

# Thiosix<sup>®</sup>

Information  
brochure  
about Thiosix,  
Crohn's disease and  
ulcerative colitis



## Inhoud

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## Introduction

Your physician has prescribed Thiosix® (tioguanine).

Thiosix is medication for the treatment of inflammatory bowel diseases. These are chronic bowel diseases, also called IBDs. The two most common inflammatory bowel diseases are Crohn's disease and ulcerative colitis.

This brochure provides information about Crohn's disease, ulcerative colitis and the treatment with Thiosix. We recommend that you carefully read the Thiosix package insert. This brochure does not replace the package insert.

Do you have any questions after reading this brochure or the insert? Please contact your gastroenterologist or gastroenterology nurse.

**Read the package insert before using Thiosix.**

▼ This medicinal product is subject to additional monitoring. Thanks to this, new safety information can be established quickly. You can contribute to this by reporting all the adverse effects you may experience. You can learn how to do this in section 2.15.

# 1. Inflammatory Bowel Diseases

## 1.1. What are inflammatory bowel diseases?

Inflammatory bowel diseases are inflammations of the gastrointestinal tract and also called IBD. The two most common inflammatory bowel diseases are Crohn's disease and ulcerative colitis. The disease has a variable, sometimes erratic progression, with alternating periods of inflammation and recovery. The severity and nature of the complaints that arise vary by person, but are often present for life. Medication can suppress intestinal inflammation, but they cannot cure the disease permanently.

There are currently more than 80,000 people in the Netherlands with chronic intestinal inflammation. This is approximately 1 in 200 people. Each year, an estimated 1,500 new patients are diagnosed with ulcerative colitis in the Netherlands. Crohn's disease affects about 1,000 new patients annually.

## 1.2. What is Crohn's disease?

When you suffer from Crohn's disease, inflammation can occur in the entire gastrointestinal tract, from mouth to anus. In most patients, however, inflammation is only present in the small intestine, large intestine or rectum. The intestinal wall is not completely inflamed, but healthy and inflamed areas alternate.

Crohn's disease involves small inflammations (ulcers) in the intestinal wall that can be quite deep. The ulcers can also keep growing and connect with other organs. This is called a fistula. Scar tissue can make the intestine more narrow, and blockages may occur. It might also result in a loss of blood, causing anaemia. If the symptoms are severe or persist for a long period, the function of the intestine may decrease slowly, resulting in weight loss and a lack of vitamins and minerals. Your physical condition will also decline due to a reduced appetite.

## The most common symptoms of Crohn's disease are:

- *Diarrhoea or loose stools*
- *Abdominal pain*
- *Fever*
- *Emaciation*
- *Growth retardation*
- *Blood loss*
- *Anaemia*
- *Fatigue*

Crohn's disease usually occurs in people between 15 and 30 years, and is more common among women than men.

## 1.3. What is ulcerative colitis?

When you suffer from ulcerative colitis (colon refers to the large intestine and *-itis* means inflammation), inflammations occur in the mucosa of the intestinal wall in the large intestine and the rectum. Usually, the inflammation begins in the rectum and extends up to the colon. In many people, the left part of the large intestine becomes inflamed, as this is the part that connects to the rectum. The inflammation of the intestine forms a contiguous inflamed area.

When you suffer from ulcerative colitis, ulcers occur in the surface of the intestinal wall. Fistulas and blockages are rare. Sometimes, there are also inflammations outside the large intestine and the rectum.

## The most common symptoms of ulcerative colitis are:

- *Diarrhoea or loose stools*
- *Abdominal pain*
- *Abdomen distensions*
- *Fever*
- *Abnormal loss of weight*
- *Blood loss*
- *Anaemia*
- *Fatigue*

Ulcerative colitis usually appears in young adults and middle-aged people and is more common among men than women.

#### 1.4. What is the cause of inflammatory bowel diseases?

There are several factors that play a role in the cause of inflammatory bowel diseases. The inflammations that occur with IBD relate to a disturbed immune system that targets normal intestinal bacteria in the intestines, resulting in damage to the structures of the intestinal wall. Certain bacteria in the intestines can cause the disease. The exact type of bacteria is still unclear, however. Research shows that certain foods and the use of antibiotics may be risk factors for the emergence of IBD because of their effect on the bacteria in the intestines. This is still being investigated. Too much stress can also cause gastrointestinal symptoms, which is not the precise cause of the disease, but does affect the severity of symptoms. And finally, smoking has an effect. Generally, smoking is bad for your health. When you suffer from Crohn's disease, smoking increases the chance of its development and it has an adverse effect on the progression of the disease. However, when you suffer from ulcerative colitis, there is a small increased risk of getting the disease after you stop smoking, and smoking seems to protect against attacks. It is still unclear why this is the case.

#### 1.5. How are Crohn's disease and ulcerative colitis treated?

The treatment of inflammatory bowel disease consists of prescribing medication. Unfortunately, the disease is still not curable through medication. There are various types available. These medication have an inhibiting effect on inflammation and suppress the symptoms. It also prevents new inflammations. The medication must be taken for a longer period of time, even if there are no or fewer complaints. This way, the disease is kept under control. Finding the most effective medication may take some time.

When medication does not work adequately or if narrowing or closing of the intestine occurs, surgery may be needed. A temporary or permanent colostomy may also be a solution for the complaints.

## 2. Thiosix

### 2.1. What is Thiosix?

Thiosix is intended for the maintenance treatment of inflammatory bowel diseases (Crohn's disease or ulcerative colitis). Thiosix can be prescribed by your physician if you do not respond to treatment with azathioprine or mercaptopurine or if you are intolerant to these.

### 2.2. What dosages are available?

Thiosix is available in two doses:

- tablet 10 mg tioguanine
- tablet 20 mg tioguanine

The tablets are white/yellowish and are packaged in a blister pack with 10 tablets. There are a total of three strips in a box.

The daily dose for inflammatory bowel diseases is 0.3 mg per kg body-weight with a maximum dose of 25 mg per day. The exact dose is determined by your physician.

### 2.3. How does Thiosix work?

Thiosix is immunosuppressive medication.

Tioguanine is the active substance in Thiosix which inhibits the immune system. This suppresses the inflammatory process in the intestines. The complaints will reduce as a result. Thiosix can be prescribed for a longer period of time and is therefore called maintenance therapy.

### 2.4. What are the effects of Thiosix?

Thiosix inhibits the inflammation in the intestines. This will reduce complaints such as diarrhoea and abdominal pain. The first effects are noticeable after several weeks to about three months after starting with Thiosix.

## 2.5. Who should use Thiosix?

Thiosix is prescribed to adults with inflammatory bowel diseases (Crohn's disease or ulcerative colitis). This is possible when treatment with azathioprine or mercaptopurine is ineffective, or when these drugs cannot be used.

## 2.6. When can you start with Thiosix?

You can only use Thiosix when it is prescribed by a doctor, usually a gastroenterologist. It can therefore only be obtained with a prescription. A physician prescribes Thiosix if it turns out that other medication is ineffective, or if a patient is intolerant to these.

## 2.7. How should I take Thiosix?

You take Thiosix once per day (unless otherwise instructed by your physician). You must swallow the tablet without chewing with half a glass of water. Your body is the most efficient at absorbing Thiosix if you take it at an empty stomach, at least half an hour before a meal. If the drug is taken during the meal, this may reduce its efficacy.

## 2.8. What should I do if I forget a tablet or have swallowed too many?

If you swallow more Thiosix tablets than prescribed, you should contact your physician immediately.

If a tablet is forgotten, do not take a double dose.

## 2.9. How long should I use Thiosix?

The dose and duration of treatment with Thiosix individually determined for each patient by a physician. The severity of the complaints also determines how long the drug should be used. If there is no noticeable effect after six months, you may consult with your physician on discontinuing the treatment.

## 2.10. Can I get another attack despite the use of Thiosix?

The first effects of Thiosix will be noticeable after a few weeks to about three months. In the meantime, complaints may still be present.

## 2.11. Do I need to be closely supervised?

While you use Thiosix, your treating physician will regularly examine your liver functions and check your blood count. This will be after 1, 2, 4, 8 and 12 weeks at start of the treatment and approximately every three months after that.

## 2.12. How should I store Thiosix?

Thiosix has no special storage conditions. It must be kept at a dry place and out of the reach and sight of children. It may no longer be used after the expiry date (see packaging below EXP).

## 2.13. What should I do with unused tablets?

All unused tablets should be returned to the pharmacist. It may not be flushed down the drain or toilet or thrown in the garbage. Thioguanine, the active substance in Thiosix, is very strong. The powder of a broken tablet should not be blown away and touched or inhaled.

## 2.14. What are possible adverse effects of Thiosix?

Because Thiosix has a powerful effect on the division of the cells of the immune system and other body cells, there may be adverse effects. This happens in places where cell division usually happen quickly. These are the bone marrow and the mucous membranes in the mouth, stomach and intestines. The extent to which these adverse effects occur, is different for each person. The most common adverse effects are:

- **An increased risk of infections and bleeding**

Thiosix can suppress bone marrow function, causing the body to create fewer white blood cells and platelets. This may result in nosebleeds, subcutaneous bleeding or unexplained bruising. There is also an increased risk of infections due to viruses, bacteria or fungi. These include include colds, laryngitis, flu, boils and other skin infections

- **Gastro-intestinal complaints**

Thiosix can affect the mucous membrane of the oesophagus, stomach and intestines, which can result in nausea, vomiting, diarrhoea, abdominal pain, stomach pain, heartburn and a lack of appetite. Eating more frequently, in small portions, may help.

- **Sore mouth, tongue or throat**

Thiosix affects the mucous membranes of the mouth or throat which can make eating and drinking painful. Sucking on ice cubes can help.

- **Liver complaints**

Thiosix has an increased risk of liver disorders. You may experience yellow discolouration of the skin and whites of the eyes, as well as pain in the upper abdomen.

## 2.15. What should I do if adverse effects occur?

Adverse effects must always be reported to your treating physician or your pharmacist. This also applies to adverse effects that are not mentioned in the package insert of the drug. The continuation of the treatment will then be discussed. Some adverse effects generally disappear after discontinuation of therapy. You can also report adverse effects directly to the Dutch Pharmacovigilance Centre Lareb. This can be done through [www.lareb.nl](http://www.lareb.nl). This helps us obtain more information about the possible adverse effects of this medication.

## 2.16. Can Thiosix be combined with other medication?

Thiosix interacts with other medication. This is because of its active substances. These are found in the package insert of the drug under the headline 'composition'. It is important that you inform your physician of the different types of medication you use. When in doubt about combining different types of medication, you must always consult your physician or pharmacy.

Medications with major interaction effects are:

- **Vaccinations**

You can be more susceptible to infections as a result of the treatment with Thiosix. It is recommended you refrain from receiving living vaccines.

## 2.17. What should I do if I get pregnant?

Talk to your physician if you are pregnant. The use of tioguanine tablets during pregnancy, especially in the first trimester, is not recommended. Tioguanine should only be taken during pregnancy after consultation with your physician.

You may not breastfeed while using tioguanine tablets.

## 2.18. Is my skin more sensitive to sunlight?

You can be sensitive to the sun when using Thiosix. This can cause discolouration of the skin or rashes. Avoid direct sunlight as much as possible, cover your skin and use sunscreen with a high protection factor.

## Useful addresses

### Maag Lever Darm Stichting

www.mlds.nl

E-mail: info@mls.nl

T: 033 752 3500

### Crohn en Colitis Ulcerosa Vereniging Nederland

www.crohn-colitis.nl

E-mail: info@crohn-colitis.nl

T: 0348 420 780

### Website

www.thiosix.nl

### customerservice

For questions about Thiosix, you can contact the Customer Service department on the free phone number 0800 – 022 8400 or at [customerservice@teva.nl](mailto:customerservice@teva.nl)

## Index

### IBD

*Abbreviation of Inflammatory Bowel Diseases, or IBD. These are chronic bowel inflammations.*

### Immune system

*The system that protects your body against the intrusion of pathogens and other foreign substances.*

### Crohn's disease

*Chronic bowel disease where inflammation occur in the entire gastrointestinal tract, from the mouth to the anus. Most infections occur in the small intestine, large intestine or rectum.*

### Fistula

*A corridor or tunnel between the intestinal wall and other organs that can develop after an inflammation.*

### Ulcerative colitis

*Chronic bowel disease where inflammation of the lining of the intestinal wall occurs in the colon and rectum.*

### Thiosix

*Medication prescribed as maintenance treatment for inflammatory bowel diseases.*

### Immune suppressants

*Medication that suppresses the immune system.*

### Intolerance

*Not being able to tolerate something. This could be several things, such as a type of medication.*

### Tioguanine

*The active ingredient in Thiosix, which inhibits the immune system.*





Thiosix is a product of Teva Netherlands.

Teva Nederland BV  
Postbus 552  
2003 RN Haarlem  
0800-0228400

