### AKAMIN®

#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking AKAMIN?

AKAMIN contains the active ingredient minocycline (as hydrochloride dihydrate). AKAMIN is used to treat certain infections caused by bacteria and to control acne which is resistant to other antibiotics. For more information, see Section <u>1. Why am I using AKAMIN?</u> in the full CMI.

# 2. What should I know before I take AKAMIN?

Do not use if you have ever had an allergic reaction to minocycline, any other tetracycline antibiotics or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use AKAMIN? in the full CMI.

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

Some medicines may interfere with AKAMIN and affect how it works. A list of these medicines is in Section <u>3.</u> What if I am taking other medicines? in the full CMI.

### 4. How do I take AKAMIN?

- For treating infections: the usual dose is 200 mg to start with, followed by 100 mg every 12 hours.
- For controlling acne, the usual dose is 50mg twice a day.

More instructions can be found in Section <u>4. How do I</u> <u>use AKAMIN?</u> in the full CMI.

# 5. What should I know while taking AKAMIN?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist that you visit that you are using AKAMIN.</li> </ul>
	<ul> <li>If you become pregnant while you are taking AKAMIN, tell your doctor immediately.</li> </ul>
	<ul> <li>If you are being treated for an infection, take the full course of tablets prescribed, even if you</li> </ul>

	<ul> <li>feel better after a few days.</li> <li>Before starting any new medicine, tell your doctor or pharmacist that you are taking AKAMIN.</li> <li>If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking AKAMIN.</li> <li>Tell your doctor, if you get thrush or any other infection while taking, or soon after stopping AKAMIN.</li> </ul>
Things you should not do	<ul> <li>Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.</li> <li>Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> <li>Do not use AKAMIN to treat any other medical</li> </ul>

	complaints unless your doctor tells you to.
Driving or using machines	<ul> <li>Be careful before you drive or use any machines or tools until you know how AKAMIN affects you.</li> <li>AKAMIN may cause dizziness or light- headedness in some people.</li> </ul>
Drinking alcohol	<ul> <li>If you drink alcohol, dizziness or light- headedness may be worse.</li> </ul>
Looking after your medicine	<ul> <li>Store below 25°C.</li> <li>Heat and dampness can destroy some medicines.</li> </ul>

For more information, see Section <u>5. What should I know</u> while using AKAMIN? in the full CMI.

### 6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

### AKAMIN®

Active ingredient(s): [minocycline (as hydrochloride dihydrate)]

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using AKAMIN. 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 AKAMIN.

#### Where to find information in this leaflet:

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

### 1. Why am I taking AKAMIN?

**AKAMIN contains the active ingredient minocycline** (as hydrochloride dihydrate). AKAMIN is an antibiotic that belongs to a group of medicines called tetracyclines. They work by stopping the growth of bacteria which cause infections or make acne worse. AKAMIN is used to treat certain infections caused by bacteria, and to control acne, which is resistant to other antibiotics.

AKAMIN will not work against infections caused by viruses such as colds or flu.

# Ask your doctor if you have any questions about why AKAMIN has been prescribed for you.

Your doctor may have prescribed AKAMIN for another reason.

There is no evidence that AKAMIN is addictive.

# 2. What should I know before I take AKAMIN?

### Warnings

### Do not use AKAMIN if:

 you are allergic to medicines containing minocycline (e.g. Minomycin), any other tetracycline antibiotics (e.g. Doryx, Doxylin, Vibramycin, Vibra-Tabs) or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing.

- you are taking preparations containing:
  - vitamin A
  - retinoids, which are medications used to treat:

- skin problems such as isotretinoin (e.g., Roaccutane, Oratane) and acitretin (Neotigason)
- a certain type of leukaemia such as tretinoin (Vesanoid)

Taking AKAMIN with any of these preparations may lead to serious unwanted side effects.

# Ask your doctor or pharmacist if you are not sure if you are taking one of these medicines.

- you are pregnant or breastfeeding.
- you have systemic lupus erythematosus (Lupus).
- you have severe kidney disease.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

### Use in Children

# Do not give AKAMIN to children of eight years and under unless directed by the child's doctor.

Tetracycline medicines, including AKAMIN, may cause permanent staining and enamel loss in developing teeth, and reduced bone growth.

### Check with your doctor if you:

- have allergies to any other medicines, foods, dyes or preservatives.
- have any other health problems, including kidney or liver problems.

 plan to have surgery, including dental surgery, especially if it requires a general anaesthetic.

During treatment, you 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 <u>6. Are there any side effects</u>?

### **Pregnancy and breastfeeding**

#### Do not take AKAMIN if you are pregnant, breastfeeding or if you intend to become pregnant or breastfeed.

AKAMIN is not recommended in the second and third terms of pregnancy as it may harm your developing baby. This may include enamel loss and staining of your baby's teeth.

High doses of tetracyclines may also cause liver problems in pregnant women.

AKAMIN passes into breast milk and may cause enamel loss and staining of your baby's teeth.

Your doctor will discuss the risks and benefits of using AKAMIN if you are pregnant or breastfeeding.

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

Tell your doctor or pharmacist if you 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 and AKAMIN may interfere with each other and affect how it works. These include:

- preparations containing vitamin A including vitamin supplements
- retinoids used for skin problems, such as isotretinoin (Roaccutane, Oratane), acitretin (Neotigason) or for leukaemia such as tretinoin (Vesanoid)
- medicines used to prevent blood clots, such as warfarin (Coumadin, Marevan)
- penicillins, another group of antibiotics (e.g. Amoxil)
- diuretics, also called fluid or water tablets (e.g. Lasix, Moduretic, Aldactone)
- methoxyflurane (Penthrax), an inhalation general anaesthetic

Tell the doctor or dentist that you are taking AKAMIN if you expect to have surgery or dental work with a general anaesthetic.

• the contraceptive pill (birth control pill).

Talk to your doctor about the additional need for a barrier method of contraception (e.g. condom or diaphragm) while taking AKAMIN. AKAMIN may decrease the effectiveness of some birth control pills.

You may need to take different amounts of your medicine, or you may need to take different medicines.

# Medicines which interfere with the absorption of AKAMIN include:

 antacids (containing aluminium, calcium or magnesium) used for indigestion  preparations containing iron including vitamin supplements.

You can still take these medicines while you are taking AKAMIN. However, you must take AKAMIN at least 2 hours before or 2 hours after taking any of these medicines to make sure there is no problem with absorption.

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

### 4. How do I take AKAMIN?

### Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

### If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

### How much to take

- For treating infections, the usual dose for adults is 200 mg initially, followed by 100 mg every 12 hours.
- For controlling acne, the usual dose is 50 mg twice a day.

However, depending on your condition and your response to this medicine, your doctor may ask you to take a different dose.

People with kidney problems may require smaller doses.

### When to take AKAMIN

#### Take AKAMIN during or immediately after a meal.

This will reduce the chances of stomach upset.

#### Take AKAMIN at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

#### How to take **AKAMIN**

Swallow the tablets whole with a full glass of water or milk while sitting or standing upright.

### Stay upright for at least 30 minutes. Do not lie down immediately after taking AKAMIN.

This is to help avoid irritation to your oesophagus (food pipe), which you may feel as heartburn or indigestion.

### How long to take AKAMIN for

Keep taking AKAMIN until you finish the tablets or for as long as your doctor recommends. Your doctor may prescribe AKAMIN for long periods.

For treating infections, your doctor will tell you when to stop taking AKAMIN, as the length of treatment varies depending on the condition you have. This is usually 24 to 48 hours after the fever and signs of infection have gone.

# Do not stop taking AKAMIN, even if you feel better after a few days, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

For controlling acne, AKAMIN is normally taken for a few months.

### If you forget to use AKAMIN

AKAMIN should be used regularly at the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you miss your dose at the usual time, and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

# Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

### If you take too much AKAMIN

If you think that you have used too much AKAMIN, you may need urgent medical attention.

### You should immediately:

 phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

If you take too much AKAMIN you may experience the following symptoms: nausea, vomiting, stomach pain, fall in blood pressure, tiredness.

# 5. What should I know while taking AKAMIN?

### Things you should do

Before starting any new medicine, tell your doctor or pharmacist that you are taking AKAMIN.

### Call your doctor straight away if you:

 develop a persistent headache with one or more of the following symptoms - nausea, vomiting, blurred vision or dizziness.

These may be signs of a rare condition associated with the use of minocycline called benign intracranial hypertension (increased pressure within the skull).

- are taking AKAMIN for an infection and your symptoms do not improve within a few days, or if they become worse.
- become pregnant while you are taking AKAMIN.

 develop symptoms of thrush (a sore, white mouth or tongue, vaginal itching or discharge) while taking or soon after stopping AKAMIN.

Sometimes the use of AKAMIN allows fungi to grow and the above symptoms to occur. AKAMIN does not work against fungi.

• If you get severe diarrhoea. Do this even if it occurs several weeks after you have stopped taking AKAMIN.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. **Do not take any medicines for the diarrhoea without checking with your doctor.** 

Remind any doctor, dentist or pharmacist you visit that you are using AKAMIN.

# If you are taking AKAMIN for a long time, visit your doctor regularly so that they can check on your progress.

Your doctor may want you to have some blood tests from time to time.

### Things you should not do

# • Do not stop taking AKAMIN or change the dose, without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. Your infection may not clear completely or may return.

- Do not use AKAMIN to treat any other conditions unless your doctor tells you to.
- Do not let yourself run out of AKAMIN over the weekend or on holidays.
- Do not give AKAMIN to anyone else, even if they have the same condition as you.

### Things to be careful of

#### Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a SPF 30+ sunscreen.

AKAMIN may cause your skin to be much more sensitive to sunlight than it is normally. This may cause a skin rash, itching, redness or severe sunburn.

### If your skin does appear to be burning, stop taking AKAMIN and tell your doctor.

### Driving or using machines

### Be careful before you drive or use any machines or tools until you know how AKAMIN affects you.

AKAMIN may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly. Keep your tablets in the original container until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Store AKAMIN in a cool dry place that stays below 25°C. Protect 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.

Heat and dampness can destroy some medicines.

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

### Getting rid of any unwanted medicine

If you no longer need 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 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 have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<ul> <li>dizziness, lightheadedness, unsteadiness</li> <li>headache</li> <li>blurred vision, hearing loss</li> <li>feeling sick (nausea), vomiting, diarrhoea</li> <li>loss of appetite</li> <li>sore mouth or tongue</li> <li>difficulty in swallowing</li> <li>oral thrush (white, furry sore tongue and mouth)</li> <li>vaginal thrush (sore and itchy vagina, vaginal discharge)</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul> <li>swelling and itching in the anal and genital areas</li> </ul>	
<ul> <li>heartburn, which may be due to irritation and ulceration of the oesophagus (food pipe).</li> </ul>	

### **Serious side effects**

Serious side effects	What to do
<ul> <li>symptoms of a rare condition called benign intracranial hypertension (increased pressure within the skull) such as persistent headache along with one or more of the following - nausea, vomiting, blurred vision or dizziness</li> <li>severe diarrhoea, usually with blood and mucus, stomach pain and fever</li> <li>severe upper stomach pains, often with nausea and vomiting</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul> <li>signs of frequent infections such as fever, chills, sore throat or mouth ulcers</li> <li>bruising or bleeding more easily than normal</li> <li>being short of breath when exercising, often with tiredness, headaches, dizziness and looking pale and yellowing of the skin and/or eyes</li> <li>swollen, stiff or painful joints</li> <li>passing less urine than</li> </ul>	
<ul> <li>normal</li> <li>signs of liver disease such as feeling generally unwell, loss of appetite, yellowing of the eyes or skin (jaundice), fever, itching and dark coloured urine</li> <li>skin rash, itching, redness, flaking or blistering</li> <li>symptoms of severe sunburn (such as redness, itching,</li> </ul>	

Serious side effects	What to do
swelling, blistering) that may occur more quickly than normal	
<ul> <li>convulsions or seizures</li> <li>sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.</li> </ul>	

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

### Contact your doctor if you notice any staining of your skin, teeth, tongue, lips, gums or nails.

Slight blue-black colour staining of the skin, teeth, nails, inside of the mouth, eyes, tears, breast milk or sweat has been reported. Staining may appear at any time during AKAMIN therapy but is more common during long-term treatment. Inform your doctor without delay if you notice any staining so that your treatment can be reviewed.

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

### After finishing AKAMIN

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with AKAMIN:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps.

These may be signs of a serious condition affecting your bowel.

#### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. 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 medicines.

### 7. Product details

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

### What AKAMIN 50 tablets contain

Active ingredient (main ingredient)	minocycline 50 mg (as hydrochloride dihydrate)
Other ingredients (inactive ingredients)	<ul> <li>lactose monohydrate</li> <li>sodium starch glycollate</li> <li>povidone</li> <li>microcrystalline cellulose</li> <li>sodium lauryl sulfate</li> <li>magnesium stearate</li> <li>Opadry Orange OY-23022</li> </ul>
Potential allergens	contains sulfites and sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

### What AKAMIN looks like

AKAMIN 50 are a gold coloured, convex, film coated tablet, 6mm in diameter, debossed with "MC" on one side and the Greek alpha symbol on the other (AUST R 70852).

### Who distributes **AKAMIN**

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 www.viatris.com.au Phone: 1800 274 276

This leaflet was prepared in May 2024.

AKAMIN® is a Viatris company trade mark.

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