

- φρίκια
- ρίγος
- αυξημένη αρτηριακή πίεση
- οίδημα των χειλιών
- αίσθημα καύσου
- εξάνθημα σε όλο το σώμα
- πόνος στις αρθρώσεις
- οίδημα των ποδιών
- γρήγορος ρυθμός της καρδιάς.

Εάν κάποια ανεπιθύμητη ενέργεια γίνεται σοβαρή, ή αν παρατηρήσετε κάποια ανεπιθύμητη ενέργεια που δεν αναφέρεται στο παρόν φύλλο οδηγιών, παρακαλείσθε να ενημερώσετε το γιατρό ή το φαρμακοποιό σας.

## 5. ΠΩΣ ΝΑ ΦΥΛΑΣΣΕΤΑΙ ΤΟ TREDAPTIVE

Να φυλάσσεται σε μέρη που δεν το φθάνουν και δεν το βλέπουν τα παιδιά.

Να μη χρησιμοποιείτε το Tredaptive μετά την ημερομηνία λήξης (λήξη) που αναφέρεται στο κουτί και στην κυψέλη.

Κυψέλες PVC/Aclar: Να φυλάσσονται στην αρχική συσκευασία για να προστατεύονται από το φως και την υγρασία.

Κυψέλες Aluminium/Aluminium: Να μην φυλάσσονται σε θερμοκρασία πάνω από 30°C. Να φυλάσσονται στην αρχική συσκευασία για να προστατεύονται από το φως και την υγρασία.

Τα φάρμακα δεν πρέπει να απορρίπτονται στο νερό της αποχέτευσης ή στα σκουπίδια. Ρωτήστε το φαρμακοποιό σας πώς να πετάξετε τα φάρμακα που δεν χρειάζονται πια. Αυτά τα μέτρα θα βοηθήσουν στην προστασία του περιβάλλοντος.

## 6. ΛΟΙΠΕΣ ΠΛΗΡΟΦΟΡΙΕΣ

### Τι περιέχει το Tredaptive

- Οι δραστικές ουσίες είναι το νικοτινικό οξύ και η λαροπιπράντη. Κάθε δισκίο περιέχει 1000 mg νικοτινικού οξέος και 20 mg λαροπιπράντης.
- Τα άλλα συστατικά είναι: υπομελλόζη (E464), πυριτίου οξείδιο πήγμα άνυδρο (E551), στεαρυλοφουμαρικό νάτριο, υδροξυπροπυλοκυτταρίνη (E463), μικροκρυσταλλική κυτταρίνη (E460), καρμελλόζη νατριούχος διασταυρούμενη, λακτόζη μονοϋδρική, και μαγνήσιο στεατικό.

**Εμφάνιση του TREDAPTIVE και περιεχόμενο της συσκευασίας**  
Κάθε δισκίο ελεγχόμενης αποδέσμευσης είναι δισκίο σε σχήμα καψακίου, λευκό έως υπόλευκο, με το ανάγλυφο '552' στη μία πλευρά.

Αδιαφανείς κυψέλες PVC/Aclar με push-through aluminium lidding σε μεγέθη συσκευασίας των 14, 28, 56, 84, 98, 168, ή 196 δισκίων ελεγχόμενης αποδέσμευσης και 49 x 1 δισκία ελεγχόμενης αποδέσμευσης σε διάτρητη κυψέλη μονάδων δόσης.

Κυψέλες Aluminium/Aluminium Blister με push-through lidding σε μεγέθη συσκευασίας των 14, 28, 56 δισκία ελεγχόμενης αποδέσμευσης.

Μπορεί να μην κυκλοφορούν όλες οι συσκευασίες.

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Για οποιαδήποτε πληροφορία σχετικά με το παρόν φαρμακευτικό προϊόν, παρακαλείσθε να απευθυνθείτε στον τοπικό αντιπρόσωπο του κατόχου της άδειας κυκλοφορίας:

**Το παρόν φύλλο οδηγιών χρήσης εγκρίθηκε για τελευταία φορά τον Ιούλιο 2008**

Λεπτομερή πληροφοριακά στοιχεία για το προϊόν είναι διαθέσιμα στην ιστοσελίδα του Ευρωπαϊκού Οργανισμού Φαρμάκων (EMA): <http://www.ema.europa.eu/>.

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## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Tredaptive® 1000 mg/20 mg modified-release tablets

nicotinic acid/laropirant

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- 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.

### In this leaflet:

1. What Tredaptive is and what it is used for
2. Before you take Tredaptive
3. How to take Tredaptive
4. Possible side effects
5. How to store Tredaptive
6. Further information

## 1. WHAT TREDAPTIVE IS AND WHAT IT IS USED FOR

The name of your medicine is Tredaptive. It contains two different active substances:

- nicotinic acid, a lipid modifying medicine, and
- laropirant, which reduces symptoms of flushing, a common side effect of nicotinic acid.

The medicine comes as a modified-release tablet. This means one or more active substances are released slowly over a period of time.

### Tredaptive is used in addition to diet

- to lower your 'bad' cholesterol level. It does this by lowering the levels of total cholesterol, LDL cholesterol, fatty substances called triglycerides and apo B (a part of LDL) in the blood;
- to raise levels of 'good' cholesterol (HDL cholesterol) and apo A-I (a part of HDL).

### What should I know about cholesterol?

Cholesterol is one of several fats found in your blood. Your total cholesterol is made up mainly of 'bad' (LDL) and 'good' (HDL) cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your arteries and form plaque. Over time, this plaque build-up can lead to a clogging of your arteries. This clogging can slow or block blood flow to vital organs such as the heart and brain. When the blood flow is blocked, the result can be 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 because it protects against heart disease.

Triglycerides are another fat in your blood. They may raise your risk of having heart problems.

In most people, at first there are no signs of cholesterol problems. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly to keep track of your cholesterol and discuss your goals with your doctor.

**Tredaptive is used if you need to** improve cholesterol and fat levels in your blood (primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia):

- when you cannot control your cholesterol levels with a statin (class of cholesterol-lowering medicines working in the liver);
- when you cannot tolerate a statin or when a statin is not recommended for you.

Tredaptive can be used by itself or with other medicines to treat cholesterol problems. You should stay on a diet designed to lower cholesterol or other non-pharmacological treatments (e.g. exercise, weight reduction) while you take this medicine.

## 2. BEFORE YOU TAKE TREDAPTIVE

### Do not take Tredaptive if

- you are allergic (hypersensitive) to nicotinic acid, to laropirant, or to any of the other ingredients of Tredaptive (listed in section 6).
- you currently have liver problems.
- you have an ulcer in your stomach.
- you have arterial bleeding.

Do not take Tredaptive if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tredaptive.

### Take special care with Tredaptive

Tell your doctor about all of your medical conditions. Check with your doctor or pharmacist before and while taking your medicine if:

- you have any allergies.
- you have ever had liver disease, jaundice (a liver disorder causing yellowing of the skin and whites of the eyes), or hepatobiliary (liver and bile duct) disease.
- you have kidney problems.
- you have thyroid problems.
- you drink large amounts of alcohol.
- you or close family members have a hereditary muscle disorder, or you have ever had muscle problems during treatment with cholesterol-lowering medicines called "statins" or fibrates.

- you have unexplained muscle pain, muscle tenderness, or muscle weakness. If you have these symptoms talk to your doctor immediately.
- you have high blood sugar or diabetes.
- you have heart problems.
- you are going to have an operation.
- you have gout.
- you have low levels of phosphorus.
- you are over 70 years old.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Tredaptive.

### Blood tests and monitoring

- See your doctor regularly to check your LDL (bad) and HDL (good) cholesterol levels and your triglyceride level.
- Your doctor should do a blood test before you start taking Tredaptive to check how well your liver is working.
- Your doctor may also want you to periodically have blood tests after you start taking Tredaptive, to check how well your liver is working and for other side effects.

### Children and adolescents

Tredaptive has not been studied in children and adolescents who are under 18 years of age.

### Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, vitamins, and herbal supplements.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines used to lower blood pressure.
- medicines used to lower cholesterol called 'statins', a class of medicine that works in the liver.
- medicines used to lower cholesterol called 'bile acid sequestrants', such as colestyramine.
- zidovudine, a medicine used for HIV.
- midazolam, a medicine to make you sleepy before some medical procedures.
- vitamins or supplements that contain nicotinic acid.
- clopidogrel, a medicine to help prevent harmful blood clots.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Tredaptive.

### Taking Tredaptive with food and drink

- Take Tredaptive with food.
- To lower your chance of flushing, avoid drinking alcohol or hot drinks near the time you take your dose of Tredaptive.
- It is important to follow the advice given in section 3 **How to take Tredaptive**.

### Pregnancy and breast-feeding

Talk with your doctor before taking Tredaptive if:

- You are pregnant or plan to become pregnant. It is not known if Tredaptive will harm your unborn baby.
- You are breast-feeding or plan to breast-feed. It is not known if Tredaptive will pass into your breast milk. However, nicotinic acid a component of Tredaptive does pass into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide if Tredaptive is right for you.

### Driving and using machines

The effects of Tredaptive on the ability to drive and use machines have not been studied. However, some people get dizzy after taking Tredaptive. If you get dizzy, you should avoid driving or operating machines after taking Tredaptive.

### Important information about some of the ingredients of Tredaptive

Tredaptive contains 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 medicine.

## 3. HOW TO TAKE TREDAPTIVE

Always take Tredaptive exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### How much to take

- You should start by taking one tablet a day.
- After 4 weeks, your doctor may raise your dose to two tablets a day.

### How to take

- Take Tredaptive once a day, in the evening or at bedtime.
- Take Tredaptive with food.
- Swallow each tablet whole. In order for your medicine to work as intended, do not split, break, crush, or chew the tablet before you swallow it.
- Avoid drinking alcohol or hot drinks near the time you take your dose of Tredaptive. This will lower your chance of flushing (redness of the skin, feeling warm, itching, or tingling, particularly in your head, neck, chest and upper back).
- Taking aspirin before you take Tredaptive does not reduce your flushing more than taking Tredaptive alone. Therefore, taking aspirin to reduce flushing symptoms is not necessary. If you take aspirin for any other reason, continue to follow your doctor's advice.

### If you take more Tredaptive than you should

- In the event of an overdose, the following adverse events were reported: flushing, headache, pruritus (itching), nausea, dizziness, vomiting, diarrhoea, abdominal pain/discomfort, and back pain.