Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MINOMYCIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking MINOMYCIN against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What MINOMYCIN is used for

The name of your medicine is MINOMYCIN. It contains the active ingredient minocycline hydrochloride.

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

MINOMYCIN belongs to a group of antibiotics called tetracyclines. They work by stopping the growth of bacteria.

Your doctor may have prescribed MINOMYCIN for another purpose.

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

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

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

MINOMYCIN is not addictive.

Before you take it

When you must not take it Do not take MINOMYCIN if:

- 1. you have ever had an allergic reaction to:
- minocycline, or any other tetracycline antibiotics
- any of the ingredients listed at the end of this leaflet

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

2. you are pregnant or breastfeeding.

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.

If you are a woman of child bearing age, you should avoid becoming pregnant while taking MINOMYCIN.

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

- 3. you have a disease called systemic lupus erythematosus (Lupus).
- 4. you have severe kidney disease.

If you are not sure whether you should be taking MINOMYCIN, talk to your doctor.

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

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

the expiry date (EXP) printed on the pack has passed.

It may have no effect at all, or worse, an entirely unexpected effect, if you take it after the expiry date.

the packaging is torn or shows signs of tampering.

If this is the case, take the tablets back to your pharmacist.

Before you start to take it

You must tell your doctor if:

- 1. you are allergic to any foods, dyes, preservatives or any other medicines
- 2. you have any other health problems, including kidney disease
- 3. you plan to become pregnant.

Taking other medicines

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

There may be interference between MINOMYCIN and some other medicines, including:

- 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
- the contraceptive pill (birth control pills). MINOMYCIN 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 if you expect to have surgery or dental work with a general anaesthetic.

These medicines may be affected by MINOMYCIN 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MINOMYCIN.

How to take it

Take MINOMYCIN exactly as your doctor has prescribed.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help. How much to take

For treating infections, the usual dose of MINOMYCIN 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 it

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.

When to take it

Take your medicine 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

Your doctor may prescribe MINOMYCIN for long periods.

Check with your doctor if you are not sure how long you should be taking it.

For treating infections, MINOMYCIN must be taken for at least 48 hours after you feel well and the fever has gone.

For controlling acne, MINOMYCIN 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

If you forget to take it

you to stop.

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 it as soon as you remember, then go back to taking it as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

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 take too much (overdose)

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

Keep telephone numbers for these places handy.

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

While you are taking it

Things you must do

Tell all doctors, dentists and pharmacists you visit that you are taking MINOMYCIN.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are taking MINOMYCIN.

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

If you develop a persistent headache with one or more of the other symptoms you should see your doctor as soon as possible. Minocycline is rarely associated with a serious condition called benign intracranial hypertension which can cause headache, nausea, vomiting, blurred vision, dizziness.

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.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness or light-headedness in some people.

Be careful when drinking alcohol while you are taking this medicine.

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

MINOMYCIN 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 outdoors, wear protective clothing and use a SPF 15+ sunscreen.

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

If you get thrush or any other infection while taking, or soon after stopping MINOMYCIN, tell your doctor.

Overgrowth of certain organisms not sensitive to MINOMYCIN can sometimes occur

If you get severe diarrhoea, immediately contact your doctor. Do this even if it occurs several weeks after stopping MINOMYCIN.

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.

Side effects

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

This medicine is effective against some infections and acne in most people, but may have unwanted side effects in some. 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.

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

The more common side effects are:

- nausea
- · vomiting
- diarrhoea
- dizziness, light-headedness, unsteadiness
- loss of appetite
- · headaches
- · rash or hives
- allergic reactions such as swelling of face or tongue
- · difficulty in swallowing
- burning in the throat or food tube

Rare side effects include:

- · increased sensitivity to sunlight
- infection by other bacteria or organisms resistant to MINOMYCIN (eg intestinal thrush)
- staining of skin, mouth, teeth or nails

Very rarely:

- · painful joints
- · inflammation of the bowel
- · blurred vision
- · liver, kidney or blood disorders
- · severe allergic reactions
- drug-induced hepatitis and acute liver failure

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

After using it

Storage

Keep this medicine where young children cannot reach it.

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

Keep MINOMYCIN in a cool, dry place where it stays below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your tablets in their container until it is time to take them.

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

Disposal

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

Product description

What it looks like

MINOMYCIN - round, convex, orange film coated tablet with a score line on one side, and plain on the other.

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

The 50 mg tablets are in blister strips in packs of 4 or 60 tablets. Not all pack sizes are distributed in Australia.

Ingredients

Each MINOMYCIN 50 mg tablet contains minocycline (as hydrochloride) as the active ingredient and the following inactive ingredients:

- · Lactose monohydrate
- · Sodium starch glycollate
- Povidone
- Sorbitol
- · microcrystalline cellulose
- · Stearic Acid
- · Magnesium Stearate
- Opadry Orange YS-1R-2402

Manufacturer

Aspen Pharma Pty Ltd 34-36 Chandos Street St Leonards NSW 2065 Australia

Australian Registration Number:

MINOMYCIN 50 mg tablets: AUST R 47054

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