

# KOZENIS

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using KOZENIS?

KOZENIS contains the active ingredient tafenoquine. KOZENIS is used to eliminate certain forms of malaria (specifically *Plasmodium vivax*) and help prevent it from coming back. It is given with another medicine (chloroquine) that treats the acute (blood) stage of malaria.

For more information, see Section [1. Why am I using KOZENIS?](#) in the full CMI.

### 2. What should I know before I use KOZENIS?

Do not take KOZENIS if you/your child has a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency or if you/your child do not know your G6PD status or have not had a blood test for G6PD deficiency.

Do not use if you/your child has ever had an allergic reaction to tafenoquine or to a similar medicine called primaquine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you/your child have any other medical conditions, take any other medicines, or if you are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use KOZENIS?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with KOZENIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use KOZENIS?

- KOZENIS should be taken with a meal to make sure the right amount of medicine is absorbed.
- KOZENIS is given on the first or second day of a course of chloroquine, which is another medicine for malaria.
- **Adults, adolescents and children (weighing greater than 35 kg):** Take two 150 mg tablets together as a single 300 mg dose.
- **Adolescents and children (2 years of age and over) weighing 10 kg to 35 kg:** Your doctor will decide on the correct dose of KOZENIS for your child, depending on the weight of the child.

More instructions can be found in Section [4. How do I use KOZENIS?](#) in the full CMI.

### 5. What should I know while using KOZENIS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, surgeon or pharmacist you visit if you/your child has taken KOZENIS in the past 3 months.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li><li>• If you/your child are going to have any blood tests, tell your doctor if you/your child have taken KOZENIS in the past 3 months.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give your medicine to anyone else, even if they have the same condition.</li><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the pack until it is time to take them.</li><li>• Store it in a cool dry place away from moisture, heat or sunlight.</li></ul>

For more information, see Section [5. What should I know while using KOZENIS?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effects are difficulty sleeping, headache, dizziness, nausea and vomiting.

See a doctor as soon as possible if you develop a rash or if you notice anything that is making you feel unwell.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# KOZENIS

Active ingredient: *tafenoquine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using KOZENIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KOZENIS.**

Where to find information in this leaflet:

- [1. Why am I using KOZENIS?](#)
- [2. What should I know before I use KOZENIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use KOZENIS?](#)
- [5. What should I know while using KOZENIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using KOZENIS?

**KOZENIS contains the active ingredient tafenoquine.**

Malaria is a serious disease spread by infected mosquitos.

**KOZENIS is used to eliminate certain forms of malaria (specifically *Plasmodium vivax*) and help prevent it from coming back. It is given with another medicine (chloroquine) that treats the acute (blood) stage of malaria.**

You must get medical advice on which anti-malarial medicines to take. You must ask your doctor or pharmacist if KOZENIS is suitable for the type of malaria to be treated.

The safety and efficacy of tafenoquine have not been established in children under 2 years of age.

### 2. What should I know before I use KOZENIS?

#### Warnings

**Do not use KOZENIS if:**

- you/your child has a condition called glucose-6-phosphate dehydrogenase (G6PD) deficiency (sometimes known as favism)
- you do not know your/your child's G6PD status or have not had a blood test for G6PD deficiency
- you know or think that you are pregnant (see 'Pregnancy and breastfeeding')
- you are breastfeeding a baby who is known to have G6PD deficiency or hasn't been tested for it (see 'Pregnancy and breastfeeding')
- you/your child are allergic to tafenoquine, or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you/your child can use this medicine.

**Check with your doctor if you/your child:**

- have currently or previously experienced serious psychiatric disorders such as depression or psychosis

- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you/your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**Do not take KOZENIS if you are pregnant.**

You should avoid becoming pregnancy for at least 3 months after taking KOZENIS. If you do become pregnant within 3 months after taking KOZENIS, tell your doctor.

**Do not take KOZENIS if you are breastfeeding a baby who has G6PD deficiency or has not been tested for it.**

It is not known whether the ingredients of KOZENIS can pass into breast milk. Check with your doctor if you plan to breastfeed, even if you know your child is not G6PD deficient.

#### Before you start to take it

Because KOZENIS can cause a breakdown of red blood cells in the bloodstream (haemolysis) in persons with G6PD deficiency, a screening test must be performed before you/your child take KOZENIS to see if you/your child has such a deficiency.

After you/your child have taken KOZENIS, contact your doctor if you/your child develop symptoms of haemolytic anaemia (a condition in which red blood cells are destroyed and removed from the bloodstream before their normal lifespan is over). Symptoms of haemolytic anaemia include darkening of the urine, dizziness, confusion, tiredness, or shortness of breath.

KOZENIS stays in your/your child's body for up to 3 months. Contact your doctor if adverse reactions occur during this time.

Tafenoquine may cause changes in the haemoglobin in your red blood cells (methaemoglobinemia). Tell your doctor if you/your child have been previously told that you/your child have been diagnosed with methaemoglobinemia or a related enzyme deficiency.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with KOZENIS and affect how it works.**

These include:

- metformin, to treat diabetes.

Some medicines may be affected by KOZENIS or may affect how well it works. You/your child may need different amounts of your medicines, or you/your child may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you/your child are taking and if these affect KOZENIS.**

## 4. How do I use KOZENIS?

### How much to take

Always take KOZENIS exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

#### 150 mg Film-coated tablets:

**Adults, adolescents and children (weighing greater than 35 kg)**

- Take two 150 mg tablets of KOZENIS together as a single 300 mg dose.

#### 50 mg Film-coated dispersible tablets:

**Adolescents and children (aged at least 2 years) weighing 10 kg to 35 kg**

Your doctor will decide on the correct dose of KOZENIS for your child, depending on the weight of the child.

### When to take KOZENIS

- KOZENIS should be taken with a meal to make sure the right amount of medicine is absorbed.

### How to take KOZENIS

- KOZENIS is given on the first or second day of a course of chloroquine, which is another medicine for malaria.

#### 150 mg Film-coated tablets:

- Do not break or crush the tablets.

#### 50 mg Film-coated dispersible tablets:

- If you (or your child) vomits within 60 minutes of taking KOZENIS please contact your doctor.
- The tablet(s) should be fully dispersed before swallowing. Only water should be used for dispersion. The amount of water for dispersion will depend on the number of tablets prescribed (see "Instructions for Use" leaflet in the pack).

### If you/your child use too much KOZENIS

If you think that you/your child have used too much KOZENIS, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using KOZENIS?

### Things you should do

#### Call your doctor straight away if you:

- Become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit if you/your child has taken KOZENIS in the past 3 months.

If you/your child are going to have surgery, tell the surgeon if you/your child have taken this medicine in the past 3 months. It may affect other medicines used during surgery.

If you/your child are about to have any blood tests, tell your doctor if you/your child have taken this medicine in the past 3 months. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that you/your child's progress can be checked.

### Things you should not do

- Do not take KOZENIS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you/your child.
- Do not stop taking your medicine or lower you/your child's dosage without checking with your doctor.

### Driving or using machines

KOZENIS is unlikely to affect your ability to drive or use machines.

### Looking after your medicine

- Keep your tablets in the pack until it is time to take them.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you/your child no longer needs to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you/your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you/your child have any further questions about side effects.

### Less Serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Nausea</li><li>• Vomiting</li><li>• Headache</li><li>• Dizziness</li></ul>	<b>Speak to your doctor if you have any of these less</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Anxiety</li> <li>Feeling drowsy</li> <li>Abnormal dreams</li> <li>Difficulty sleeping</li> <li>Uncomfortable sensitivity to light</li> <li>Effects on the part of your eye called the cornea which may cause changes in your vision</li> </ul> <p>Side effects that may show up in blood tests:</p> <ul style="list-style-type: none"> <li>Decreased red blood cells</li> <li>Increased abnormal red blood cells (methaemoglobinaemia)</li> <li>Increased liver enzymes</li> <li>Increased blood creatinine</li> </ul>	<p><b>serious side effects and they worry you.</b></p>

### Serious Side Effects

Serious side effects	What to do
<p><b>Effects on red blood cells</b></p> <p>Breakdown of red blood cell (haemolytic anaemia). Signs or symptoms may include:</p> <ul style="list-style-type: none"> <li>Darkening of the urine</li> <li>Dizziness</li> <li>Confusion</li> <li>Tiredness, or shortness of breath</li> </ul> <p>Abnormal haemoglobin in the blood (methaemoglobinaemia). Signs or symptoms may include:</p> <ul style="list-style-type: none"> <li>Bluish colouring of the skin, typically starting with the lips</li> <li>Darkening of the urine</li> <li>Dizziness</li> <li>Confusion</li> <li>Tiredness or shortness of breath.</li> </ul> <p><b>Severe allergic reactions</b></p> <p>These are rare in people taking KOZENIS. Signs or symptoms may include</p> <ul style="list-style-type: none"> <li>Raised and itchy rash (hives)</li> <li>Swelling, sometimes of the face lips or mouth (angioedema), causing difficulty in breathing</li> <li>Collapse or loss of consciousness</li> </ul>	<p><b>Call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you/your child feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you/your child have received medical advice for any side effects you/your child experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your/your child's medicines.**

## 7. Product details

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

### What KOZENIS contains

<b>Active ingredient (main ingredient)</b>	tafenoquine
<b>Other ingredients (inactive ingredients)</b>	<p><b>Film-coated tablets:</b></p> <p>Microcrystalline Cellulose Mannitol Magnesium Stearate Hypromellose Titanium Dioxide Iron Oxide Red macrogol</p> <p><b>Film-coated dispersible tablets:</b></p> <p>Microcrystalline Cellulose Hypromellose Sucralose Magnesium Stearate Iron oxide yellow Macrogol Polyvinyl alcohol Purified talc Titanium dioxide</p>

**Do not take this medicine if you/your child are allergic to any of these ingredients.**

### What KOZENIS looks like

#### Film-coated tablets:

KOZENIS 150 mg tablets are pink, capsule-shaped and marked with 'GS J11' on one side (AUST R 297214).

#### Film-coated dispersible tablets:

KOZENIS 50 mg tablets are yellow, round-shaped and marked with 'GS INC' on one side (AUST R 350774).

### Who distributes KOZENIS

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford Victoria 3067

Australia

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