Consumer Medication Information Leaflet (RiMUP) **RETEN FIVE SOLUTION 5G/100ML®**

Minoxidil (5g/100ml)

What is in the leaflet

- 1. What Reten Five is used for
- 2. How Reten Five works
- 3. Before you use Reten Five
- 4. How to use Reten Five
- While you are using it 5.
- Side effects 6.
- Storage and Disposal of Reten Five 7.
- Product Description 8.
- Manufacturer and Product Registration 9. Holder
- 10. Date of Revision

What Reten Five is used for

Reten Five is used in the treatment of hair loss and baldness in adult men and some women.

How Reten Five works

Reten Five possible work by increasing diameter of hair shaft, stimulate active growth phase and enhancing microcirculation to hair follicles. The exact way that Reten Five work is not known.

Before you use Reten Five

- When you must not use it

• You are hypersensitive to the active ingredient or any other ingredients in the formulation.

• You are under 18 years old or over 65 years old.

- Before you start to use it

Tell your doctor if you:

• Have any unusual or allergic reaction to minoxidil or other ingredients in this preparation

• Have any other skin problems, an irritation, or a sunburn on the scalp

- Have heart problems or high blood pressure
- Have tumour of the adrenal gland
- Are using other topical preparation
- Are pregnant or nursing
- Are HIV positive

• Have kidney problems

If you are not sure whether you should start taking this product, consult your doctor.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different

amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Blood pressure lowering medicines, e.g: guanethidine
- Medicines used on skin, e.g: tretinoin, anthtalin/ditranol, corticosteroids, and occulusive ointment bases

· Paracetamol and diethylcarbamazine which might counter minoxidil effects

- Pregnancy and lactation

There is no sufficient study done on the use of minoxidil during pregnancy. Thus, it should only be used if the potential benefit outweighs the potential risk to the foetus.

Minoxidil can be absorbed and excreted into breast milk, therefore nursing is not recommended.

How to use Reten Five

Use the solution exactly as directed by your doctor.

Apply on clean unbroken scalp, massage scalp gently using fingertips. Wash hands thoroughly after application.

Note:

• Do not use if there's any cut or inflammation.

• If accidentally contact with eye, mucous membrane or broken skin, the affected area should be washed with running water.

- How much to use

Use 6 sprays (equiv. to 1.0ml solution) for each application, twice daily. The total daily dose should not exceed 2mL.

- When to use it Apply twice per day.

- How long to use it

It usually takes 4 months to observe any sign of hair growth, results may vary.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

As Reten Five is topically applied, an overdose is unlikely. However, seek medical attention if you accidentally ingest the solution. Symptoms may include faintness or dizziness, low blood pressure and irregular heartbeat. If this happens, then you should immediately go to your nearest hospital emergency department or tell your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

• Tell your doctor if you notice continued itching, redness, or burning of your scalp after you apply Reten Five. If the itching, redness, or burning is severe, wash the medicine off and check with your doctor before using it again.

• Hair loss may continue for 2 weeks after you start using Reten Five. Tell your doctor if your hair loss continues after 2 weeks. Also, tell your doctor if your hair growth does not increase after using Reten Five for 4 months.

• Stop using Reten Five and inform your doctor if you experience any of the side effects (irregular heartbeat, chest pain, swelling, low blood pressure) which might have resulted from systemic absorption of minoxidil.

• Reten Five should be applied only on the scalp, do not apply on other areas of the body.

• Make sue scalp is clean, free from inflammation, cut and skin disease before application.

• Headgear should only be worn at least one hour after application.

- Things you must not do

• Do not use Reten Five on any part of your body other than your scalp. Application to other body parts can be dangerous.

• Do not use other topical products on your scalp during treatment with Reten Five, unless otherwise directed by your doctor

- Things to be careful of

• Minoxidil topical solution is not known to influence ability to drive or operate machinery. However, it is advisable to know how this medicine affects you before driving or operating machinery.

Side effects

Like all medicines, Reten Five can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Scaling
- Itching
- Dry skin
- Flushing
- Skin inflammation
- Burning sensation
- Rash
- Changes in hair colour or texture
- Abnormal / excessive growth of hair

Rare:

- Allergic reactions
- Allergic rhinitis
- Facial swelling
- Hair loss
- Oily scalp
- Inflammation of the follicle
- Spinning sensation
- Weakness
- Dizziness
- Eye irritation
- Headache
- Rapid heart beat
- Low blood pressure
- Loss of consciousness
- Light headedness
- Inflammation of the nerve
- High blood pressure
- Swelling of feet and ankle
- Rapid irregular heart beat
- Visual disturbances
- Chest pain
- Shortness of breath
- Hepatitis / inflammation of the liver
- Kidney stone

Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website<u>npra.gov.my</u> [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Reten Five <u>Storage</u>

Keep medicines in original packaging. Store in a cool (below 30° C), dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car. Keep all medicines out of the reach of children.

- <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- <u>What it looks like</u> Reten Five is a clear colourless solution.

- Ingredients

- Active ingredient Each 100ml contains 5g Minoxidil.

- Inactive ingredients Propylene glycol, alcohol, purified water, sodium thiosulphate, phosphoric acid

- <u>Packing</u> It is packed in 30ml and 60ml bottles.

- <u>MAL Number</u> MAL12010007AZ

Manufacturer

T.O Pharma Co. Ltd. 101 Soi 124, Ladprao Rd. Bangkok 10310, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

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