

# TROBALT TABLET

Retigabine (50mg, 100mg, 200mg, 300mg, 400mg)

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## What is in this leaflet

1. What TROBALT is used for
2. How TROBALT works
3. Before you use TROBALT
4. How to use TROBALT
5. While you are using it
6. Side Effects
7. Storage and Disposal of TROBALT
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What TROBALT is used for

It is used with other medicines to treat adults who have a form of epilepsy that affects one part of the brain, called partial onset seizures. These seizures may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

## How TROBALT works

Trobalt is one of a group of medicines called *antiepileptics*. It works by preventing the brain overactivity that causes epileptic seizures (also called fits).

## Before you use TROBALT

### - When you must not use it

Do not take Trobalt if you are allergic (*hypersensitive*) to retigabine or any of the other ingredients of Trobalt. Tell your doctor if this applies to you, and do not take Trobalt.

Trobalt is not recommended for children aged under 18. The safety and effectiveness are not yet known in this age group.

### - Before you start to use it

Before you take Trobalt your doctor needs to know:

- if you are 65 years of age or above.
- if you have kidney or liver problems.

- if you have eye disorder
  - if you have skin disorder
  - if you have urinary disorder
  - if you have heart disease
  - if you have mental disorder
- Tell your doctor if any of these applies to you. The doctor may decide to give you a reduced dose.

### - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Trobalt may increase the level of digoxin (used to treat heart problems) in your blood. Tell your doctor if you are taking digoxin.

Trobalt may affect some anaesthetics (for example thiopental sodium). If you are going to have an operation under a general anaesthetic: Tell the doctor that you are taking Trobalt, well in advance. Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

## How to use TROBALT

### - How much to use

Always take Trobalt exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The usual maximum starting dose of Trobalt is 100 mg, taken three times a day (a total of 300 mg a day). Your doctor may gradually adjust your dose over a few weeks so that your seizures are better controlled, and side effects are kept to a minimum. The maximum dose is 400 mg taken three times a day (a total of 1,200 mg a day).

If you are over 65 years you will usually be given a reduced starting dose and your doctor may limit the maximum dose to 900 mg a day.

If you have kidney or liver problems, your doctor may give you a reduced dose of Trobalt.

### - When to use it

Swallow the tablet whole. Do not chew, crush or split the tablet. You can take Trobalt with or without food.

### - How long to use it

Take Trobalt for as long as your doctor recommends. Do not stop unless your doctor advises you to.

If you suddenly stop taking Trobalt, your seizures may come back or get worse. Do not reduce your dose unless your doctor tells you to. To stop taking Trobalt, it is important that the dose is reduced gradually, over at least 3 weeks

### - If you forget to use it

If you miss any doses, just take one dose as soon as you remember. Then leave at least 3 hours before your next dose. Do not take more than one dose at a time to make up for missed doses. If you are not sure what to do, ask your doctor or pharmacist.

### - If you use too much (overdose)

If you take too many tablets of Trobalt, you may be more likely to have side effects, or any of these symptoms:

- feeling agitated, aggressive or irritable
- effects on heart rhythm.

Contact your doctor or pharmacist for advice if you

# TROBALT TABLET

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ever take more Trobalt than you are prescribed. If possible, show them the medicine pack.

## **While you are using it**

### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Trobalt.

Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

Do not take any more Trobalt than your doctor has recommended. It may take a few weeks to find the right dose of Trobalt for you.

Do not give Trobalt to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

*Look out for serious symptoms*  
Trobalt can cause serious side effects, including an inability to pass urine (*urinary retention*) and mental health problems. You must look out for certain symptoms while you are taking Trobalt, to reduce the risk of any problems.

#### *Heart conditions*

Trobalt can affect heart rhythm. This is more likely to affect you:

- if you are taking other medicines
- if you have an existing heart problem
- if you have low potassium (*hypokalaemia*) or low magnesium (*hypomagnesaemia*) in your blood.

- if you are 65 years of age or above

Tell your doctor if any of these apply to you, or if you notice any unusual changes in your heart beat (such as beating too fast or too slow). You may need extra check-ups (including an electrocardiogram [ECG], which is a test which records the electrical activity of your heart) while you are taking Trobalt.

#### *Thoughts of harming yourself or suicide*

A small number of people being treated with antiepileptics such as Trobalt have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

#### *If you need a blood or urine test*

Trobalt can affect the results of some tests. If you need a blood or urine test: Tell the person who orders the test that you are taking Trobalt.

#### *Discolouration of skin, nails, lips and eyes, and eye disorders*

Tell your doctor if you experience any changes in vision or discolouration of your skin, nails or lips.

#### *Alcohol and Trobalt*

Drinking alcohol with Trobalt can make your vision blurred. Take extra care until you know how Trobalt and alcohol affect you.

#### *Pregnancy and breast-feeding*

You must only take Trobalt during pregnancy if your doctor tells you. There is no information about the safety of Trobalt in pregnant women. You must use a reliable method of contraception to avoid

becoming pregnant while you are being treated with Trobalt. Talk to your doctor if you are pregnant, think you could be pregnant, or if you plan to become pregnant. Do not stop treatment without first discussing it with your doctor.

It is not known whether the ingredients of Trobalt can pass into breast-milk.

Talk to your doctor about breast-feeding while you are taking Trobalt. The doctor will weigh up the benefit to you against any risk to your baby of taking Trobalt while you are breast-feeding.

#### *Driving and using machines*

Trobalt can make you feel dizzy or drowsy and cause double or blurred vision. Do not drive or use machines until you know how Trobalt affects you.

You must talk to your doctor about the effect of your epilepsy on driving and using machines.

#### **Side Effects**

Like all medicines, Trobalt can cause side effects, although not everybody gets them.

#### *Look out for serious symptoms*

Problems passing urine  
These are common in people taking Trobalt, and can lead to not being able to pass urine at all. This is most likely to happen during the first few months of treatment with Trobalt. Symptoms include:

- pain when passing urine (*dysuria*)
- difficulty in starting to urinate (*urinary hesitation*)
- not being able to pass urine (*urinary retention*).

Tell your doctor immediately if you get any of these symptoms.

# TROBALT TABLET

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## *Mental health problems*

These are common in people taking Trobalt, and are most likely to happen during the first few months of treatment.

Symptoms include:

- confusion
- psychotic disorders (severe mental health problems)
- hallucinations (seeing or hearing things that are not there).

Tell your doctor as soon as possible if you get any of these symptoms. Your doctor may decide that Trobalt is not suitable for you.

## *Very common side effects*

These may affect more than 1 in 10 people:

- dizziness
- drowsiness
- lack of energy.

If any of these effects gets serious, tell your doctor or pharmacist.

## *Common side effects*

These may affect up to 1 in 10 people:

- blood in the urine; abnormally coloured urine
- feeling disorientated; anxiety
- memory problems (*amnesia*)
- difficulty in reading, writing or saying what you mean, or difficulty in understanding words
- attention problems
- lack of co-ordination; spinning sensation (*vertigo*); balance problems; problems walking
- tremors; sudden jerking of muscles (*myoclonus*)
- tingling or numbness of the hands or feet
- double or blurred vision
- constipation; feeling sick (*nausea*); indigestion; dry mouth
- weight gain; increased appetite
- swelling of lower legs and feet

- feeling weak or generally unwell
- changes in liver function, which will show up in blood tests.

If any of these effects gets serious, tell your doctor or pharmacist.

## *Elderly*

If you are 65 years or older, you may be at increased risk of central nervous system events, urinary retention, atrial fibrillation and irregular heart beat.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## **Storage and Disposal of TROBALT**

### - Storage

Keep out of the reach and sight of children.

Do not use Trobalt after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **Product Description**

### - What it looks like

50 mg tablets:

- Purple, round, film-coated tablets, marked “RTG 50” on one side.

100 mg tablets:

- Green, round, film-coated tablets, marked “RTG 100” on one side.

200 mg tablets:

- Yellow, oblong, film-coated tablets, marked “RTG-200” on one side.

300 mg tablets:

- Green, oblong, film-coated tablets, marked “RTG-300” on one side.

400 mg tablets:

- Purple, oblong, film-coated tablets, marked “RTG-400” on one side.

### - Ingredients

- Active ingredient(s)

50 mg, 100 mg, 200 mg, 300 mg or 400 mg Retigabine

- Inactive ingredient(s)

Tablet core:

Croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose

Film-coat:

Trobalt Tablet 50 mg & 400 mg:

- Indigo carmine aluminium lake, carmine, polyvinyl alcohol, macrogol/PEG 3350, titanium dioxide, talc

Trobalt Tablet 100 mg & 300 mg:

- Indigo carmine aluminium lake, iron oxide yellow, polyvinyl alcohol,

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macrogol/PEG 3350,  
titanium dioxide, talc

**Date of Revision**  
- 11/03/2016

Trobalt Tablet 200 mg:

- Iron oxide yellow, polyvinyl alcohol, macrogol/PEG 3350, titanium dioxide, talc

**Serial Number:**  
BPFK(R4/1)080316/00070

- MAL number

Trobalt Tablet 50mg:

- MAL20122183ARZ

Trobalt Tablet 100mg:

- MAL20122184ARZ

Trobalt Tablet 200mg:

- MAL20122185ARZ

Trobalt Tablet 300mg:

- MAL20122186ARZ

Trobalt Tablet 400mg:

- MAL20122187ARZ

**Manufacturer**

GlaxoSmithKline LLC  
1011 North Arendell Avenue  
Zebulon, North Carolina  
USA

**Repacker**

Standard Packs: 50mg, 100mg,  
200mg, 300mg, and 400mg:  
Glaxo Wellcome S.A.  
Aranda de Duero,  
Spain

Starter Packs: 50mg + 100mg

(multi strength):  
Catalent UK Packaging  
Limited,  
Bolton BL5 3XX,  
United Kingdom

**Product Registration Holder**

GlaxoSmithKline  
Pharmaceutical Sdn. Bhd.  
Level 6, Quill 9,  
112 Jalan Semangat  
46300 Petaling Jaya,  
Selangor, Malaysia