

Package Leaflet: Information for the User

Oxybutynin hydrochloride Brillpharma 2.5mg/5ml Oral solution
oxybutynin hydrochlorideSpace for
PharmacoCode8 mm
27 mm**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Oxybutynin hydrochloride Brillpharma is and what it is used for
2. What you need to know before you take Oxybutynin hydrochloride Brillpharma
3. How to take Oxybutynin hydrochloride Brillpharma
4. Possible side effects
5. How to store Oxybutynin hydrochloride Brillpharma
6. Contents of the pack and other information

1. What Oxybutynin hydrochloride Brillpharma is and what it is used for

Oxybutynin hydrochloride Brillpharma contains a medicine called oxybutynin hydrochloride. This belongs to two groups of medicines called 'anticholinergics' and 'antispasmodics'. It works by relaxing the muscles of the bladder and stops sudden muscle contractions (spasms). This helps control the release of water (urine).

Oxybutynin hydrochloride Brillpharma can be used in adults and children 5 years or older to treat:

- loss of control in passing water (urinary incontinence)
- increased need or urgency to pass water (urine)
- night time bedwetting, when other treatments have not worked

You must talk to a doctor if you do not feel better or if you feel worse

2. What you need to know before you take Oxybutynin hydrochloride Brillpharma**Do not take Oxybutynin hydrochloride Brillpharma if:**

- You are allergic (hypersensitive) to oxybutynin hydrochloride or any of the other ingredients (see section 6 'Contents of the pack and other information').

Signs of allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- You have a rare muscle illness called 'Myasthenia gravis'
- if you have glaucoma (increased pressure in the eye, sometimes sudden and painful with blurred vision or loss of vision).
- if your gut (stomach or intestine) is blocked, perforated or not working properly.
- if you have a severe form of a condition known as 'ulcerative colitis'.
- if you have sudden widening of the colon, which causes abdominal pain, fever or shock known as 'toxic megacolon'.
- You have a blockage that makes it difficult for you to pass water (urine).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Oxybutynin.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Oxybutynin if:

- You have kidney or liver problems
- You are 65 years of age or older
- you have brain problems (such as hallucinations, agitation, confusion, drowsiness)
- you have bowel problems (such as bowel obstruction, bowel laziness, inflammation of bowel)
- you have an illness affecting the nerves called 'autonomic neuropath' (e.g. Parkinson's disease).
- You have an overactive thyroid gland ('Hyperthyroidism')
- You have heart disease or high blood pressure
- You have an irregular heart beat (palpitations) and/or increased or rapid heart beat
- You have an enlarged prostate gland (prostatic hypertrophy)
- You have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm), gastro-oesophageal reflux and/or you are using medicinal products that can cause or worsen oesophagitis.
- You have a raised body temperature or fever
- You will be taking this medicine in a hot climate
- Oxybutynin may reduce the amount of saliva resulting in tooth decay or fungal infection of mouth
- Oxybutynin can cause glaucoma (increased pressure in the eye), please contact your doctor immediately if you suffer any blurred vision, loss of vision or have pain in the eye

Children and adolescents

Do not give this medicine to children under the age of 5 years.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Oxybutynin

Other medicines and Oxybutynin hydrochloride Brillpharma:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Oxybutynin hydrochloride Brillpharma can affect the way some medicines work. Also some medicines can affect the way Oxybutynin hydrochloride Brillpharma works.

In particular tell your doctor if you are taking any of the following:

- Other anticholinergic or antimuscarinic medicines - such as some medicines for irritable bowel syndrome, asthma or incontinence, motion sickness or movement disorders associated with Parkinson's disease.
- Medicines used to make you feel sleepy (sedatives) or if you are feeling sick (nausea) or have vertigo- such as prochlorperazine or chlorpromazine.
- Medicines used to treat certain mental illnesses - such as clozapine, phenothiazines, haloperidol or benperidol (butyrophenones).
- Medicines for depression - such as amitriptyline, imipramine or dosulepin ('tricyclic antidepressants') and lithium
- Amantadine, procyclidine, levodopa and biperidin- used in Parkinson's disease or to treat and prevent some viral infections
- Aminopenicillins, tetracyclines, sulfamethoxazole, cotrimoxazole drugs used for inhibition of bacterial infections
- Digoxin, quinidine, disopyramide, procainamide and lidocaine - used to treat heart problems
- Dipyridamole – used to treat blood problems
- Antihistamines - used to treat allergies
- Paracetamol – use to treat pain
- Phenylbutazone – use to treat inflammation
- Atropine which is used to treat certain types of poisonings, a slow heart rate, some eye conditions or is given during surgery.
- Medicines for stomach and bowel related problems - such as Domperidone, Metoclopramide, Bethanechol.
- Medicines used to treat dementia e. g. donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors).
- CYP3A inhibitor e. g. ketoconazole, itraconazole or fluconazole used to treat fungal infections or erythromycin or other macrolide antibiotics used to treat bacterial infections.

Oxybutynin hydrochloride Brillpharma with food, beverages and alcohol

Alcohol may increase drowsiness caused by oxybutynin.

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk. Breast feeding while using Oxybutynin is therefore not recommended.

Driving and using machines

You may feel drowsy or have blurred vision while you are taking this medicine. If this happens, do not drive or use any tools or machines.

Oxybutynin hydrochloride Brillpharma contains sodium benzoate

This medicine contains 2.5 mg Sodium benzoate in 10ml which is equivalent to 0.25 mg/ml.

Information on sodium content

Sodium - This medicine contains less than 1 mmol sodium (23 mg) per 10ml, that is to say essentially 'sodium-free'.

3. How to take Oxybutynin hydrochloride Brillpharma

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses are given below. These may be changed by your doctor:

Adults

- The usual dose is 5mg (10ml) two or three times a day
- Your doctor may decide to increase to the maximum dose of 5mg (10ml) four times a day

Elderly

- The usual dose is 2.5mg (5ml) twice a day
- Your doctor may decide to increase this to 5mg (10ml) twice a day

Children (over 5 years)

- The usual dose is 2.5mg (5ml) twice a day
- Your doctor may decide to increase this to 5mg (10ml) two or three times a day
- If you are giving it to a child to prevent bedwetting, give the last dose just before bedtime

Method of administration

You should use the enclosed 5 ml oral syringe (graduated at every 0.5 ml) together with the enclosed adaptor to attach the syringe to the bottle. This helps you to take a dose from the bottle.

For oral use

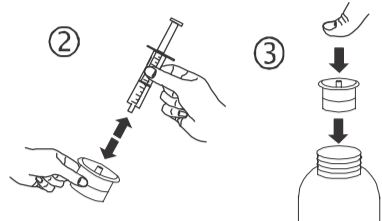
Instructions for use

- Open the bottle: press the cap and turn it anticlockwise (figure 1)

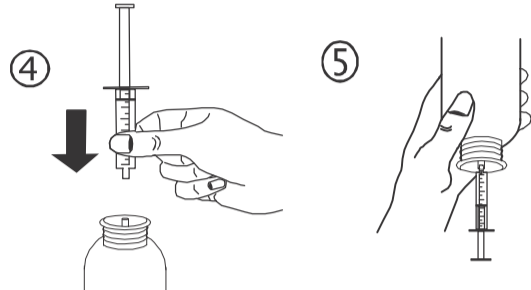


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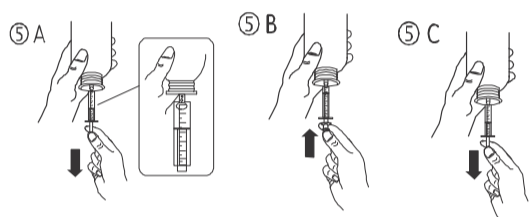
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is well fixed.



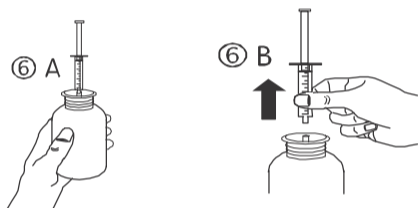
- Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).



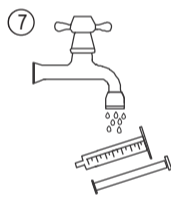
- Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe into your mouth.
- After dosing, wash the syringe with water (figure 7).



If you take more Oxybutynin hydrochloride Brillpharma than you should

Contact your nearest hospital casualty department or tell your doctor immediately. Take the medicine pack with you. This is so the doctor knows what you have taken. Taking too much Oxybutynin can be very dangerous. You may become very restless or excited, flushed or get dizzy or light-headed. Your heart beat may become very fast, uneven or forceful. You may get breathing problems or numbness or go into a coma.

If you forget to take Oxybutynin hydrochloride Brillpharma

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Oxybutynin hydrochloride Brillpharma

Keep taking Oxybutynin hydrochloride Brillpharma until your doctor tells you to stop. Do not stop taking Oxybutynin hydrochloride Brillpharma just because you feel better. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Oxybutynin hydrochloride Brillpharma and contact your doctor immediately if you develop the following symptoms:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You feel reduced sweating, leading to overheating in hot environments.

Other side effects:

Very Common (may affect more than 1 in 10 people):

- Dry mouth, constipation, nausea
- Dizziness, headache, drowsiness
- Dry skin
- Blurring of vision

Common (may affect up to 1 in 10 people):

- Diarrhoea, vomiting
- Confusional state
- Dry eyes,
- Flushing especially in children

- Inability or difficulty in passing water (urine)
- A forceful heartbeat that may be rapid or irregular

Uncommon (may affect up to 1 in 100 people):

- Stomach pain, loss of appetite (anorexia), decrease appetite, difficulty in swallowing (dysphagia)

Not known: cannot be estimated from the available data:

- A bladder infection (Urinary tract infection)
- Indigestion or heart burn (acid reflux) in patients with risk (elderly or patients with constipation)
- Fits (convulsions)
- Agitation, anxiety, drowsiness, disorientation
- Mental disorders in elderly.
- Seeing or hearing things that are not there (hallucinations)
- Nightmares
- Increased pressure in the eyes sometimes sudden and painful with blurred vision or loss of vision (glaucoma)
- Heat stroke
- Difficulty passing water (urine)
- Becoming dependent on Oxybutynin
- Feeling excessive suspicious and distrustful of others
- Depression
- Dilation of pupil (mydriasis)
- Itchy, lumpy rash (urticaria)
- Absence of sweating (hypohidrosis)
- Skin that is more sensitive to the sun (photosensitivity)
- Rash
- Cognitive disorders
- Nosebleed
- Angioedema
- Muscle weakness, pain or cramps

Additional side effects in children

Children are at higher risk of the effects.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxybutynin hydrochloride Brillpharma

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after 'Exp'. The expiry date refers to the last day of that month.
- Store in the original container in order to protect from light.
- Discard after 30 days of first opening. Store in the original packaging after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Oxybutynin hydrochloride Brillpharma contains

The active ingredient is oxybutynin hydrochloride. Each 5 ml of oral solution contains 2.5 mg Oxybutynin hydrochloride.

The other ingredients are citric acid monohydrate (E330), sodium benzoate (E211), sodium citrate (E331), sucralose (E955), raspberry flavour, purified water.

What Oxybutynin hydrochloride Brillpharma looks like and contents of the pack

Oxybutynin hydrochloride Brillpharma is a clear, colourless oral solution with characteristic raspberry odour.

This medicine is supplied in amber colored glass bottle with a child resistant closure, containing 150ml of oral solution, in a carton.

This carton also contains a 5ml oral syringe (graduated at every 0.5 ml) with adaptor.

Marketing Authorisation Holder and Manufacturer:

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Manufacturer:

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Oxybutynin hydrochloride Brillpharma 2.5mg/5ml Oral solution; PL 40496/0009

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To request a copy of this leaflet in Braille, large print or audio format then please contact the marketing authorisation holder at the address (or email) above.