MINOXIDIL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Minoxidil. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What Minoxidil is used for

The name of your medicine is Minoxidil. Minoxidil is a liquid that is to be used only on your scalp. Minoxidil is used as a long-term treatment for common baldness. Minoxidil is not a cure for baldness but in some people it can improve hair regrowth. However it is not known exactly how Minoxidil works. Minoxidil does not always work well for everybody. You should discuss what results you might expect from Minoxidil with your doctor or pharmacist. If Minoxidil is effective for you, the initial growth of new hair may be soft downy hair, and may be difficult to see. After further treatment it is likely that your hair regrowth will change and become the same colour and thickness as the rest of your hair. Treatment with Minoxidil is longterm therapy for regrowth of your hair. You will need to continue using Minoxidil to keep your new hair and also stop additional hair loss. If you stop using Minoxidil you will probably lose the hair that has already grown back. This hair loss will occur about three to four months after stopping treatment. The balding process will also start again. There is not enough information to recommend the use of this medicine for children under the age of 18 years or in people over 65 vears.

Minoxidil is not addictive.

Before you use Minoxidil

When you must not use it

Do not use Minoxidil if you have an allergy to: any medicine containing the active ingredient, minoxidil or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin

Do not use Minoxidil if:

- you do not have a family history
- of hair loss
- your hair loss is sudden or unexplained
- your scalp is red, inflamed, irritated, infected or painful
- you are under 18 or over 65 years of age.

Do not use this medicine if you are pregnant. It may affect your developing baby if you use it during pregnancy. Do not breast-feed if you are using this medicine. The active ingredient in Minoxidil passes into breast milk and there is a possibility that your baby may be affected.

Do not use 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 using this medicine, talk to your doctor or pharmacist.

Before you start to use it

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

pharmacist before using Minoxidil if you have any heart problems. If you have not told your doctor or pharmacist about any of the above, tell them before you start using Minoxidil.

Using other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Minoxidil may interfere with each other. These include:

- medicines used to treat high blood pressure and heart problems
- paracetamol
- diethylcarbamazine

These medicines may be affected by Minoxidil or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you. Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Minoxidil

How to use Minoxidil

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help. Minoxidil must only be applied when the hair and scalp are completely dry and the scalp is healthy and intact. Apply one dose (1 mL) of Minoxidil to the bald area of your scalp twice a day, preferably morning and night. This dose should be used no matter what the size of the bald spot is. Do not use more than two doses a day. Massage the solution lightly into your scalp and wash your hands well afterwards. The dropper provided with the bottle is designed to measure 1 mL of the solution. At

Minoxidil 1

least four months of treatment with Minoxidil may be necessary before you will be able to see the evidence of hair regrowth. The response of patients to Minoxidil may vary widely, and some patients have better results than others. Once you stop using Minoxidil the hair loss process will begin again.

How to use the dropper

Make sure that the scalp is dry.

- 1. Unscrew the child resistant cap from the bottle.
- 2. Ensure that the dropper is immersed in the solution and squeeze the bulb to fill the dropper to the 1.0 mL line. The dropper now contains 1 mL (one dose) of the solution.
- 3. Aim the dropper to the area of the scalp to be treated, lifting any hair out of the area with your fingers or a comb. Gently squeeze the dropper bulb and apply the solution drop by drop. Massage the solution gently into your scalp with your fingers. Wash your hands after you have finished massaging the solution into your scalp.
- 4. Replace the child resistant cap by screwing it firmly onto the bottle. Wash the dropper well with warm water and allow to dry.

If you forget to use it

If you forget to use Minoxidil and it is almost time for you to apply Minoxidil again, skip the dose you missed and apply your next dose of Minoxidil when you are meant to. Otherwise apply your Minoxidil as soon as you remember, and then go back to using your Minoxidil as you would normally. Do not apply more than 1mL of Minoxidil or apply it more than twice a day 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 use your medicine, ask your pharmacist for some hints.

If you accidentally swallow Minoxidil

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 Minoxidil is swallowed. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you have swallowed Minoxidil you may experience symptoms such as fast heart rate; lightheadedness, dizziness, or fainting; or swelling or puffiness of the body.

While you are using Minoxidil

Things you must do

If you intend to have your hair dyed or permed, tell your hairdresser that you are using Minoxidil. It may be best not to use Minoxidil for 24 hours before having your hair dyed or permed to avoid any possible interactions between the chemicals in the different products. Only apply Minoxidil to a clean, dry scalp. It is not necessary to shampoo before applying Minoxidil, however if you do wash your hair wait until your hair is absolutely dry before applying Minoxidil. A hair dryer may be used to dry your hair, but do not use it to dry the Minoxidil solution. Apply Minoxidil before using any other common hair products. Hair spray and other common hair products are usually able to be used after Minoxidil has been applied.

Minoxidil should be applied 4 hours before using any sunscreen on your scalp. If necessary, a sunscreen may be applied 2 hours after using Minoxidil. If you have used a sunscreen you should shampoo your hair and scalp before next applying Minoxidil. Wait at least one hour before wearing a hat or other head covering after applying Minoxidil. If there has been no regrowth of hair after using Minoxidil for 6 months speak to your doctor or pharmacist as there may be no point in continuing. If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Minoxidil. Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine. If you become pregnant while using this medicine, tell your doctor immediately. If you are about to have any laboratory tests (e.g. blood or

urine), tell your doctor that you are using this medicine.

Things you must not do

Do not wet or wash your scalp for at least four hours after applying Minoxidil.

Do not use a hair dryer on your head to dry the Minoxidil solution. Do not use Minoxidil if your scalp is sunburnt. If you get sunburnt wait until the sunburn heals before using Minoxidil. Do not swallow Minoxidil as this could cause serious side effects. Do not apply Minoxidil to any part of your body other than your scalp. Avoid contact of Minoxidil with your eves and broken or irritated skin. If there is accidental contact of Minoxidil with the eyes, broken or irritated skin, mouth, nose or ears wash the area with large amounts of cool tap water. Do not use Minoxidil to treat any other complaints unless your doctor tells you to. Do not give your Minoxidil to anyone else, even if they have the same condition as you. Do not use Minoxidil more than twice a day. Do not stop using your Minoxidil or change the amount used without checking with your doctor or pharmacist. Do not smoke while applying Minoxidil. Minoxidil is a flammable product.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Minoxidil. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you notice any of the following and they worry you

- headache
- excessive hair growth on other parts of the body increased hair loss
- problems with your sexual performance

These side effects are usually mild. Tell your doctor as soon as possible if you notice any of the following:

Minoxidil 2

- rapid heart rate
- unexplained rapid weight gain of 2 to 3 kg or more
- dizziness, lightheadedness, fainting
- problems with vision
- itching, redness or other irritation of the scalp where the solution is being applied
- dry or flaking skin on the scalp
- eczema

The above list includes serious side effects which may require medical attention. Serious side effects are rare. If any of the following happen, stop using Minoxidil and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- pain in the chest, arm or shoulder
- signs of severe indigestion
- shortness of breath or difficulty breathing
- swelling or puffiness of hands, face,
- · ankles or stomach

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare. Other side effects not listed above may also occur in some people. Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Minoxidil

Storage

Keep your Minoxidil in a cool dry place where the temperature stays below 25°C.

Minoxidil is a flammable product and must be kept away from heat, sparks, and naked flames. Do not smoke while you are applying Minoxidil. Do not store Minoxidil or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines. Keep it 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 or pharmacist tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Minoxidil is a clear colourless to pale yellow solution. It is available in a box containing two 60 mL bottles and one dropper for applying the solution.

Ingredients

Minoxidil contains minoxidil 50 mg/mL as the active ingredient. It also contains the inactive ingredients:

- propylene glycol
- ethanol
- water

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Minoxidil is supplied in Australia by:

Bellwether Pharma Limited Suite 1, Level 1, 1175 Toorak Road Camberwell VIC 3124

This leaflet was prepared in May 2005.

Australian registration number: AUST R 82363

Minoxidil 3