risk of developing diabetes;
- if you have severe lung disease;
- if you have porphyria (a rare hereditary blood disease);
- if you are taking medicine that contains “statins”, such as INECHOL, you might be at risk of developing weakness of skeletal muscles that control body movement (arms and legs) and breathing (myasthenia gravis) or weakness of the muscles that control eye and eyelid movement (ocular myasthenia).

Children

INECHOL is not recommended in children under the age of 10.

Other medicines and INECHOL

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

Tell your doctor if you are taking, have recently taken or might take any other medicine(s) with any of the following active ingredients.

Taking INECHOL with any of the following medicines can increase the risk of muscle problems (some of these have already been listed in the above section 'Do not take INECHOL'):

- medicines with an active ingredient like itraconazole, ketoconazole, fluconazole, posaconazole or voriconazole (used to treat fungal infections),
- fibrates with active ingredients like gemfibrozil and bezafibrate (used to lower cholesterol),
- ciclosporin (often used in organ transplant patients),
- danazol (used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus),
- amiodarone (used to treat an irregular heartbeat),
- verapamil, diltiazem or amlodipine (used to treat high blood pressure, chest pain associated with heart disease, or other heart conditions),
- fusidic acid (to treat a bacterial infection),

If you need to take oral fusidic acid, you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart INECHOL. Taking INECHOL with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (used to treat AIDS),
- hepatitis C antiviral medicines such as boceprevir, telaprevir, elbasvir or grazoprevir (used to treat

hepatitis C virus infection),

- nefazodone (used to treat depression),
- medicines with the active ingredient cobicistat,
- erythromycin, clarithromycin, daptomycin or telithromycin (used to treat bacterial infections),
- cholestyramine (also used to lower cholesterol), because it affects the way INECHOL works,
- medicines with an active ingredient to prevent blood clots, such as warfarin, fluindione (anticoagulants),
- lomitapide (used to treat a serious and rare genetic cholesterol condition),
- grapefruit juice (may increase your risk of experiencing muscle problems),
- colchicine (used to treat gout),
- rifampicin (used to treat tuberculosis),
- large amounts (1 gram or more each day) of niacin or nicotinic acid (also used to lower cholesterol).

INECHOL with food and drink

INECHOL can be taken with or without food. Grapefruit juice contains one or more components that alter the metabolism of some medicines, including INECHOL. Consuming grapefruit juice should be avoided as it may increase your risk of muscle problems.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, 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 INECHOL.

Do not take INECHOL if you are pregnant, trying to get pregnant or are breastfeeding your baby (see 'Do not take INECHOL').

Driving and using machines

INECHOL can cause dizziness.

It is not always possible to predict to what extent INECHOL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which INECHOL affects them.

INECHOL contains lactose monohydrate

INECHOL contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking INECHOL.

3. How to take INECHOL

Do not share medicines prescribed for you with any other person. Always take INECHOL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting, and during treatment with INECHOL, you should be on a diet to lower your cholesterol.

Adults:

The usual starting dose, depending on your condition, is one INECHOL 10/20 mg tablet per day.

One tablet is to be taken in the evening, either with or without food. The dosage range is 10/10 mg to 10/80 mg per day.

If your doctor has prescribed INECHOL with a bile acid sequestrant such as cholestyramine (a medicine to lower cholesterol), INECHOL should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Children:

INECHOL is not for use in children (see 'Do not take INECHOL')

Your doctor will tell you how long your treatment with INECHOL will last. Do not stop treatment early because cholesterol level may increase again. If you have the impression that the effect of INECHOL is too strong or too weak, tell your doctor or pharmacist.

If you take more INECHOL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take INECHOL

If you forget to take INECHOL, take a dose as soon as you remember, then continue to take INECHOL at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking INECHOL

If you stop taking INECHOL without consulting your doctor, your cholesterol levels may rise again.

4. Possible side effects

INECHOL can have side effects.

Not all side effects reported for INECHOL are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking INECHOL, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;

- pain or inflammation of the joints, unusual bruising, skin eruptions and swelling, skin sensitivity to the sun, fever, flushing, feeling unwell.

These are all very serious side effects. If you have them, you may have had a serious reaction to INECHOL.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- muscle breakdown (with symptoms such as muscle pain, tenderness, weakness, swollen muscles, tendon rupture/tear, kidney disorder with reddish-brown urine;
- liver problems (you may experience jaundice – yellowing of the skin and eyes - stomach pain and swelling, dark coloured urine);
- an increase in blood sugar which could lead to problems if you are a diabetic (your diabetic medicine may need to be adjusted).

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:

- headache;
- cough;
- viral infections, sore throat (pharyngitis), sinusitis, chest infections;
- stomach pain/disturbances, flatulence, diarrhoea;
- muscle pain, back pain;
- extreme tiredness, chest pain;
- elevations in laboratory blood tests of liver (transaminases) and/or muscle (CK) function.

Less frequent side effects:

- low red blood cell count (anaemia); reduction in blood cell counts, which may cause bruising/bleeding (thrombocytopenia), increased blood clotting time (longer than normal bleeding);
- weight loss;
- sleep disorder, trouble sleeping, depression;
- dizziness, pins and needles, poor memory, weakness/ numbness/pain (peripheral neuropathy);
- inflammation of the pancreas often with severe abdominal pain, pain that worsens with deep breathing or pain that travels to the right shoulder or back;
- gastrointestinal problems such as wind, discomfort or bloating, indigestion or heartburn, nausea, vomiting, dry mouth, constipation;
- itchy or red skin, rash, hair loss, skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring (erythema multiforme);
- pain in the joints or neck, back pain, muscle pain and weakness with skin rash, muscle cramps, muscle spasm, inflammation of the muscle, weakness in the arm and leg muscles, double vision and difficulties with speech and chewing (myasthenia gravis);
- abnormal lack of energy, feeling generally unwell, swelling of the hands or feet
- abnormal liver function test results.

The following side effects have been reported but the frequency for them to occur is not known:

- difficulty breathing, chest infection;
- decrease in appetite;
- changes to the content of your urine which will be seen in a test performed by your doctor, kidney failure;
- trouble remembering, learning new things, concentrating, or making decisions, nightmares, sleep disturbances;
- hot flush, high blood pressure;
- gall stones, inflammation of the gall bladder;

- erectile dysfunction, sexual dysfunction, decreased sex drive, testicular pain, impotence;
- weakness of skeletal muscles that control body movement (arms and legs) and breathing (myasthenia gravis);
- weakness of the muscles that control eye and eyelid movement (ocular myasthenia).

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of INECHOL.

5. How to store INECHOL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the blisters in the carton until required for use.
- Do not use after the expiry date stated on the carton / label.
- 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 INECHOL contains:

The active substances are ezetimibe and simvastatin.

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

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

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

The other ingredients are: ascorbic acid, butylated hydroxy anisole, citric acid monohydrate, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium lauryl sulphate.

What INECHOL looks like and contents of the pack

INECHOL 10/10: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES1 on the other side.

INECHOL 10/20: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES2 on the other side.

INECHOL 10/40: A white to off-white, oval, biconvex tablet debossed with M on one side of the tablet and ES3 on the other side.

Contents of the pack:

PVC/Aclar blister pack comprises of white opaque PVC (polyvinyl chloride) laminated with aclar on one side (PVC/Aclar) and hard tempered aluminium foil coated with VMCH heat seal lacquer on the other side.

Alternatively, PVC/PVdC-Aluminium foil blister pack comprises of white opaque, PVC coated with PVdC on one side and hard tempered aluminium foil coated with VMCH heat seal lacquer on the other side.

Blister strips will be placed in an outer cardboard carton. Pack size of 30's.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd.

1.3.2.1 Approved PIL

INECHOL 10/10, 10/20, 10/40 (48/7.5/0444/5/6)

*Each tablet contains 10,0 mg Ezetimibe and 10,0 mg, 20,0 mg
or 40,0 mg Simvastatin, respectively*

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INECHOL 10/10 mg: 48/7.5/0444

INECHOL 10/20 mg: 48/7.5/0445

INECHOL 10/40 mg: 48/7.5/0446

Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.