Package leaflet: Information for the user

Glycopyrronium Bromide 1mg tablets
Glycopyrronium Bromide 2mg tablets

glycopyrronium bromide or (glycopyrrolate)

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 e ects, talk to your doctor or pharmacist. This includes any possible side e ects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Glycopyrronium bromide tablets are and what they are used for
2. What you need to know before you take Glycopyrronium bromide tablets
3. How to take Glycopyrronium bromide tablets
4. Possible side e ects
5. How to store Glycopyrronium bromide tablets
6. Contents of the pack and other information

1. What Glycopyrronium bromide tablets are and what they are used for

Glycopyrronium bromide (the active substance in Glycopyrronium bromide tablets) belongs to a group of medicines called quaternary ammonium anticholinergics, which are agents that block or reduce the transmission between nerve cells. This reduced transmission can de-activate the cells that produce saliva.

Glycopyrronium bromide tablets are used to treat excessive production of saliva (sialorrhoea) in patients su ering from long term neurological disorders which have occurred in childhood, in patients aged 3 years and older.

Sialorrhoea (drooling or excessive salivation) is a common symptom of many diseases of the nerves and muscles. It is mostly caused by poor control of muscles in the face. Acute sialorrhoea may be associated with inflammation, dental infections or infections of the mouth. Glycopyrronium bromide tablets act on the salivary glands to reduce production of saliva.

2. What you need to know before you take Glycopyrronium bromide tablets

DO NOT take Glycopyrronium bromide tablets if you:
- are allergic to glycopyrronium bromide or any of the other ingredients of this medicine (listed in section 6)
- are pregnant or breast feeding
- su er from glaucoma (increased pressure in the eye)
- are unable to completely empty the bladder (urinary retention)
- have severe kidney disease
- have an enlarged prostate gland (prostatic hypertrophy)
- have an obstruction of the stomach (pyloric stenosis) or bowel causing vomiting
- have ulcerative colitis (inflammation of the intestine)
- have diarrhoea (frequent, loose watery stools)
- have stomach ache and swelling (paralytic ileus)
- have myasthenia gravis (muscle weakness and fatigue)
- are over 65 years of age
- are taking any of the following medicines (see section 'Other medicines and glycopyrronium bromide tablets'):
  - potassium chloride solid oral dose;
  - anticholinergic medicines.

Tell your doctor if you are not sure about any of the above.

Warnings and precautions
Talk to your doctor or pharmacist before taking Glycopyrronium bromide tablets if you (or the patient) have:
- heart disease, irregular heartbeats or high blood pressure, because this medicine can cause a change to your normal heart rate
- digestive disorders (constipation, chronic heartburn and indigestion)
- a high temperature (fever), as this medicine will reduce the amount you may sweat, making it harder for your body to cool down
- inability to sweat normally
- kidney problems or di culty passing urine because this medicines dose may need to be reduced
- abnormal blood brain barrier (the layer of cells surrounding the brain)

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

Avoid exposure to hot or very warm temperature (hot weather, high room temperature) to avoid overheating and the possibility of heat stroke. Check with the patient's doctor during hot weather to see if the dose of this medicine should be reduced.

Reduced salivation can increase the risk of dental disease, therefore the patient's teeth should be brushed daily and they should have regular dental checks.

Patients with kidney problems may be given a lower dose.

If you (or the patient) feel unwell, check your pulse and report any slow or very fast heart rate to your doctor.

Children under 3 years
This medicine is NOT recommended for use in children under 3 years of age (see section 3).

Other medicines and Glycopyrronium bromide tablets
Tell your doctor or pharmacist if you or your patient are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Taking Glycopyrronium bromide tablets with the following medicines can a ect the way Glycopyrronium bromide tablets or the listed medicines work, or can increase the risk of side e ects:
- potassium chloride solid oral dose (see section above **'DO NOT take Glycopyrronium bromide tablets if you:'**)
- anticholinergic medicines (see section above **'DO NOT take Glycopyrronium bromide tablets if you:'**)
- antispasmodics used to treat sickness or vomiting e.g. domperidone and metaclopramide
- topiramate, used to treat epilepsy
- antihistamines such as promethazine, used to treat some allergies
- neuroleptics/ antipsychotics (clozapine, haloperidol, phenothiazine), used to treat some mental illnesses
- skeletal muscle relaxants (botulinum toxin)
- antidepressants such as amitriptyline, clomipramine, lofepramine or imipramine (known as tricyclic antidepressants)
- opioids used to treat severe pain
- corticosteroids, used to treat inflammatory disease (e.g. prednisolone)

Talk to your doctor or pharmacist for further information about any medicines to avoid or if you are in doubt about any of the above medicines.

Glycopyrronium bromide tablets are not interchangeable with other glycopyrronium products without dose adjustment and when switching between products, the specific dose recommendations for each product must be followed to avoid overdose and anticholinergic side e ects.

Long term use
Long term e cacy and safety of Glycopyrronium bromide tablets has not been studied beyond 24 weeks of use. Continued use should be discussed with the patient's doctor every 3 months to check that Glycopyrronium bromide tablets are still right for the patient.

Pregnancy and breast-feeding
Glycopyrronium bromide tablets must not be given if the patient is pregnant or thinks they may be pregnant or is breastfeeding (see section 2 'Do not take'). Discuss with the patient's doctor whether there is a need for contraception.

Driving and using machines
Glycopyrronium bromide tablets may a ect vision and co-ordination. This may a ect the performance of skilled tasks such as driving, riding a bicycle, or using machines. If you are a ected in this way, DO NOT drive, ride a bike or operate machinery until your vision and coordination is completely recovered. If there is any doubt, ask your doctor for advice.

Glycopyrronium bromide tablets contain lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Glycopyrronium bromide tablets

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

This medicine is for oral use only and should be given at least one hour before or two hours after a meal. If the patient's specific needs determine that co-administration with food is required, it is important to give glycopyrronium bromide at consistent times in relation to food intake. Do not give this medicine with high fat foods. If you (or the patient) have trouble with swallowing, an oral solution may be more appropriate.

Children and adolescents aged 3 years and older and adults who have su ered from neurological disorders from childhood
The initial dose will be calculated based on the weight of the patient. Dose increases will be decided by the patient's doctor, using the table below as a guide, and will depend on both the e ect of Glycopyrronium bromide tablets and any side e ects the patient is experiencing, which is why several dose levels appear on the table below. Section 4 includes possible side e ects related to the use of Glycopyrronium bromide tablets. These should be discussed with the patient's doctor, including those for dose increases and decreases, and at any other time should you be concerned.

Glycopyrronium bromide tablets are recommended for short-term intermittent use.

The patient should be monitored at regular intervals (at least every 3 months) to check that Glycopyrronium bromide tablets are still the right treatment for them.

Weight (kg)	Dose level 1	Dose level 2	Dose level 3	Dose level 4	Dose level 5
13-17	0.3 mg	0.6 mg	0.9 mg	1.2mg	**1.5 mg**
18-22	0.4 mg	0.8 mg	1.2 mg	1.6 mg	**2.0 mg**
23-27	**0.5 mg**	**1.0 mg**	**1.5 mg**	**2.0 mg**	**2.5 mg**
28-32	0.6 mg	1.2 mg	1.8 mg	2.4 mg	**3.0 mg**
33-37	0.7 mg	1.4 mg	2.1 mg	2.8 mg	**3.0 mg**
38-42	0.8 mg	1.6 mg	2.4 mg	**3.0 mg**	**3.0 mg**
43-47	0.9 mg	1.8 mg	2.7 mg	**3.0 mg**	**3.0 mg**
>48	**1.0 mg**	**2.0 mg**	**3.0 mg**	**3.0 mg**	**3.0 mg**

The tablet product may not be suitable for certain dose levels. The tablet can be divided into equal halves. The doses achievable with this product are emphasised in **bold** in the table above.

Dose adjustments should be conducted in discussion with the caregiver to assess both the e ectiveness of this medicine and any undesirable e ects experienced until an acceptable maintenance dose is achieved.

Children under the age of 3 MUST NOT take Glycopyrronium bromide tablets.

If you take more Glycopyrronium bromide tablets than you should
If you take more than the prescribed amount of this medicine, consult your doctor or get medical advice immediately. Always take any leftover medicine with you, as well as the container and label so that the medical sta know what you have taken.

If you forget to take Glycopyrronium bromide tablets
If you remember later on that day, take that day's dose as usual. If the next dose is due, DO NOT take a double dose to make up for a forgotten dose. If you are not sure, ask your doctor or pharmacist.

If you stop taking Glycopyrronium bromide tablets
Your doctor will tell you how long to take the treatment for. DO NOT stop earlier than you are told, even if you feel better. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side e ects

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

If any of the following serious side e ects occur, stop using the medicine and seek medical advice immediately
- Constipation (di culty in passing stool) – very common
- Di culty in passing urine (urinary retention) – very common
- Pneumonia (severe chest infection) - common
- Allergic reaction (rash, itching, red raised itchy rash (hives), di culty breathing or swallowing, dizziness) –frequency not known

The following side e ects may be a sign of severe allergic reaction. If they occur, take you or your child to the nearest emergency facility and take the medicine with you.
- Swelling mainly of the tongue, lips, face or throat (possible signs of angioedema) – frequency not known

Other side e ects are:
Very Common side e ects (may a ect more than 1 in 10 people)
- Dry mouth
- Di culty in passing stools (constipation)
- Diarrhoea
- Being sick (vomiting)
- Flushing
- Nasal congestion
- Unable to completely empty the bladder (urinary retention)
- Reduced secretions in the chest
- Irritability

Common side e ects (may a ect up to 1 in 10 people)
- Upper respiratory tract infection (chest infection)
- Pneumonia (severe chest infection)
- Urinary tract infection
- Drowsiness (sleepiness)
- Agitation
- Fever (pyrexia)
- Nose bleeds (epistaxis)
- Rash

Uncommon side e ects (may a ect up to 1 in 100 people)
- Bad breath (halitosis)
- Fungal infection (thrush) of the throat (oesophageal candidiasis)
- Abnormal contractions of the digestive tract when food is ingested (gastrointestinal motility disorder)
- A disorder of the muscles and nerves in the intestine, which causes an obstruction or blockage (pseudo-obstruction)
- Widening of the pupil of the eye (mydriasis)
- Involuntary eye movement (nystagmus)
- Headache
- Dehydration
- Thirst in hot weather

Other side e ects that occur with anticholinergics but their frequency with glycopyrronium is not known
- Allergic reaction (rash, itching, red raised itchy rash (hives), di culty breathing or swallowing, dizziness)
- Severe allergic reaction; signs include swelling mainly of the tongue, lips, face or throat (angioedema)
- Restlessness; over activity; short attention span; frustration; mood changes; temper outbursts or explosive behaviour; excessive sensitivity; seriousness or sadness; frequent crying episodes; fearfulness
- Insomnia (di culty in sleeping)
- Raised pressure in the eye (which might cause glaucoma)
- Photophobia (sensitivity to light)
- Dry eyes
- Slow heart rate followed by rapid heart rate, palpitations and irregular heartbeat
- Inflammation and swelling of sinuses (sinusitis)
- Feeling sick (nausea)
- Dry skin
- Reduced ability to sweat, which can cause fever and heatstroke
- Urgent need to urinate

Side e ects can sometimes be di cult to recognise in patients with neurological problems who cannot easily tell you how they feel.

If you think a troublesome side e ect is occurring after increasing a dose, the dose should be decreased to the previous one used and your doctor contacted.
Tell your doctor if you notice any behavioural changes or any other changes.

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

5. How to store Glycopyrronium bromide tablets

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

Do not store above 25°C. Store in the original container.

Do not use Glycopyrronium bromide tablets after the expiry date which is stated on the blister/bottles and carton after EXP. The expiry date refers to the last day of that month.
HDPE bottle: Do not use after five weeks of first opening.

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.

If your tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Glycopyrronium bromide tablets contain
- The active substance is glycopyrronium bromide. Each 1 mg tablet contains 1 mg of glycopyrronium bromide. Each 2 mg tablet contains 2 mg of glycopyrronium bromide.
- The other ingredients are lactose monohydrate, anhydrous calcium hydrogen phosphate, magnesium stearate, povidone K-30 and sodium starch glycollate.

What Glycopyrronium Bromide tablets look like and contents of the pack
Glycopyrronium Bromide 1mg tablets are white to o -white, round, flat, bevelled tablets debossed with '1' on one side and a break line on the other side. The tablet can be divided into equal halves.

Glycopyrronium Bromide 2mg tablets are white to o -white, round, flat, bevelled tablets debossed with '2' on one side and a break line on the other side. The tablet can be divided into equal halves.

Glycopyrronium Bromide tablets are available in Alu-Alu blister packs containing 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 100 or 112 tablets (with or without calendar pack).
They are also available in HDPE bottles of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Dawa limited,
5 Sandridge Close,
Harrow, Middlesex,
HA1 1XD, UK.

Manufacturer
Drugsrus Limited,
5 Sandridge Close,
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