Propiverine Hydrochloride 15 mg Coated Tablets

Propiverine hydrochloride
- Read this leaflet carefully before you start taking this medicine.
- If you have any further questions, ask your doctor or pharmacist.
- This leaflet provides a summary of the information available on your medicine.
- This medicine has been prescribed for you, do not pass it on to others, it may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes severe, or you notice any side effect not listed in this leaflet please tell your doctor or pharmacist.

In this leaflet:
1. What Propiverine hydrochloride 15 mg Coated Tablets are and what they are used for
2. Before you take Propiverine hydrochloride 15 mg Coated Tablets
3. How to take Propiverine hydrochloride 15 mg Coated Tablets
4. Possible Side Effects
5. How to store Propiverine hydrochloride 15 mg Coated Tablets
6. Further Information

1. WHAT PROPIVERINE HYDROCHLORIDE 15 MG COATED TABLETS ARE AND WHAT THEY ARE USED FOR
The name of your medicine is Propiverine Hydrochloride 15 mg Coated Tablets. Each tablet contains 15 mg of the active ingredient, propiverine hydrochloride. Propiverine hydrochloride is one of a group of medicines called anticholinergics.

Propiverine Hydrochloride 15 mg Coated Tablets are used to treat people who have difficulty controlling their bladder (incontinence). It reduces the contraction of the bladder and helps to increase how much urine it can hold.

Propiverine Hydrochloride 15 mg Coated Tablets can, in some cases be used for people who have an over active bladder because of spinal injuries.

2. BEFORE YOU TAKE PROPIVERINE HYDROCHLORIDE 15 MG COATED TABLETS

Propiverine Hydrochloride 15 mg Coated Tablets is not for use in children

Do not take Propiverine Hydrochloride 15 mg Coated Tablets if you:
- have ever had an allergic reaction to Propiverine Hydrochloride 15 mg Coated Tablets or medicines like Propiverine Hydrochloride 15 mg Coated Tablets, or any of its ingredients, including cochineal red A (E124, lake) which may cause allergic reactions including asthma, particularly in those who are allergic to aspirin (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- are pregnant or breast-feeding.
or if you are suffering from any of the following conditions:

- bowel problems (e.g. bowel obstruction, severe ulcerative colitis or muscle weakness) that may lead to diarrhoea containing blood and mucous; or stomach pains;
- bladder obstruction, causing difficulty in passing urine;
- muscle weakness (myasthenia gravis);
- fever, pain and tenderness of the abdomen (toxic megacolon);
- increased pressure in the eye (uncontrolled angle closure glaucoma);
- moderate or severe liver disease;
- fast or irregular heart beat.

If any of the above affect you, or you are unsure if they do, tell your doctor who will be able to advise you.

Take special care with this medicine if:

- you have damage to the nerves which supply the internal organs (autonomic neuropathy);
- you have severe heart failure, or a fast or irregular heart beat;
- you have an enlarged prostate gland (men only);
- you suffer from heartburn and indigestion due to a back flow of acid into the food pipe (hiatus hernia with reflux oesophagitis);
- your liver or kidneys do not work properly.

Tell your doctor before taking this medicine if you have been told you have an intolerance to some sugars. This is because Propiverine Hydrochloride 15 mg Coated Tablets contain lactose, a type of sugar.

Taking Propiverine Hydrochloride 15 mg Coated Tablets with other medicines.
Please tell your doctor or pharmacist if you have recently taken any other medicines, including medicines obtained without a prescription. It is especially important that you tell your doctor if you are taking:

- medicines to treat problems, such as depression (e.g. imipramine, clomipramine and amitryptiline) anxiety or psychosis (e.g. neuroleptics such as promazine, olanzapine, quetiapine) or sleep difficulties;
- medicines belonging to a class known as sympathomimetics (these are used to treat a range of conditions; including asthma, heart conditions, eye problems);
- medicines belonging to a class known as anticholinergics (these are used to treat a range of conditions, including asthma, stomach cramps, eye problems, urinary incontinence);
- medicines to treat stomach problems or nausea and vomiting (e.g. metoclopramide);
- a medicine called amantadine (used to treat Parkinson's disease);
- a medicine called isoniazid (used to treat tuberculosis);

If you take Propiverine Hydrochloride 15 mg Coated Tablets for a long time, your doctor may occasionally test your liver function.
If you are at risk of developing glaucoma, your doctor may check your eyes, whilst you are being treated with Propiverine Hydrochloride 15 mg Coated Tablets.

**Pregnancy and breast-feeding**
Do not take this medicine if you are, or think you might be pregnant, or if you are breast-feeding.

**Driving or operating machinery**
Propiverine Hydrochloride 15 mg Coated Tablets can sometimes cause drowsiness and blurred vision. You should not drive or operate machinery until you are sure you are not affected.

3. **HOW TO TAKE PROPIVERINE HYDROCHLORIDE 15 MG COATED TABLETS**
Always take Propiverine Hydrochloride 15 mg Coated Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Propiverine Hydrochloride 15 mg Coated Tablets should be taken by mouth with or without food.

Do not crush or chew the tablets.

*Adults and elderly patients:* the usual dose is one tablet two to three times a day. Your doctor may increase your dose to one tablet four times a day, if necessary.

If you take more Propiverine Hydrochloride 15 mg Coated Tablets than you should
If you accidentally take too much of your medicine, tell your doctor *at once* or contact your nearest hospital casualty department immediately.
Take your medicine and this leaflet with you.

If you forget to take Propiverine Hydrochloride 15 mg Coated Tablets
If you forget to take a dose, just take the next dose at the usual time, **DO NOT** take a double dose.

4. **POSSIBLE SIDE-EFFECTS**
Like all medicines, Propiverine Hydrochloride 15 mg Coated Tablets can cause side effects, although not everybody gets them.

If you notice;
- Itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness.

Stop taking the tablets and tell your doctor immediately.
These may be signs of an allergic reaction.

In theory it is possible that you might suffer an acute attack of glaucoma. If you have been seeing coloured rings around lights or if you should develop severe pain in and around either eye **you should seek medical attention urgently.**
Very Common Side Effects (more than 1 in 10 people)
Dryness of the mouth.

Common Side Effects (more than 1 in 100 but less than 1 in 10 people)
Constipation, blurred vision.

Uncommon Side Effects (more than 1 in 1000 but less than 1 in 100 people)
Decreased blood pressure (with drowsiness), problems passing urine, flushing of the face and neck, shaking, dizziness, tiredness, nausea and vomiting.

Rare Side Effects (more than 1 in 10,000 but less than 1 in 1000 people)
Hypersensitivity, rash or irritation.

Very Rare Side Effects (less than 1 in 10,000)
Irregular heartbeats, confusion or restlessness.

Frequency Unknown
Hallucinations

These side effects will pass and will stop altogether within 1 to 4 days after having your dose reduced, or if you stop taking the tablets. If you are worried by these or any other effects, you should tell your doctor or pharmacist.

If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROPIVERINE HYDROCHLORIDE 15 MG COATED TABLETS

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Do not store the blister pack above 25ºC.
Keep the tablets in the original package.
Do not use after the expiry date printed on the carton.

The information in this leaflet applies only to Propiverine Hydrochloride 15 mg Coated Tablets. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

6. FURTHER INFORMATION
What Propiverine Hydrochloride 15 mg Coated Tablets contain
Each tablet contains 15.00 mg propiverine hydrochloride (equivalent to 13.64 mg propiverine) as the active ingredient along with the following inactive ingredients: lactose monohydrate; powdered cellulose; magnesium stearate; sucrose; talcum; heavy kaolin; calcium carbonate; titanium dioxide (E171); acacia gum; colloidal anhydrous silica; Macrogol 6000; glucose monohydrate; cochineal red A (E124, lake); Montan wax.

What Propiverine Hydrochloride 15 mg Coated Tablets look like and the contents of the pack
The tablets are rose-coloured biconvex, round sugar coated tablets. The carton the tablets come in contain blister packs with 28 or 56 coated tablets per carton.
Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:
Amdipharm Plc, Regency House, Miles Gray Road, Basildon, Essex SS14 3AF

The manufacturer responsible for release is:
APOGEPHA Arzneimittel GmbH, Kyffhäuserstraße 27, 01309 Dresden, Germany.

The following organisations can offer independent advice:
The Continence Foundation
307 Hatton Square
16 Baldwin’s Gardens
London EC1N 7RJ
Help line Mon-Fri 9.30-4.30 Tel: 020 7831 9831
Incontact (Self help organisation for sufferers and carers)
Freepost LON12119
London NW7 1YU
Tel: 020 7530 3401

Help line Mon-Fri 9.30 am - 1.00 pm Tel. 0845 345 0165

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