PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before taking OXYBUTYNIN 5 OETHMAAN tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OXYBUTYNIN 5 OETHMAAN 5 mg tablets

1. WHAT OXYBUTYNIN 5 OETHMAAN CONTAINS

Active ingredient:

Each **OXYBUTYNIN 5 OETHMAAN** tablet contains oxybutynin hydrochloride 5,0 mg.

Inactive ingredients:

Crospovidone, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, FD&C Blue No 2.

Contains sugar (lactose monohydrate 118,90 mg).

2. WHAT OXYBUTYNIN 5 OETHMAAN IS USED FOR

OXYBUTYNIN 5 OETHMAAN tablets are indicated for:

- The relief of certain conditions of the bladder (i.e. increased urgency to urinate, increased frequency to urinate, urinary leakage).
- Spastic bladder.

- Bedwetting during sleep at night.

3. BEFORE YOU TAKE OXYBUTYNIN 5 OETHMAAN

Do not take OXYBUTYNIN 5 OETHMAAN:

- If you are hypersensitive (allergic) any of the components of **OXYBUTYNIN 5 OETHMAAN** (see **"WHAT OXYBUTYNIN 5 OETHMAAN CONTAINS")**.
- If you have an eye condition called closed angle glaucoma.
- If have any obstruction of the bowel or any form of colitis (inflammation of the bowel).
- If you have a muscle disease called myasthenia gravis.
- If you have any type of obstructive disorder of the urinary path.
- If you have an unstable heart condition.
- If you have an underactive bladder.
- If you are pregnant or plan to become pregnant. Please consult your doctor.
- If you are younger than 5 years.
- If you are a man with an enlarged prostate and an elderly man.
- If it is a very hot day (high ambient temperature).
- If you have a condition called pyloric stenosis (the narrowing the pylorus, part of the stomach, that leads into the small intestines).

Take special care with OXYBUTYNIN 5 OETHMAAN:

- If the environmental temperature is high, as it may cause fever and heat stroke due to decreased sweating, especially in children.
- If you have a fever.
- If you are child or an elderly person.
- If you have any liver or kidney diseases.
- If you have a bowel disease called ulcerative colitis. **OXYBUTYNIN 5 OETHMAAN** may aggravate symptoms of this condition.
- If you have a heart condition.

- If you have an overactive thyroid gland.
- If you have a condition called hiatus hernia (when a part of the stomach pushes its way through a hole in the diaphragm). **OXYBUTYNIN 5 OETHMAAN** may aggravate symptoms of this condition.
- If you have diarrhoea, especially in patients who had a colostomy or ileostomy.

Taking OXYBUTYNIN 5 OETHMAAN with food or drink:

The tablets may be taken with or without food and a glass of water.

Pregnancy and breast-feeding:

Do not use **OXYBUTYNIN 5 OETHMAAN** if you are pregnant or planning to become pregnant.

Do not use **OXYBUTYNIN 5 OETHMAAN** if you are breast-feeding.

Driving and using machinery:

OXYBUTYNIN 5 OETHMAAN may cause drowsiness or blurred vision. Caution should be taken when driving or operating any machinery when using **OXYBUTYNIN 5 OETHMAAN**.

Using other medicines with OXYBUTYNIN 5 OETHMAAN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **OXYBUTYNIN 5 OETHMAAN** with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Certain medicines may enhance the effects of **OXYBUTYNIN 5 OETHMAAN** and therefore increase the risk of side-effects. These medicines include phenothiazines and butyrophenones (used for conditions of the brain), certain medication used to treat depression, amantadine (used in treatment of Parkinson's Disease), atropine, scopolamine (used for nausea) and some antihistamines (used for allergic

reactions).

4. HOW TO USE OXYBUTYNIN 5 OETHMAAN

Always take **OXYBUTYNIN 5 OETHMAAN** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of **OXYBUTYNIN 5 OETHMAAN** is too strong or too weak, talk to your doctor or pharmacist.

Adults: The usual dose is one **OXYBUTYNIN 5 OETHMAAN** tablet two to three times a day. The maximum recommended dose is one **OXYBUTYNIN 5 OETHMAAN** tablet four times per day.

Children older than 5 years: The usual dose is one **OXYBUTYNIN 5 OETHMAAN** tablet two times per day. The maximum recommended dose is one **OXYBUTYNIN 5 OETHMAAN** tablet three times per day.

Your doctor may perform certain urinary tests to ensure the effectiveness of **OXYBUTYNIN 5 OETHMAAN** prior and during your treatment.

If you take more OXYBUTYNIN 5 OETHMAAN than you should:

In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take OXYBUTYNIN 5 OETHMAAN:

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next dose at the usual time.

5. POSSIBLE SIDE EFFECTS

OXYBUTYNIN 5 OETHMAAN can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If you experience the following symptoms, please consult your doctor or nearest hospital immediately:

- Severe allergic reactions (swelling of the lips, throat, tongue, difficulty breathing)

These side-effects are very rare, but very serious.

Other side-effects may include:

- Dry mouth, difficulty swallowing and thirst.
- Decreased sweating, flushing and dryness of the skin.
- Difficulty to urinate and urinary retention.
- Blurred vision and sensitivity to light.
- An increase or decrease in heart rate, irregular heartbeat, an abnormal heart rhythm.
- Dizziness, drowsiness, weakness, sleep disturbances.
- Nausea, vomiting, constipation.
- Heartburn, chest pain, bloated feeling.
- Loss of sexual drive.
- Mental confusion (especially in elderly persons).

6. STORING AND DISPOSING OF OXYBUTYNIN 5 OETHMAAN

- Store below 25 ºC, protected from light.
- Do not remove the tablets from the container until required for use.
- Keep the blisters in the carton until required for use.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN**
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF OXYBUTYNIN 5 OETHMAAN

White, opaque polypropylene securitainers containing 100 tablets or white, opaque PVC/PVdC/Aluminium blisters containing 84 or 100 tablets.

8. IDENTIFICATION OF OXYBUTYNIN 5 OETHMAAN

OXYBUTYNIN 5 OETHMAAN is a light blue, circular, flat, bevelled edge tablet, embossed “OXB5” on one side, with a break line on the reverse side.

9. REGISTRATION NUMBER

33/5.4/0359

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Oethmaan Biosims (Pty) Ltd

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11. DATE OF PUBLICATION

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