

PATIENT INFORMATION LEAFLET

FOR

DUOLIN RESPULES

SCHEDULING STATUS: **S3**

DUOLIN RESPULES, 0,5 mg/2,5 mg in 2,5 mL, solution

Ipratropium bromide and salbutamol

Sugar free.

Read all of this leaflet carefully before you start using DUOLIN RESPULES

- Keep this leaflet, you may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DUOLIN RESPULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What DUOLIN RESPULES is and what it is used for

DUOLIN RESPULES belong to a class of medicines called bronchodilators, which improve breathing by opening up the airways. DUOLIN RESPULES are used to treat constriction of the airways or bronchospasm (tightness of the chest or wheezing).

2. What you need to know before you use DUOLIN RESPULES

Do not use DUOLIN RESPULES:

- if you are hypersensitive (allergic) to salbutamol sulphate, ipratropium bromide, atropine or its derivatives, or any of the other ingredients of DUOLIN RESPULES (listed in **section 6**).
- if you have been diagnosed with an abnormally fast heart rhythm.
- if you have been diagnosed with an enlarged heart or heart muscle disease. Please ask your doctor if you are not sure.

Do not administer DUOLIN RESPULES to children younger than 12 years of age, as safety has not been established (see **section 3**).

Warnings and precautions

Take special care with DUOLIN RESPULES:

Do not exceed the recommended maximum doses.

Excessive use of inhaled bronchodilators, including DUOLIN RESPULES, has resulted in death.

Tell your doctor or health care provider if you have been diagnosed with any of the following conditions before using DUOLIN RESPULES, as you may require a dosage adjustment or special precautions:

- You have had a recent heart attack.
- Disorders of the heart or blood vessels including:

- Decreased blood supply to the heart (ischaemic heart disease). Please discuss this with your doctor if you are unsure.
- Heart failure.
- Irregular heart rhythm.
- High blood pressure or blood vessel disease.
- An overactive thyroid gland.
- Diabetes mellitus (high blood sugar), or insufficiently controlled diabetes mellitus, as you may require additional blood sugar monitoring.
- Difficulty urinating due to obstruction of the bladder outlet or an enlarged prostate gland, since you may develop urinary retention (inability to pass urine) (see **section 4**).
- Porphyria, as safety has not been established.
- A tumour of adrenal gland tissue (phaeochromocytoma).
- Cystic fibrosis, as you may be more prone to experience constipation, diarrhoea or other gut disturbances (see **section 4**).

Immediately report to your doctor or the nearest hospital emergency department if you develop hives or itching, swelling of the lips, face, tongue or whole body, skin rash, difficulty breathing, wheezing or swelling and constriction of the throat, as these symptoms may be due to an allergic reaction (see **section 4**).

If you experience an immediate increase in wheezing and shortness of breath after using DUOLIN RESPULES, stop using DUOLIN RESPULES and immediately report to your doctor or the nearest hospital emergency room (see **section 4**). Your doctor may need to prescribe alternative treatment(s) for you.

If your chest suddenly becomes very tight and the tightness progresses rapidly, please consult your doctor immediately. You should also inform your doctor immediately if you notice that you no longer respond to treatment with DUOLIN RESPULES or if you need higher than recommended doses to open up your chest.

Do not expose your eyes to the solution or mist of DUOLIN RESPULES. There have been reports of eye complications, i.e. dilated pupils, blurred vision, increased pressure in the eye(s) (glaucoma) and eye pain, when the mist from DUOLIN RESPULES has escaped into the eyes. Should you experience any combination of the following symptoms, i.e. eye pain or discomfort, blurred vision, halos around objects or coloured images, and red eyes, you must report to your doctor immediately (see **section 4**).

You must follow the directions for use of the nebuliser and of DUOLIN RESPULES closely (see **section 3**). It is recommended that you use a nebuliser mouthpiece. If this is not available and a nebuliser mask is used, make sure that it fits properly. If you are not sure, ask your doctor or pharmacist for assistance. If you have previously been told that you are at risk of developing glaucoma, you should take particular care to protect your eyes from coming into contact with the mist.

If you develop chest pain that goes up to the chin or down the left arm and which becomes worse with exercise or after you have used DUOLIN RESPULES, immediately stop using DUOLIN RESPULES and inform your doctor. You must also inform your doctor if your feet, ankles or hands become swollen or if you develop unusual tiredness or weakness (see **section 4**).

DUOLIN RESPULES therapy may lower your blood potassium levels to potentially dangerous levels. This may cause abnormal heart rhythms (see **section 4**). Your doctor may perform blood tests to monitor your blood potassium levels, especially if:

- You have been diagnosed with severe airway obstruction.
- You are also taking xanthine derivatives (e.g. theophylline), steroids, diuretics (water tablets) or digoxin concomitantly (see **Other medicines and DUOLIN RESPULES**).

Please discuss the use of DUOLIN RESPULES with your doctor if you are a professional athlete, because DUOLIN RESPULES contains salbutamol and you may test positive for substance abuse in the context of athletic performance enhancement (doping).

A condition known as lactic acidosis has been reported in association with high therapeutic doses of salbutamol, mainly in patients being treated for an acute bronchospasm (see **section 3** and **section 4**). Increase in lactate levels may lead to shortness of breath and hyperventilation even though there may be improvement in your wheezing. If you feel that your medicine is not working as well as usual and you need to use the nebuliser more than your doctor has recommended, immediately talk to a doctor.

Children and adolescents

Do not give DUOLIN RESPULES to children younger than 12 years of age (see **Do not use DUOLIN RESPULES**).

Other medicines and DUOLIN RESPULES

Always tell your health care provider if you are using any other medicine. (This includes all complementary or traditional medicines.)

Please discuss the use of the following medicines with your doctor, as you may require a dosage adjustment or special precautions:

- Medicines called 'anticholinergics', which can be used to treat colic pain, Parkinson's disease, problems emptying your bladder (urinating), or lack of control of your bladder or bowels.
- Oxybutynin (to relieve bladder and urinary problems), chlorpheniramine or diphenhydramine (for allergies), orphenadrine or dicyclomine (for muscle spasms), bupropion (an antidepressant), or dextromethorphan (a cough suppressant).
- Timolol (for glaucoma/raised eye pressure), acebutolol, atenolol, or bisoprolol (for lowering blood pressure or treating heart disorders), or any other beta-blockers.
- Salbutamol, fenoterol, formoterol, or salmeterol (for asthma or bronchitis) or any other medicines called 'beta-agonists'.
- Aminophylline or theophylline (for asthma, bronchitis and emphysema) (see **Warnings and precautions**).
- Water tablets (also called 'diuretics'), e.g. hydrochlorothiazide, furosemide, acetazolamide, chlorthalidone or indapamide, for water retention or high blood pressure (see **Warnings and precautions**).
- Digoxin for heart failure or abnormal heart rhythms (see **Warnings and precautions**).
- Corticosteroids, e.g. prednisone or cortisone, for inflammatory conditions (see **Warnings and precautions**).
- Monoamine oxidase inhibitors, e.g. moclobemide or selegiline, used to treat depression, anxiety or Parkinson's disease.
- Amitriptyline, clomipramine, or imipramine for depression or anxiety.

Some gases used in operations (anaesthetic gases) may affect how your medicine works. If you are scheduled for surgery under general anaesthesia, please inform your doctor that you are using DUOLIN RESPULES.

DUOLIN RESPULES with food, drink and alcohol

DUOLIN RESPULES may be used irrespective of meals.

Pregnancy, breastfeeding and fertility

Do not use DUOLIN RESPULES if you are pregnant or breastfeeding your baby, as safety has not been established.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using DUOLIN RESPULES.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, should you experience dizziness, blurred vision, or you struggle to focus, you should avoid potentially hazardous tasks, such as driving or operating machines.

It is not always possible to predict to what extent DUOLIN RESPULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DUOLIN RESPULES affects them.

3. How to use DUOLIN RESPULES

Do not share medicines prescribed for you with any other person.

Always use DUOLIN RESPULES exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

DUOLIN RESPULES solution for oral inhalation may be inhaled from a suitable nebuliser or an intermittent positive pressure ventilator. The solution is for inhalation only. Do not swallow or inject the contents of DUOLIN RESPULES.

Do not exceed your prescribed dose.

If you develop acute/severe or rapidly worsening shortness of breath, immediately consult your doctor or go to the nearest hospital emergency centre (see **Warnings and precautions**).

Adults (including the elderly) and children over the age of 12 years

Treatment of acute symptoms

The usual dose is one DUOLIN RESPULES unit dose (one respule) to provide prompt relief.

In severe cases, if your attack has not been relieved by one respule, you may use two respules.

However, in this situation, you must consult your doctor or seek prompt medical attention at the nearest hospital.

Maintenance treatment

The usual dose is one respule three or four times a day.

Children under the age of 12 years

Do not administer DUOLIN RESPULES to children younger than 12 years of age, since safety has not been established (see **Do not use DUOLIN RESPULES**).

Instructions for use

1. Prepare the nebuliser according to the instructions of the manufacturer or your doctor.
2. Tear one respule from the strip.

3. Open the respule by twisting the top.
4. Squeeze the contents of the respule into the nebuliser reservoir.
5. Assemble the nebuliser and use as directed.
6. After use, discard any solution left in the nebuliser, as well as any partly used, opened respules.
7. Clean the nebuliser according to the manufacturer's instructions.

DUOLIN RESPULES contains no preservatives. Therefore, it is important that you use the contents immediately after opening the respule and that a fresh respule is used for each administration to avoid bacterial contamination. Partly used, open or damaged respules should be thrown away (see **section 5**).

Do not dilute the contents of DUOLIN RESPULES.

Do not mix DUOLIN RESPULES solution for inhalation with other medicines in the same nebuliser reservoir.

Your doctor will tell you how long your treatment with DUOLIN RESPULES will last. Do not stop treatment early, because your symptoms may return or become worse.

If you have the impression that the effect of DUOLIN RESPULES is too strong or too weak, please speak to your doctor or pharmacist.

If you use more DUOLIN RESPULES than you should

If you use more DUOLIN RESPULES more often than you should, or if you swallow the contents of the respules, you may develop headache, blurred vision, increased hunger, thirst or urination, low or high blood pressure, shortness of breath, muscle cramps or pain, muscle tremor, increased heart

rate, palpitations, chest pain going up the neck or down the arm, redness of the skin or dry mouth.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use DUOLIN RESPULES

Always use DUOLIN RESPULES as prescribed by your doctor. If you miss a dose, use DUOLIN RESPULES as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

DUOLIN RESPULES can have side effects.

Not all side effects reported for DUOLIN RESPULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DUOLIN RESPULES, please consult your health care provider for advice.

If any of the following happens, stop using DUOLIN RESPULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

Less frequent side effects:

- allergic reactions with coughing, shortness of breath, wheezing, swelling of the lips, face, tongue, throat, or whole body, hives or itching, skin rash, low blood pressure, or collapse (see **Warnings and precautions**),
- dilated pupils, eye pain, blurred vision, an eye condition called 'narrow-angle glaucoma', increased pressure in the eye, halos around objects or coloured images, painful, stinging or red eyes, swelling of the eyes (see **Warnings and precautions**),

- palpitations or abnormal heart rhythms, extreme tiredness, or muscle aches or pains, as these symptoms may be caused by low blood levels of potassium (see **Warnings and precautions**),
- chest pain going up to the chin or down the left arm (see **Warnings and precautions**),
- inability to pass urine (see **Warnings and precautions**).

These are all very serious side effects. If you have them, you may have had a serious reaction to DUOLIN RESPULES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent side effects:

- excessive hunger, or thirst, frequent urination, fatigue, poor wound healing, dry or itchy skin, tingling in your feet, erectile dysfunction, or recurrent infections, which may be caused by raised blood sugar levels (see **Warnings and precautions**),
- high blood pressure,
- ulcers inside the mouth or on the lips,
- any skin rash,
- muscle cramps, spasms or weakness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- hoarseness or any other voice disorder,
- dry mouth,

- muscle tremor,
- dizziness, headache,
- cough, throat irritation,
- nausea, vomiting, loose stools, or constipation.

Less frequent side effects:

- agitation, restlessness, anxiety, sleep disturbances, nervousness, or mood changes (mental disorder),
- tremor,
- dry throat,
- indigestion, stomach pain,
- increased sweating.

Side effects with unknown frequency:

- infection and inflammation in children including viral infection (like colds or flu), stuffy nose, runny nose, post-nasal drip, or sore throat,
- a condition known as lactic acidosis, which may cause stomach pain, hyperventilation, shortness of breath even though there may be improvement in your wheezing, cold feet and hands, irregular heartbeat or thirst (see **Warnings and precautions**).

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or

telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of DUOLIN RESPULES.

5. How to store DUOLIN RESPULES

Store at or below 25 °C.

Protect from light. Do not freeze.

Do not use if the solution is discoloured.

Store all medicines out of reach of children.

Keep the respules in the outer carton.

Do not use after the expiry date stated on the packaging material. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DUOLIN RESPULES contains

The active substances in DUOLIN RESPULES are ipratropium bromide and salbutamol. Each 2,5 mL solution (in a single dose respule) contains ipratropium bromide micronised equivalent to ipratropium bromide (anhydrous) 0,5 mg and salbutamol sulphate equivalent to salbutamol 2,5 mg. The other ingredients are sodium chloride, sulphuric acid (for pH-adjustment) and water for injection.

What DUOLIN RESPULES looks like and contents of the pack

DUOLIN RESPULES are clear polyethylene bottles (respules) containing 2,5 mL of a clear, colourless solution free of visible particles.

DUOLIN RESPULES are packed as single dose units (plastic vials/respules made from LDPE granules) in strips of 5 in a triple laminated foil pouch and in an outer carton containing 10, 25, 30, 60, or 90 respules.

Not all pack sizes may be marketed.

Holder of certificate of registration

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