Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Akamin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Akamin against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Akamin is used for

Akamin is used to:

- treat certain infections caused by bacteria
- · control acne

Akamin is an antibiotic that belongs to a group of medicines called tetracyclines. These medicines work by stopping the growth of bacteria which cause infections or make acne worse.

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.

Akamin is available only with a doctor's prescription.

There is no evidence that Akamin is addictive.

Before you take Akamin

When you must not take it

Do not take Akamin if you are allergic to:

- medicines containing minocycline (e.g. Minomycin)
- medicines containing any other tetracycline antibiotic (e.g. Doryx, Doxylin, Vibramycin, Vibra-Tabs)
- 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.

Do not take Akamin if you are taking preparations containing:

- vitamin A
- retinoids, which are medicines used to treat
 - skin problems such as isotretinoin (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.

Do not take Akamin if you are pregnant.

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.

Do not take Akamin if you are breastfeeding.

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

Do not take Akamin if you have any of the following medical conditions:

- · severe kidney disease
- systemic lupus erythematosus (SLE).

Do not give Akamin to a child aged 8 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.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

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

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

- · kidney problems
- · liver problems.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you plan to have surgery, including dental surgery, especially if it requires a general anaesthetic.

If you have not told your doctor about any of the above, tell him/her before you start taking Akamin.

Taking other medicines

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

Some medicines and Akamin may interfere with each other. 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

• 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.

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.

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

How to 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.

How to take it

Swallow the tablets or capsules 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.

When to take it

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 long to take it for

Keep taking Akamin until you finish the tablets or capsules, or for as long as your doctor recommends.

For 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 take it

If 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 or capsules 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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Akamin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Akamin you may

experience the following symptoms: nausea, vomiting, stomach pain, fall in blood pressure, tiredness.

While you are taking Akamin

Things you must do

If you develop a persistent headache with one or more of the following symptoms nausea, vomiting, blurred vision or dizziness; see your doctor immediately.

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

If you are taking Akamin for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor

If you become pregnant while you are taking Akamin, tell your doctor immediately.

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.

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.

If you get a sore, white mouth or tongue while taking or soon after stopping Akamin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Akamin allows fungi to grow and the above symptoms to occur. Akamin does not work against fungi.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Akamin. Tell all the doctors, dentists and pharmacists who are treating you that you are taking 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 must 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 let yourself run out of Akamin over the weekend or on holidays.

Do not use Akamin to treat any other conditions unless your doctor tells you to.

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. Be careful driving or operating machinery until you know how Akamin affects you.

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

Side effects

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

Akamin helps most people with their infections or acne, but it may have unwanted side effects in some 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 this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you notice any of the following and they worry you:

- · dizziness, lightheadedness, unsteadiness
- headache
- · blurred vision, hearing loss
- feeling sick (nausea), vomiting, diarrhoea
- loss of appetite
- · sore mouth or tongue
- · difficulty in swallowing
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge)
- swelling and itching in the anal and genital areas

 heartburn, which may be due to irritation and ulceration of the oesophagus (food pipe).

The above list includes the milder side effects of Akamin.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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
- severe diarrhoea, usually with blood and mucus, stomach pain and fever
- severe upper stomach pains, often with nausea and vomiting
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal
- being short of breath when exercising, often with tiredness, headaches, dizziness and looking pale and yellowing of the skin and/or eyes
- · swollen, stiff or painful joints
- · passing less urine than normal
- 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
- skin rash, itching, redness, flaking or blistering
- symptoms of severe sunburn (such as redness, itching, swelling, blistering) that may occur more quickly than normal
- · convulsions or seizures
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

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.

After taking Akamin

Storage

Keep your tablets/capsules in the bottle until it is time to take them.

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

Keep your tablets or capsules in a cool dry place where the temperature stays below 25C.

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

Heat and dampness can destroy some medicines.

Keep Akamin where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Akamin, or your tablets or capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Akamin is available in two strengths:

- Akamin 50 mg round, gold coloured, film-coated tablet, marked MC on one side and Greek alpha symbol on the other side. Each bottle contains 60 tablets.
- Akamin 100 mg white and grey capsule, marked MC 100 on the white half and Greek alpha symbol on the grey half. Each bottle contains 11 capsules.

Ingredients

The active ingredient in Akamin tablets and capsules is minocycline hydrochloride dihydrate.

Akamin 50 tablets

Each Akamin 50 mg tablet contains 50 mg of minocycline.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- sodium starch glycollate
- povidone
- microcrystalline cellulose
- · sodium lauryl sulfate
- magnesium stearate
- Opadry Orange OY-23022

Akamin tablets contain sulfites, soy products, galactose and sugars (as lactose). Akamin tablets are gluten free.

Akamin 100 capsules

Each Akamin 100 capsule contains 100 mg of minocycline.

The capsules also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- magnesium stearate
- titanium dioxide
- iron oxide black
- sodium lauryl sulfate
- colloidal anhydrous silica
- potable water
- gelatin
- TekPrint SW-9008 Black Ink

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Akamin capsules contain sugars (as lactose).

Akamin capsules are gluten free.

Manufacturer

Akamin is made in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond 30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian Registration Numbers

50 mg tablets - AUST R 70852

 $100\ mg$ capsules - AUST R 53641

This leaflet was prepared in September 2019.

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