**Package leaflet: Information for the user**

**Axhidrox pump-pack 2.2 mg/pump actuation cream**

glycopyrronium

**Read all of this leaflet carefully before you start using 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 Axhidrox is and what it is used for

Axhidrox contains the active substance glycopyrronium and belongs to a group of sweat reducing medicines called antihidrotics.

Axhidrox is used for topical treatment of severe primary axillary hyperhidrosis in adults.

Primary axillary hyperhidrosis causes excessive sweating in both armpits without any apparent reason like sports, hard physical work, hot weather, certain diseases or medicines. A feature of primary axillary hyperhidrosis is that it occurs usually during the day but not during sleep.

External use of Axhidrox in the armpits leads to reduced sweat production in the sweat glands.

## 2. What you need to know before you use Axhidrox

**Do not use Axhidrox if you**

– are allergic to glycopyrronium or any of the other ingredients of this medicine (listed in section 6).

– have an eye disease where the pressure is high in your eye (glaucoma).

– have or have had acute bleeding with unstable heart and blood circulation status.

– have a chronic inflammatory disease of the large bowel (severe ulcerative colitis).

– have or have had a chronic inflammation of the large bowel complicated by severe extension of the colon (toxic megacolon complicating ulcerative colitis).
– have or have had a blockage of the bowel as a result of paralysis of the bowel muscles (paralytic ileus).
– have an immune response disease affecting muscles (myasthenia gravis) or the salivary or lacrimal glands (Sjögren syndrome).

**Warnings and precautions**

Talk to your doctor or pharmacist before using Axhidrox, if you:

– have or have had prostate or bladder problems, or problems passing urine.

  Stop using this medicine and consult a doctor if you notice symptoms of urinary retention like urination in a weak stream or drops, increased need to urinate, feeling of a full or insufficiently emptied bladder.
– have severe kidney disorders, including dialysis-dependent kidney failure.
– have dysfunctions of the blood brain barrier, such as after traumatic brain injury within the past year, chemotherapy, radiation therapy of the head, surgery of the skull and brain, or due to intravenous drug abuse.
– have a heart disease, heart failure, irregular heartbeat or high blood pressure.
– have inflamed or injured skin of the armpits since this may increase the risk of local side effects.

  Use Axhidrox only after complete remission of the skin disease or after healing of the wound.

Do not apply the cream to any other part of the body than the armpits and avoid any contact of the cream with the eyes, nose or mouth or with other persons.

– Apply Axhidrox with the dispenser cap only, not with your fingers. If the cream gets into the eyes, it can cause temporary enlargement of the pupils and blurred vision. If any cream gets into the mouth or nose, the production of saliva or nasal secretions may be reduced. If the eyes, nose or mouth come in contact with the cream, these areas should be immediately rinsed with plenty of water to reduce the risk of local side effects.
– Cover the treated armpits with clothes during intercourse because side effects cannot be ruled out in case other persons come in contact with the cream.

If you notice a dry mouth, carefully clean your teeth. Have your teeth checked regularly by your dentist, as the risk of caries can be increased.

**Children**

Do not use Axhidrox in children under 18 years because the safety and efficacy of this medicine has not been studied in this age group.

**Other medicines and Axhidrox**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Some medicines may affect or be affected by Axhidrox.

These medicines include:

– topiramate, used to treat epilepsy and migraine
– sedative antihistamines, used to treat allergies or sleep disorders

– tricyclic antidepressants, used to treat depressions
– monoamine oxidase inhibitors, used to treat depressions or Parkinson's disease
– neuroleptics or antipsychotics, used to treat mental illness or anxiety
– opioids, used to treat pain or coughing

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There are no data for the use of Axhidrox in pregnant women and it is not known whether the active substance of this medicine passes into human milk. Your doctor will discuss with you whether you can use Axhidrox during pregnancy. If you are breast-feeding, you and your doctor must make a decision whether to discontinue breast-feeding or to discontinue Axhidrox therapy taking into account the benefit of breast-feeding for your child and the benefit of therapy for you. This is because your baby should not come in contact with the cream or the treated skin.

**Driving and using machines**

Blurred vision, drowsiness, tiredness and dizziness may occur following administration of Axhidrox (see section 4). Blurred vision in particular may occur if Axhidrox gets into the eyes. Do not drive, use machines or perform dangerous work or sports until these effects disappear.

**Axhidrox contains benzyl alcohol, propylene glycol and cetostearyl alcohol**

This medicine contains 2.7 mg benzyl alcohol per pump actuation. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains 8.1 mg propylene glycol per pump actuation.

This medicine contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

## 3. How to use Axhidrox

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

Apply Axhidrox only on the skin in your armpits and only with the cap of the pump, not with your fingers (see section 2, "Warnings and precautions").

The recommended dose is two pump actuations per armpit.

During the first 4 weeks of treatment, apply Axhidrox to each armpit evenly, once a day, preferably in the evening.

From the 5$^{th}$ week on, you may reduce the frequency of application to twice a week, depending on the reduction of sweat production.

**Preparation of the pump before the first use**

To obtain the recommended dose, you must remove the air trapped in the pump, as follows:

– Pull off the cap of the pump.
– Put a piece of paper on the table. Hold the pump at an angle (see illustration), press the pump down repeatedly until cream comes out of the opening.

– Slowly push the pump down fully another 10 times and put the dispensed cream onto the paper. Dispose the paper with the dispensed cream in the waste bin only.
– The pump is now ready for use. Repeated preparation of the pump is not necessary for subsequent use.

**Application of the cream with the cap of the pump**

– Pull off the cap of the pump.
– Hold the pump in your hand with the opening of the pump towards the removed cap.
– Press the pump all the way down twice to apply the recommended amount of cream to the top of the cap (see illustration).

– Evenly distribute the cream with the cap in one armpit.
– Repeat this process for the second armpit.
– Afterwards, you must wash the cap of the pump and, for safety, your hands immediately and thoroughly with soap and water. This is important to avoid contact of the cream with nose, eyes or mouth (see section 2, “Warnings and precautions”).
– Tick off the number of treatments in the table on the outer carton (see section 6). One treatment corresponds to 4 pump actuations, i.e. 2 pump actuations per armpit.

**If you use more Axhidrox than you should**

Overdosing is unlikely to occur if you use Axhidrox only in the armpits as described.

However, if Axhidrox is applied too frequently or excessively, the possible side effects may increase (see section 4).

Therefore, Axhidrox must not be used on other parts (palms, feet, face) or on large areas of the body with increased sweating. Excessively reduced sweating could lead to overheating of the body and possibly life-threatening heatstroke. Stop using Axhidrox and seek medical advice immediately if you notice an increasing sensation of heat or increased body temperature.

**If you forget to use Axhidrox**

Do not use a double dose to make up for a forgotten dose.

**If you stop using Axhidrox**

If you or your doctor decide to stop using Axhidrox, excessive sweating will occur again.

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 using** Axhidrox and contact your doctor or nearest emergency department immediately, if you get the following serious side effect:

– swelling mainly of the face, lips or throat which makes it difficult to swallow or breathe, itching and rashes. This could be a sign of a severe allergic reaction or angioedema (frequency not known, cannot be estimated from the available data), so that you may need urgent medical treatment.
– blurred vision (common side effect)

(see section 2, “Driving and using machines”).

**The following further side effects were observed:**

**Very common** side effect (may affect more than 1 in 10 people)

– dry mouth

**Common** side effects (may affect up to 1 in 10 people)

– in the treated armpit: irritation, pain, itching, eczema, skin inflammation, rash, skin reddening, nodules
– dry nose
– dry eyes
– dry skin
– headache
– constipation

**Uncommon** side effects (may affect up to 1 in 100 people)

– in the treated armpit: dryness, acne, swelling, hardening of the skin, scar, small blisters, wound, pustules, inflamed hair follicle
– eczema
– itching, itching all over the body
– skin rash
– skin reddening
– long-term skin eczema (atopic dermatitis)
– skin irritation
– skin plaque (raised, firm, superficial skin changes over 1 cm in size)
– acne
– nettle rash
– abnormal body odour
– skin condition resembling psoriasis (parapsoriasis)
– dry lips, hands, mucous membrane, throat
– absence of saliva
– blocked nose
– itchy, red or irritated eyes
– different sizes of pupils
– dilated pupils
– visual impairment
– abdominal distension
– hard stools
– indigestion
– nausea

– pain in the mouth and throat
– throat tightness
– drowsiness
– tiredness
– disturbed attention
– anxiety
– restlessness
– disturbed sleep, poor quality sleep
– dizziness
– head discomfort
– disturbed bladder emptying
– excessive sweating
– reduced number of blood platelets seen in blood test
– high heart rate
– alteration of the heart rhythm (called “prolonged QT interval”, seen on ECG, electrical activity of the heart)
– increased liver enzymes, bilirubin and volume of red blood cells seen in blood test
– decreased concentration of haemoglobin in red blood cells seen in blood test

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Axhidrox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and on the carton after ‘EXP’. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first pump actuation, the medicine may be used for a maximum of 12 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Axhidrox contains**

– The active substance is glycopyrronium (as glycopyrronium bromide).
1 g cream contains glycopyrronium bromide, equivalent to 8 mg glycopyrronium. One

actuation of the pump delivers 270 mg cream which contains glycopyrronium bromide, corresponding to 2.2 mg glycopyrronium.

– The other ingredients are benzyl alcohol (E1519), propylene glycol (E1520) and cetostearyl alcohol (see section 2), citric acid (E330), glycerol monostearate 40–55, macrogol 20 glycerol monostearate, sodium citrate (E331), octyldodecanol and purified water.

**What Axhidrox looks like and contents of the pack**

Axhidrox is a white glossy cream, available in packs containing one multidose container with a pump and a cap. The multidose container contains 50 g cream. After pump preparation, the pump delivers 124 pump actuations which are sufficient for 31 treatments of both armpits.

Tick the number of treatments in the table on the outer carton. After 31 treatments, you should not continue to use the pump, even if the multidose container is not completely empty.

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