VOXYTANE TABLET

Oxybutynin Chloride (5mg)

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What Voxytane is used for

Voxytane is used for the relief of symptoms of bladder instability such as urgent and frequent urination, urinary leakage, painful or discomfort during urination.

How Voxytane works

Oxybutynin relaxes the bladder smooth muscle. Oxybutynin increases urinary bladder capacity, diminishes the frequency of contractions of the bladder muscle and delays the initial desire to void. Thus, it decreases the urgency and frequency of incontinent episodes and voluntary urination.

Before you use Voxytane

- When you must not use it

Do not take this medicine without consulting any Doctor or Pharmacist.

Do not take this medicine if you have the following medical conditions:

- Allergic (hypersensitivity) to Oxybutynin or other ingredients listed at the end of this leaflet
- Raised eye pressure
- Unable to urinate
- Prostate tumor
- Inflammation of major airways in the lungs
- Muscle disorder such as myasthenia
- Inflammation and ulcers (sores) in digestive tract / dilatation of large intestine
- Intestinal muscle weakness
- Involuntary urination at night

Voxytane is not recommended for children under 5 years.

Pregnancy and lactation

Please consult your doctor before start to take Voxytane if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Voxytane against the benefits they expect it will have for you.

Oxybutynin is found in breast milk, therefore it should not be taken by breast feeding mothers.

- <u>Before you start use it</u>

Consult your doctor or pharmacist for advice before taking Voxytane.

Oxybutynin should be used with caution in elderly.

Tell your doctor if you have or have had any of the following medical conditions:

- Overactive thyroid (hyperthyroidism)
- Heart disease
- Heart failure
- Irregular heartbeat
- Protrusion of stomach (hiatal hernia)
- Fast resting heart rate (tachycardia)
- High blood pressure
- Muscle weakness (myasthenia gravis)
- Enlargement of the prostate gland (prostatic hypertrophy)
- Liver or kidney impairment

- Taking other medicines

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

Some medicines when taken with Voxytane may interfere with each other. Please tell your doctor if you are taking medicines such as:

- Amantadine (antiviral and medicines which used to treat a progressive disorder of the nervous system that affects movement)
- Antiparkinsonian drugs such as biperiden, levodopa
- Antihistamines
- Antipsychotics such as phenothiazines, butyrophenones, clozapine
- Quinidine (used to treat or prevent irregular heartbeats)
- Tricyclic antidepressants
- Atropine (used to treat pesticide poisonings and to decrease saliva production during surgery)
- Antispasmodics (to suppress muscle spasms)
- Dipyridamole (to inhibit blood clot formation)

How to use Voxytane

- How much to use

- Use according to instructions given by your doctor or pharmacist.
- For adult, take 5mg two to three times a day, or up to maximum of four times a day. For children over 5 years, take 5mg two times a day.
- This medicine is to be taken orally with a full glass of water.
- Do not exceed the recommended dose unless otherwise prescribed by doctor

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Voxytane for as long as your doctor recommends.

- 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)

In any cases of overdose, please call your doctor or seek emergency medical attention immediately if below symptoms occur.

Symptoms:

- restlessness
- tremor
- irritability
- seizures
- confusion and hallucinations (experience in which you see, hear, feel, or smell something that does not exist)
- flushing
- fever
- dehydration
- irregular heartbeat
- vomiting
- urinary retention
- drowsiness

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Voxytane.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Voxytane to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Avoid becoming overheated and in hot weather. Oxybutynin can decrease perspiration and you may be more prone to heat stroke and fever.

This medicine may cause drowsiness and may increase the effects of alcohol. If affected, do not drive a motor vehicle or operate machinery. Avoid alcoholic drinks.

Side effects

Side effects include dry mouth with difficulty in swallowing and talking, thirst, reduced mucus secretions in the airway, dilatation of the pupils with loss of accommodation and extreme sensitivity to light, facial flushing and dry skin, transient slowing down of heart beat followed by increase in heart rate with feeling of heart pounding and irregular heart beat, difficulty in urination as well as constipation.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public →Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Voxytane

- Storage

Store below 25°C. Protect from direct sunlight, heat and moisture. Always keep in its original packaging provided.

Keep out of reach of children.

- Disposal

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

- What it looks like

Voxytane 5mg Tablet is white coloured, round uncoated tablet with flat surface on both side and score on one side.

- Ingredients

- Active ingredient: Oxybutynin Chloride
- Inactive ingredients:
 Lactose (Super Tab), Corn starch,
 Microcrystalline cellulose, Sodium
 Starch Glycolate, Colloidal silicon
 dioxide, Magnesium Stearate
- <u>MAL number:</u> MAL09072781ACZ

Manufacturer

Winwa Medical Sdn Bhd 1952, Lorong I.K.S. Bukit Minyak 3, Taman I.K.S. Bukit Minyak, 14000 Bukit Mertajam, Pulau Pinang, Malaysia.

Product Registration Holder

Pharm-D Sdn Bhd 8B, Jalan 1/137C, Bedford Business Park, Off Jalan Kelang Lama, 58000 Kuala Lumpur, Malaysia.

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