

**CONSUMER INFORMATION**  
**Product Monograph Part III**

Pr **CATENA**<sup>®</sup>

**idebenone**  
**150 mg tablets**

**Santhera Pharmaceuticals (Switzerland) Ltd.**

**Submission Control No. 117672**

The Consumer Information Section (Part III) of the Product Monograph for CATENA has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on July 23, 2008, and does not necessarily reflect the most current information for the product.

**For the most up-to-date product information, please consult your health care professional.**

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

### PART III: CONSUMER INFORMATION

#### CATENA<sup>®</sup> idebenone

*CATENA<sup>®</sup>, indicated for the treatment of Friedreich's Ataxia, has been approved with conditions, pending the results of studies to verify its clinical benefit. For more information, patients are advised to contact their healthcare provider.*

#### What is a Notice of Compliance with Conditions (NOC/c)?

An NOC/c is a form of market approval granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products approved under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

This leaflet is part III of a three-part "Product Monograph" published when CATENA<sup>®</sup> was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CATENA<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

##### What the medication is used for:

CATENA<sup>®</sup> has been prescribed by your doctor for a disease of the nervous system called Friedreich's Ataxia. Friedreich's Ataxia is an inherited disease that causes progressive damage to the nervous system, resulting in symptoms ranging from difficulty walking to speech problems. "Ataxia" refers to coordination problems. Friedreich's Ataxia results from the breakdown of nerve tissue in the spinal cord, which makes directing muscle movement of the arms and legs difficult. Friedreich's Ataxia also frequently leads to heart disease. Your doctor may give you further information about why this medicine has been prescribed for you.

##### What it does:

It is not known exactly how CATENA<sup>®</sup> works. However, it is believed to increase the supply of energy to cells in the body. Additionally, it has antioxidant properties and may protect the cells in the body that are damaged by Friedreich's Ataxia.

##### When it should not be used:

Do not take CATENA<sup>®</sup> if:

- you are allergic (hypersensitive) to CATENA<sup>®</sup> or any of the other ingredients of CATENA<sup>®</sup>;
- you have any liver or kidney disease;
- you are pregnant or breastfeeding.

##### What the medicinal ingredient is:

The medicinal ingredient in CATENA<sup>®</sup> is idebenone.

##### What the important nonmedicinal ingredients are:

CATENA<sup>®</sup> also contains: croscarmellose sodium lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 3350, polyvinyl alcohol, povidone K25, silicon dioxide, talc, titanium dioxide (CI 77891), FD&C yellow No. 6 aluminium lake (CI 15985).

##### What dosage forms it comes in:

Each tablet of CATENA<sup>®</sup> contains 150 mg of idebenone.

CATENA<sup>®</sup> tablets are orange, round film-coated tablets engraved with "150" on one side and with the "Santhera logo" on the other side.

CATENA<sup>®</sup> is supplied in white plastic bottles containing 90, 180, 270 or 450 tablets.

#### WARNINGS AND PRECAUTIONS

**BEFORE** you use CATENA<sup>®</sup> talk to your doctor or pharmacist if:

- you are taking or have recently taken any other medicines, including medicines obtained without a prescription;
- you have liver disease or if your blood tests show that you have abnormal elevations of some liver enzymes (transaminases);
- you have kidney disease;
- you are pregnant or could become pregnant. CATENA<sup>®</sup> should not be taken if you are pregnant;
- you are breastfeeding or intend to breastfeed. CATENA<sup>®</sup> should not be taken if you are breastfeeding;
- you are allergic to CATENA<sup>®</sup> or any other ingredient in the formulation or components of the container;
- you experience any fever (increase in temperature). This may be a sign of a decrease in the number of white blood cells, which are important in fighting an infection.

Do not drive or use machinery if you feel dizzy when you take CATENA<sup>®</sup>.

##### Coloured Urine

Tell your doctor if you notice a reddish brown colour in your urine. CATENA<sup>®</sup> can cause this harmless change in the colour of your urine. This effect does not require any change to your treatment with CATENA<sup>®</sup>. Problems of the urinary tract can sometimes be detected based on a change in the colour of urine. Your doctor may decide to do a routine urine analysis to make sure that this colouring of your urine is not hiding other problems.

Lactose is a nonmedicinal ingredient in CATENA<sup>®</sup>. Do not take CATENA<sup>®</sup> if a doctor has told you that you have one of the

following rare hereditary diseases:

- Galactose intolerance;
- Lapp lactase deficiency;
- Glucose-galactose malabsorption.

CATENA<sup>®</sup> contains the colouring agent FD&C yellow No. 6 aluminium lake (CI 15985). It is also known as tartrazine. In some people, it may cause allergic reactions.

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.

### INTERACTIONS WITH THIS MEDICATION

CATENA<sup>®</sup> has not been studied in combination with all drugs that might interact. No effects were seen when CATENA<sup>®</sup> was taken at the same time as lithium, amitriptyline, donepezil or fluvoxamine. Talk to your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### PROPER USE OF THIS MEDICATION

The dose and number of tablets of CATENA<sup>®</sup> is based on the medication dose your doctor recommends for you and how much you weigh.

#### Usual dose:

- If you weigh less than or equal to 45 kilograms, take 1 tablet three times a day. That is, take a total of 3 tablets per day.
- If you weigh more than 45 kilograms, take 2 tablets three times a day. That is a total of 6 tablets per day.

Your doctor may recommend taking a higher dose of CATENA<sup>®</sup>:

- If you weigh less than or equal to 45 kilograms, take 3 tablets three times a day. That is, take a total of 9 tablets per day.
- If you weigh more than 45 kilograms, take 5 tablets three times a day. That is a total of 15 tablets per day.

There is no benefit in increasing the dose above what your doctor recommends. However, you may encounter more side effects.

You should take this medicine by mouth.

You should swallow CATENA<sup>®</sup> tablets whole. The tablets should not be chewed.

**You should always take CATENA<sup>®</sup> with food.**

You should take CATENA<sup>®</sup> at the same time of day each day, such as in the morning at breakfast, with lunch at mid-day and with dinner in the evening.

The doctor may need to take blood tests before you start taking CATENA<sup>®</sup>, periodically during your treatment or when making adjustments to the dosage of CATENA<sup>®</sup>.

#### Overdose:

If you have accidentally taken too many tablets, contact your doctor or the regional Poison Control Centre.

#### Missed dose:

If you forget to take your tablet, take the next tablet(s) as originally planned. Do not take a double dose to make up for a forgotten tablet.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CATENA<sup>®</sup> can cause side effects, although not everybody gets them.

The most common side effects of CATENA<sup>®</sup> are: diarrhea, nausea, dyspepsia (stomach pain or discomfort).

### SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Liver disorder Symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine		✓*	
	Low blood cell count Symptoms include cold/flu-like symptoms such as <b>sudden</b> lack of energy, fever, cough, sore throat or any other sign of infection (such as urinary problems)		✓*	
	Bruising or unusual bleeding from the skin or other areas		✓*	
	Allergic reactions Symptoms include red and lumpy skin rash, hives, swelling, trouble breathing			✓*

\* If you think you have these side effects, it is important that you seek medical advice from your doctor straight away.

*This is not a complete list of side effects. If any of the side effects gets serious, or if you notice any side effects not listed here, contact your doctor or pharmacist.*

### HOW TO STORE IT

Keep out of the reach of children.

Store CATENA<sup>®</sup> at 15°–30° C.

Do not use CATENA<sup>®</sup> after the expiry date, which is stated on the carton and the bottle.

#### **REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345  
By toll-free fax: 1-866-678-6789  
Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:  
Canada Vigilance National Office  
Marketed Health Products Safety and Effectiveness  
Information Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your healthcare provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

#### **MORE INFORMATION**

This document plus the full Product Monograph, prepared for health professionals can be obtained by contacting the Canadian Importer, GMD Distributing Inc., at:

1-866-270-1733

It is also available on the Health Canada website: [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)

This leaflet was prepared by Santhera Pharmaceuticals (Switzerland) Ltd.

Last revised: October 21, 2008

© Santhera Pharmaceuticals (Switzerland) Ltd, October 2008.