

# **Apo-Oxybutynin**

## ***Oxybutynin hydrochloride***

5mg Tablets and 5mg/5mL Syrup

---

## **What is in this leaflet**

---

Please read this leaflet carefully before you start using Apo-Oxybutynin.

This leaflet answers some common questions about Apo-Oxybutynin. 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 using Apo-Oxybutynin against the benefits they expect it will have for you.

**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 Apo-Oxybutynin is used for**

---

The name of your medicine is Apo-Oxybutynin tablet or Apo-Oxybutynin Syrup. It contains the active ingredient oxybutynin.

Apo-Oxybutynin is used for:

- The treatment of an overactive bladder. It helps to decrease the urgency and the frequency of urination.  
Overactive bladder makes it hard to control when you urinate (pass water). Overactive bladder can make you urinate more often (increased frequency) or make you feel the need to urinate often (urgency). Overactive bladder can also lead to accidental urine loss (leaking or wetting oneself). Apo-Oxybutynin works by relaxing the bladder smooth muscle and helps to decrease muscle spasm. This delays the initial desire and the urge to urinate.

Your doctor may have prescribed Apo-Oxybutynin for another reason.

Ask your doctor if you have any questions about why Apo-Oxybutynin has been prescribed for you.

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

There is no evidence that this medicine is addictive.

Apo-Oxybutynin should not be administered to children under the age of 5 years.

---

## Before you use Apo-Oxybutynin

---

### ***When you must not use it***

Do not use Apo-Oxybutynin if:

- **You are hypersensitive to, or have had an allergic reaction to oxybutynin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **You have the following health/medical conditions:**
  - Urinary tract blockage
  - Unstable cardiovascular status in acute haemorrhage (heart problems with severe bleeding)
  - Weak intestinal muscles of the elderly or debilitated patients
  - Urinary retention (your bladder does not empty or does not empty completely when you urinate)
  - Gastric retention (Your stomach empties slowly or incompletely after a meal)
  - Partial or complete obstruction of the intestine
  - Toxic megacolon (a very inflated large intestine)
  - Uncontrolled narrow-angle glaucoma (high pressure in your eye)
  - Severe ulcerative colitis (inflamed bowel)
  - Myasthenia gravis (nerve weakness)
- **Apo-Oxybutynin should not be administered to children under the age of 5 years.**
- **The expiry date (EXP) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Oxybutynin, talk to your doctor.

## ***Before you start to use it***

Tell your doctor if:

**1. You have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**2. You have or have had any medical conditions, especially the following:**

- Liver disease
- Kidney disease
- Diarrhoea (especially in patients with ileostomy or colostomy)
- Bladder obstruction (blockage)
- Gastrointestinal obstruction (blockage in the digestive system)
- Non-severe ulcerative colitis (inflamed bowel)
- Prostatic hypertrophy (enlargement of the prostate gland)
- Gastric reflux disease or oesophagitis (inflamed oesophagus, the tube between your mouth and stomach)
- Hyperthyroidism
- Cardiovascular disease (including coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia and hypertension)
- A neurological disorder (including autonomic neuropathy, cognitive impairment or Parkinson's disease)
- Severe bleeding
- Myasthenia gravis (nerve weakness)
- Uncontrolled narrow-angle glaucoma (high pressure in your eye)

**3. You are currently pregnant or you plan to become pregnant.**

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

**4. You are currently breastfeeding or you plan to breast-feed.**

**Do not take this medicine whilst breastfeeding.**

Oxybutynin can pass into breast milk and may affect your baby and restrict the amount of breast milk you produce. Your doctor will discuss with you the risks and benefits of taking Oxybutynin when breast-feeding.

**5. You are planning to have surgery or an anaesthetic.**

**6. You are currently receiving or are planning to receive dental treatment.**

If you have not told your doctor about any of the above, tell them before you start using Apo-Oxybutynin.

## ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Oxybutynin.

Some medicines may interfere with Apo-Oxybutynin. These include:

- Other anticholinergic drugs (used to treat incontinence)
- Bisphosphonates (used to strengthen bone)
- digoxin - used to treat diseases of the heart (irregular heart rate, chronic heart failure)
- L-dopa - used to treat a disease of the brain affecting movement (Parkinson's disease)
- phenothiazines - a group of anti-psychotic drugs
- butyrophenones - a group of anti-psychotic drugs
- tricyclic antidepressants - used to treat depression
- amantidine - used to treat viral infection
- hyoscine - a muscle relaxant
- prokinetic drugs - medicines used to promote stomach emptying
- some antihistamines - used to treat the symptoms of hayfever

These medicines may be affected by Apo-Oxybutynin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with oxybutynin.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Oxybutynin.

---

## **How to use Apo-Oxybutynin**

---

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

The label should be carefully read

### ***How much to take***

#### **Adults**

The usual dosage is 5mg (1 x 5mg tablet or 5mL of 5mg/5mL syrup) taken 2 to 3 times daily.

The maximum recommended dose is 5mg (1 x 5mg tablet or 5mL of 5mg/5mL syrup) taken 4 times daily.

### **Elderly patients**

Initially treatment should be 2.5mg (0.5 x 5mg tablet or 2.5mL of 5mg/5mL syrup) taken 2 times daily, and increased as necessary.

The maximum dose would be the same as stated for adults.

### **Children over 5 years**

The usual dosage is 5mg (1 x 5mg tablet or 5mL of 5mg/5mL syrup) taken twice daily.

The maximum recommended dose is 5mg (1 x 5mg tablet or 5mL of 5mg/5mL syrup) taken 3 times daily.

APO-OXYBUTYNIN is not recommended for children under 5 years.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

### **How to take it**

Swallow the tablet(s) with a glass of water.

Swallow the syrup

### ***When to take it***

Up to 5mg (1 x 5mg tablet or 5mL of 5mg/5mL syrup) of Oxybutynin may be given as single dose. Doses above 5mg (1 x 5mg tablet or 5mL of 5mg/5mL syrup) should be divided into daily doses.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

### ***How long to take it***

Continue taking your medicine for as long as your doctor tells you.

Apo-Oxybutynin helps control your condition, but does not cure it. Therefore, you must take it every day.

Your doctor will advise you when you can stop taking Apo-Oxybutynin completely.

### ***If you forget to take it***

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

### **Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

---

## **While you are using Apo-Oxybutynin**

---

### ***Things you must do***

Immediately stop taking Apo-Oxybutynin and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Oxybutynin.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Apo-Oxybutynin.

If you are about to have any blood tests, tell your doctor that you are being given this medicine. It may interfere with the results of some tests.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Oxybutynin.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Oxybutynin.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Oxybutynin to last weekends and holidays.

### ***Things you must not do***

**Do not give Apo-Oxybutynin to anyone else, even if they have the same condition as you.**

**Do not take your medicine to treat any other condition unless your doctor tells you to.**

**Do not stop taking your medicine, or change the dosage, without first checking with your doctor.**

**Do not take any other medicine while you are taking Apo-Oxybutynin without first telling your doctor.**

**Do not take Apo-Oxybutynin for a longer time than your doctor has prescribed.**

### ***Things to be careful of***

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Oxybutynin affects you.

Dizziness, fatigue or blurred vision may occur during treatment with oxybutynin, patients driving vehicles or operating machinery should exercise caution until they have determined their reaction to the drug. If you become drowsy or have blurred vision do not drive.

Drinking alcohol may increase sleepiness.

Taking other sedatives may increase the drowsiness that may be caused by Apo-Oxybutynin.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Oxybutynin treatment may decrease sweating. You may overheat or get a fever or heat stroke if you are in warm or hot temperatures or get overheated during exercise. This is particularly relevant to children who often run around playing in the sun.

---

## **In case of overdose**

---

### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Oxybutynin.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Too much oxybutynin has been associated with:

- Excitation of the nervous system (restless or excited)
- Flushing, fever, light headedness or dizziness
- Difficulty in breathing
- Numbness in the hands or feet
- Dehydration
- Irregular heart beat (Cardiac arrhythmia)
- Vomiting
- Difficulty passing Urine (urinary retention)

---

## Side Effects

---

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Oxybutynin or if you have any questions or concerns.

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 adverse effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Oxybutynin is generally well tolerated.

### **Tell your doctor or if you notice any of the following:**

This list includes the most common side effects. Mostly, these are mild and transient:

- Constipation
- Diarrhoea
- Dry Mouth
- Nausea or vomiting
- Reduced sweating
- Flatulence
- Sleepiness or Drowsiness
- Headache
- Abdominal pain
- Back pain
- Loss of appetite
- Heartburn
- Dry skin

If you take other medicines that cause dry mouth, constipation, or sleepiness, Apo-Oxybutynin can increase these effects.

**Tell your doctor immediately if you notice any of the following.**

These may be serious side effects. You may need medical attention.

- If you notice any symptoms of an allergic reaction such as shortness of breath, wheezing or troubled breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- fast or irregular heartbeat
- flushing
- dizziness
- unusual tiredness or weakness
- restlessness or trouble sleeping
- hallucinations
- nightmares
- confusion, nervousness (feeling anxious) or severe suspiciousness (paranoia)
- agitation
- convulsions, fits or seizures
- eye problems, including dry eyes or blurred vision
- difficulty urinating
- skin rash
- decreased flow of breast milk
- impotence

**If you or someone you know or care for experience any of the following, stop taking Oxybutynin and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

- fever or heat stroke
- numbness in the hands or feet
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes also called jaundice

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

---

## **After using Apo-Oxybutynin**

---

### **Storage**

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C for the Apo-Oxybutynin tablets and between 15-25°C for Apo-Oxybutynin syrup.

Do not store your medicine, 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 this medicine 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 tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

---

## **Product description**

---

### ***What it looks like***

Apo-Oxybutynin 5mg tablets are round, blue, biconvex tablets. 8mm in diameter, identified APO over 5 on one side, other side plain.

APO-OXYBUTYNIN 5mg/5mL syrup is a clear, green coloured, slightly viscous syrup with a berry odour and flavour.

Apo-Oxybutynin 5mg tablets are available in bottle of 100 or 500 tablets.

Apo-Oxybutynin 5mg/5mL syrup is available in bottle of 473mL.

\* Not all strengths, pack types and/or pack sizes may be available.

### ***Ingredients***

#### Active ingredient:

Each tablet contains 5mg oxybutynin hydrochloride as the active ingredient.

Each 1mL of syrup contains 1mg oxybutynin hydrochloride as the active ingredient.

### Inactive ingredients:

Apo-Oxybutynin 5mg tablets contain the following excipients:

- FD&C Blue No.1 (Brilliant Blue FCF, C.I. 42090, E133)
- Lactose monohydrate
- Magnesium Stearate
- Microcrystalline cellulose.

Apo-Oxybutynin 5mg tablets are gluten free.

Apo-Oxybutynin 5mg tablets contain lactose.

Apo-Oxybutynin 5mg/5mL syrup contains the following excipients:

- FD&C Green No.3 (Fast green FCF, C.I. 42053, E143)
- Artificial Berry Flavour
- Citric acid monohydrate
- Glycerol (Glycerine)
- Purified water
- Sodium citrate dehydrate
- Sorbitol
- Sucrose
- Methyl paraben (Methyl hydroxybenzoate)

Apo-Oxybutynin 5mg/5mL syrup is lactose and gluten free.

---

## **Sponsor Details**

---

Apo-Oxybutynin is supplied in New Zealand by:

**Apotex NZ Ltd**  
32 Hillside Road  
Glenfield  
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

Email: NZcustomerservice@apotex.com

---

## **Date of Preparation**

---

This leaflet was prepared on 10 May 2018.