## MINOMYCIN 50 tablets

### **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.

#### 1. Why am I using MINOMYCIN 50?

MINOMYCIN 50 tablet contains the active ingredient minocycline hydrochloride dihydrate. MINOMYCIN 50 is used to treat acne, which is resistant to other antibiotics. It is also used to treat various other infections.

For more information, see Section 1. Why am I using MINOMYCIN 50? in the full CMI.

#### 2. What should I know before I use MINOMYCIN 50?

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 fpregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MINOMYCIN 50? in the full CMI.

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

Some medicines may interfere with MINOMYCIN 50 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 MINOMYCIN 50?

- 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 100 mg daily, preferably in two separate doses of 50 mg each.

More instructions can be found in Section 4. How do I use MINOMYCIN 50? in the full CMI.

#### 5. What should I know while using MINOMYCIN 50?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using MINOMYCIN 50.</li> <li>If you become pregnant while taking MINOMYCIN 50, tell your doctor immediately.</li> <li>If you are being treated for an infection, take the full course of tablets prescribed, even if you feel better after a few days.</li> <li>Before starting any new medicine, tell your doctor or pharmacist that you are taking MINOMYCIN 50.</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 MINOMYCIN 50.</li> <li>Tell your doctor, if you get thrush or any other infection while taking, or soon after stopping MINOMYCIN 50.</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 MINOMYCIN 50 to treat any other medical complaints unless your doctor says to</li> </ul>		
Driving or using machines	<ul> <li>Be careful before you drive or use any machines or tools until you know how MINOMYCIN 50 affects you.</li> <li>MINOMYCIN 50 may cause dizziness or light-headedness in some people.</li> </ul>		
Drinking alcohol	If you drink alcohol, dizziness or light-headedness may be worse.		
Looking after your medicine	Store below 25°C.		

For more information, see Section 5. What should I know while using MINOMYCIN 50? 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 6. Are there any side effects? in the full CMI.

## **MINOMYCIN 50 tablets**

Active ingredient: minocycline hydrochloride dihydrate

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

This leaflet provides important information about using MINOMYCIN 50. 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 MINOMYCIN 50.

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

- 1. Why am I using MINOMYCIN 50?
- 2. What should I know before I use MINOMYCIN 50?
- 3. What if I am taking other medicines?
- 4. How do I use MINOMYCIN 50?
- 5. What should I know while using MINOMYCIN 50?
- 6. Are there any side effects?
- 7. Product details

#### 1. Why am I using MINOMYCIN 50?

MINOMYCIN 50 contains the active minocycline hydrochloride dihydrate. MINOMYCIN 50 belongs to a group of antibiotics called tetracyclines. They work by stopping the growth of bacteria.

MINOMYCIN 50 is used to treat acne, which is resistant to other antibiotics. It is also used to treat various other infections.

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

MINOMYCIN 50 is not addictive.

Your doctor may have prescribed MINOMYCIN 50 for another purpose.

# 2. What should I know before I use MINOMYCIN 50?

#### Warnings

#### Do not use MINOMYCIN 50 if:

 you are allergic to minocycline, any other tetracycline antibiotics or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- o rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing
- difficulty breathing

Always check the ingredients to make sure you can use this medicine.

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

- you have severe kidney disease.
- The expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

#### Use in children

Do not give MINOMYCIN 50 to children of eight years and under unless directed by the child's doctor.

MINOMYCIN 50, like other tetracyclines, may cause enamel loss and permanent staining of teeth.

#### Check with your doctor if you:

- are allergic to any foods, dyes, preservatives or any other medicines.
- have any other health problems, including kidney disease.

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</u>. Are there any side effects?

#### Pregnancy and breastfeeding

Do not use this medicine if you are pregnant, breastfeeding, intend to become pregnant or breastfeed.

As with many medicines, tetracyclines may harm the developing or breastfeeding baby. This may include enamel loss and staining of the child's teeth.

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

Your doctor will discuss the risks and benefits of using MINOMYCIN 50 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 may interfere with MINOMYCIN 50 and affect how it works. These include:

- preparations containing vitamin A and some medicines used for skin problems such as isotretinoin or etretinate
- · warfarin, a medicine used to stop blood clotting
- antacids used for indigestion
- preparations containing iron
- another group of antibiotics called penicillins
- contraceptive pill (birth control pills). MINOMYCIN 50 may decrease the effectiveness of some birth control pills. Your doctor may advise you to use an additional method of contraception.
- Some tetracyclines may interact with a general anaesthetic called Penthrane. Tell the doctor or dentist

that you are taking MINOMYCIN 50 if you expect to have surgery or dental work with a general anaesthetic.

These medicines may be affected by MINOMYCIN 50 or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MINOMYCIN 50.

### 4. How do I use MINOMYCIN 50?

Take MINOMYCIN 50 exactly as your doctor has prescribed.

#### How much to take

- 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 100 mg daily, preferably in two separate doses of 50 mg each.

#### **How to take MINOMYCIN 50**

- Swallow the tablets whole with a full glass of water or milk. This medicine may be taken with food.
- Do not take it immediately before lying down.

#### How long to take MINOMYCIN 50

- Your doctor may prescribe MINOMYCIN 50 for long periods.
- Check with your doctor if you are not sure how long you should be taking it.
- For treating infections, MINOMYCIN 50 must be taken for at least 48 hours after you feel well and the fever has gone.
- For controlling acne, MINOMYCIN 50 is normally taken for a few months.
- Visit your doctor regularly. They may do blood tests to check your progress.
- Continue taking it until your doctor tells you to stop.

#### If you forget to use MINOMYCIN 50

MINOMYCIN 50 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 it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

#### If you use too much MINOMYCIN 50

If you think that you have used too much MINOMYCIN 50, 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.

If you take too much MINOMYCIN 50 you may experience the following symptoms: nausea, vomiting, stomach pain, fall in blood pressure, tiredness.

# 5. What should I know while using MINOMYCIN 50?

### Things you should do

- If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking MINOMYCIN 50.
- If you become pregnant while taking MINOMYCIN 50, tell your doctor immediately.
- If you are being treated for an infection, take the full course of tablets prescribed, even if you feel better after a few days.

If you do not complete the full course, the bacteria may still be present and your infection may return.

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

- develop a persistent headache with one or more of the other symptoms. Minocycline is rarely associated with a serious condition called benign intracranial hypertension which can cause headache, nausea, vomiting, blurred vision, dizziness.
- If you get thrush or any other infection while taking, or soon after stopping MINOMYCIN 50.
   Overgrowth of certain organisms not sensitive to MINOMYCIN 50 can sometimes occur.
- If you get severe diarrhoea. Do this even if it occurs several weeks after stopping MINOMYCIN 50.
   This may be a sign of a serious side effect that affects the bowel.

Do not take any medicines to treat this diarrhoea unless directed by your doctor.

Remind any doctor, dentist or pharmacist you visit that you are using MINOMYCIN 50.

#### Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use MINOMYCIN 50 to treat any other medical complaints unless your doctor says to.

#### Things to be careful of

- If outdoors, wear protective clothing and use a SPF 15+ sunscreen.
  - MINOMYCIN 50 may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.
- If your skin does appear to be burning, stop taking MINOMYCIN 50 and tell your doctor.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how MINOMYCIN 50 affects you.

MINOMYCIN 50 may cause dizziness or light-headedness in some people.

#### **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.

Store it in a cool dry place below 25°C 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.

#### 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> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

- 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).

#### Serious side effects

Serious side effects

<ul> <li>symptoms of a rare condition</li> </ul>				
calle	d benign int	tracrania	al	
hype	rtension (ir	creased	l pr	essure
with	in the skull)	such as	pe	rsistent
head	lache along	with on	e o	r more
of th	e following	- nausea	a, v	omiting,
blurr	ed vision o	r dizzine	SS	

- 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

#### Allergy-related:

 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. What to do

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.

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 MINOMYCIN 50 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.

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

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

#### 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 MINOMYCIN 50 contains

Active ingredient (main ingredient)	minocycline hydrochloride dihydrate, 50 mg	
Other ingredients (inactive ingredients)	<ul> <li>Lactose monohydrate</li> <li>Sodium starch glycollate</li> <li>Povidone</li> <li>Sorbitol</li> <li>microcrystalline cellulose</li> <li>Stearic Acid</li> <li>Magnesium Stearate</li> <li>Opadry Orange YS-1R-2402</li> </ul>	

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

#### What MINOMYCIN 50 looks like

MINOMYCIN 50 is round, convex, orange film coated tablet with a scoreline on one side, and plain on the other (AUST R 47054).

The cosmetic scoreline serves no function. Do not break or split the tablet in half.

MINOMYCIN 50 is available in blister strips in packs of 4 or 60 tablets.

(Not all pack sizes are distributed in Australia.)

#### Who distributes MINOMYCIN 50

Aspen Pharma Pty Ltd 34-36 Chandos Street, St Leonards NSW 2065 Australia www.aspenpharmacare.com.au

This leaflet was prepared in December 2023.