

# CAVERTA TABLETS

Sildenafil (50mg, 100 mg)

## What is in this leaflet

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

## What **CAVERTA** is used for

**CAVERTA** are used to treat erectile dysfunction or impotence in adult men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.

## How **CAVERTA** works

**CAVERTA** contains an active ingredient called sildenafil citrate

Sildenafil citrate belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It works by relaxing the blood vessels in the penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection naturally.

**CAVERTA** will only work if you are sexually excited. It will not increase your sex drive.

**CAVERTA** is not for use in women.

This medicine is available only with a doctor's prescription.

## Before you use **CAVERTA**

- When you must not use it

## Do not take **CAVERTA**

- if you have an allergy to sildenafil or any of the ingredients of **CAVERTA** listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts

of the body, rash, itching or hives on the skin

- You must not take **CAVERTA** if you are taking any nitrate medication (usually used for heart problem) in any form. Using the two together may lead to a severe drop in your blood pressure which may be difficult to treat.
- If you are being treated for angina (pain or uncomfortable feeling in the chest) and heart failure. As you suffer from heart or blood vessel problems that make sexual intercourse inadvisable.
- you have suffered a heart attack or stroke in the last 6 months
- you have severe liver problems
- your blood pressure is unusually high or low and is not being treated effectively
- you have loss of vision in one or both eyes from an eye disease called non-arteritic anterior ischaemic optic neuropathy (NAION). This disease arises from damage to the optic nerve due to lack of blood supply.
- you have an eye disease called retinitis pigmentosa. This is a genetic disease which is characterised by tunnel vision and night blindness.

If you are not sure whether to start taking this medicine, talk to your doctor or pharmacist.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Because sexual activity may place a strain on your heart, your doctor will need to check your fitness level before you start taking **CAVERTA**.

Tell your doctor if you have or have had any of the following medical conditions:

- you have or have had problem(s) with your heart or blood vessels
- you have problems(s) with your liver or kidney(s) you suffer from any of the following conditions:

- diabetes, especially if you also have eye problems
- leukaemia (cancer of the blood)
- multiple myeloma (cancer of the bone marrow)
- sickle cell anaemia
- any disease or deformity of your penis
- bleeding problem (such as haemophilia)
- stomach ulcers
- you suffer from problem(s) with your color vision
- you have had previously experienced sudden decrease or loss of hearing which may or may not be accompanied with ringing in the ears and dizziness.
- you are taking any other medicine for treatment for impotence.

If you have not told your doctor about any of the above, tell him/her before you take **CAVERTA**.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **CAVERTA** may interfere with each other. These include:

- cimetidine (used to treat ulcers)
- some medicines used to treat fungal infections including ketoconazole or itraconazole.
- some antibiotics including erythromycin and rifampicin
- some medicines used to treat HIV including ritonavir and saquinavir
- doxazosin or medicines called alpha blockers, which are used in the treatment of high blood pressure or prostate problems
- bosentan (used in the treatment of pulmonary artery hypertension)
- amlodipine (used to treat high blood pressure)

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines. You may need different amounts of your medicines or

you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

### How to use CAVERTA

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

#### - How much to use

#### Adult

The usual dose of sildenafil is 50 mg one hour before sexual activity. Further your doctor may increase to a maximum of 100 mg or decrease to 25 mg. The maximum daily dose is 100 mg.

#### Kidney problems

If you have severe kidney problems, your doctor may prescribe a lower dose of 25 mg.

#### Liver problems

If you have liver problems, your doctor may prescribe a lower dose of 25 mg.

#### Children

This medicine should not be used in children less than 18 years.

If you are taking medicines which interact with CAVERTA (refer to section Taking other medicines) your doctor may start you on the lower dose (25 mg) of CAVERTA. Do not take more than one dose of CAVERTA in a day.

#### - When to use it

CAVERTA can be taken with or without food by swallowing the tablet whole with a full glass of water

Take your dose of CAVERTA, as advised by your doctor, one hour before you intend to have sex.

The length of time it takes for CAVERTA to start acting varies from person to person. Normally it takes between half an hour to one hour.

You may find that CAVERTA take longer to act if you take it with a heavy meal.

CAVERTA will work only if you are sexually excited.

#### - How long to use it

CAVERTA 50mg and 100mg is to be taken only prior to anticipated sexual activity and is not recommended for continuous daily use

#### - If you forget to use it

Take your dose as soon as you remember. You should not take Caverta more than once a day

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

If you are taking more than the recommended dose of CAVERTA, you are more likely to experience side effects.

Increase in dose up to 200 mg resulted in side effects like headache, flushing, dizziness, indigestion, nasal congestion, altered vision.

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CAVERTA.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### While you are using CAVERTA

#### - Things you must do

You must stop using CAVERTA if:

- You suffer a loss of eyesight in one or both eyes
- You experience loss of hearing
- You have an erection that persists for more than 4 hours
- You experience dizziness, nausea (feeling sick) a feeling of tightness, pressure or heaviness in the chest especially if you have history of heart problems.

If you experience any of the above while taking CAVERTA, you need to seek medical attention urgently.

Tell your doctor in case CAVERTA does not help you get an erection or if your erection does not last long enough to complete sexual intercourse. In such

cases, your doctor may recommend a higher dose.

If you are about to be started on any new medicine, especially nitrates, tell your doctor and pharmacist that you are taking CAVERTA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine

#### - Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use CAVERTA to treat any other complaints unless your doctor says to.

#### - Things to be careful of

Be careful drinking alcohol while taking CAVERTA. Alcohol can temporarily affect the ability to get an erection. Avoid drinking large quantities of alcohol before sexual activity.

It is recommended to avoid grapefruit juice while on therapy with CAVERTA.

If you experience dizziness or change in vision when taking CAVERTA, do not drive or operate machinery.

CAVERTA offer no protection against sexually transmitted diseases like HIV infection. Protective measures to be taken as advised by your doctor.

### Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking CAVERTA.

CAVERTA help most people suffering from erectile dysfunction or impotence, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

### **Serious side effects**

**If any of the following happens, stop taking CAVERTA and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.**

- shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, hives
- seizures (fits), seizure recurrence, fainting, stroke, blood clot/ bleeding in the brain
- decreased vision including sudden/temporary loss of vision
- eye disorders, effect on vision (including colour tinge to vision, blurred vision or reduced sharpness of vision)
- disorders of lacrimation (production or shedding of tears), bloodshot eyes/red eyes, double vision, discharge with itching of the eyes and crusty eyelids; dilated pupils; eye pain, dry eyes
- burning sensation in the eye; swelling of the eye; increased pressure in the eye
- bleeding in/at the back of the eye, visual field defect, cataract
- chest pain, heart attack, feeling of tightness, pressure or heaviness in the chest, cardiac arrest, heart failure
- unusual or dangerously fast heartbeat, increased heart rate, shock
- dizziness on standing up, especially when getting up from a sitting or lying position
- sudden decrease or loss of hearing
- prolonged and sometimes painful erections

Sudden cardiac death has also been reported.

### **Other side effects**

**Tell your doctor if you notice any of the following:**

- headache, dizziness, flushing
- loose stools, indigestion
- stuffy nose (nasal congestion)
- urinary tract infection (stinging or burning sensation, need to pass urine more frequently)
- high and low blood pressure
- ringing in the ears, ear pain

- light sensitivity

### **Laboratory abnormalities**

- abnormal ECG
- abnormal liver function tests
- high uric acid levels in the blood
- high sodium levels in the blood
- abnormal presence of blood in urine
- changes in blood sugar levels
- abnormal blood cell counts

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

**You may report any side effects or 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 CAVERTA**

#### **Storage**

Store below 30°C, protect from moisture

Keep **CAVERTA** where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep **CAVERTA** in the original blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

#### **Disposal**

If your doctor tells you to stop taking **CAVERTA**, or the tablets have passed their expiry date, ask your doctor what to do with any left over.

### **Product Description**

#### **What CAVERTA looks like**

**CAVERTA TABLETS 50 mg**  
Red coloured, rounded triangular shaped, film-coated tablet, with 'S22' engraved on one side and break line on the other side.

**CAVERTA TABLETS 100 mg**  
Red coloured, rounded triangular shaped, film-coated tablet, with 'S23' engraved on one side and break line on the other side.

#### **Ingredients**

- **Active ingredient:**  
**Sildenafil citrate** equivalent to **Sildenafil**

- **Inactive ingredients:**  
Microcrystalline cellulose;  
Anhydrous calcium hydrogen phosphate; Croscarmellose sodium; Magnesium stearate; Opadry Red 06B 55000

#### **MAL NO:**

**CAVERTA TABLETS 50 mg**  
MAL11090014A

**CAVERTA TABLETS 100 mg**  
MAL11090015A

### **Manufacturer and Product Registration Holder**

#### **RANBAXY (MALAYSIA) SDN. BHD.**

Lot 23, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah, Malaysia.

#### **Date of revision**

11/09/2015

#### **Serial Number**

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