1.3.2. Patient Information Leaflet

SCHEDULING STATUS

S3

IPRABUT 0,5 mg ipratropium bromide and 2,5 mg salbutamol per 2,5 ml solution for nebulisation

Sugar free

Read all of this leaflet carefully before you start using IPRABUT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- IPRABUT 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 IPRABUT is and what it is used for

IPRABUT contains the active substances ipratropium bromide and salbutamol (as sulphate).

IPRABUT belongs to a group of medicines called bronchodilators.

IPRABUT is used with a device called a nebuliser. This changes IPRABUT into a mist for you to breathe in. IPRABUT is used to make breathing easier in an illness called obstructive pulmonary disease.

IPRABUT works by opening up your airways.

2. What you need to know before you use IPRABUT

Do not use IPRABUT:

- if you are hypersensitive (allergic) to ipratropium, salbutamol or any of the other ingredients in IPRABUT (listed in section 6).
- if you are hypersensitive (allergic) to atropine, a medicine used to treat muscle spasms and fluid secretions, by reducing saliva, mucus or other secretions in your airway during a surgery (see Other medicines and IPRABUT).
- if you have a heart problem called 'hypertrophic obstructive cardiomyopathy'. This is where the wall between the two sides of the heart gets bigger and blocks the blood flow.
- if you have a very fast heartbeat (called 'tachydysrhythmia').

IPRABUT is not suitable for children and adolescents under 12 years of age.

Warnings and precautions

Special care should be taken with IPRABUT:

- if you develop an allergic reaction that includes an allergic skin reaction (urticaria), an itchy rash which involves the lips, eyes or tongue which may swell and constitutes a medical emergency (angioedema), rash, closing of airways (bronchospasm), swelling of the throat (oropharyngeal oedema),
- If you have difficulty breathing or wheezing getting worse (paradoxical bronchospasm), IPRABUT should be discontinued immediately,

- If you have a glaucoma or have been told that you may develop it. Ensure that IPRABUT is used correctly and that your eyes are protected, special care should be taken not to expose the eyes to the solution or mist of IPRABUT. It is recommended that the nebulised solution be administered via a mouthpiece. If this is not available and a nebuliser mask is used, it must fit properly. Tell your doctor if IPRABUT goes into your eye,
- If you have high levels of sugar in the blood (diabetes mellitus),
- if you have heart or circulation problems, or have had a recent heart attack (myocardial infarction),
- If you have an over-active thyroid gland (hyperthyroidism),
- If you have or had a rare tumour of adrenal gland tissue which is not malignant (pheochromocytoma),
- If you have prostate problems (prostatic hypertrophy),
- If you have problems passing water (bladder-neck obstruction),
- If you have an underlying heart disease (ischaemic heart disease, tachydysrhythmia or severe heart failure),
- If you experience difficulty breathing or shortness of breath (dyspnoea),
- If you develop low levels of potassium in the blood which include symptoms like weakness, fatigue, constipation, muscle cramping (hypokalaemia),
- If you have a disorder that causes production of abnormally thick, sticky mucous (cystic fibrosis),
- If you suffer from porphyria (A group of disorders caused by an over-accumulation of porphyrin which helps haemoglobin, the protein that carries oxygen in the blood),
- If you have been prescribed a high dose of IPRABUT a build-up of lactate in the body may occur which causes the blood to become acidic (lactic acidosis), symptoms can present as exhaustion or extreme fatigue, muscle cramps or pain, body weakness,

overall feelings of physical discomfort, abdominal pain or discomfort, diarrhoea, decrease in appetite, headache,

- If you have to provide a urine sample as part of sport drug testing, tell the person giving the test that you are taking IPRABUT as it contains salbutamol which may lead to a positive test result.

Children and adolescents

There is no experience with IPRABUT in children younger than 12 years.

Other medicines and IPRABUT

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Anticholinergics (e.g. atropine, tiotropium bromide): medicines used as pre-medicine before operations, after heart attacks or in treating respiratory disorders (see Do not use IPRABUT).
- Xanthine derivatives (e.g. aminophylline, theophylline): medicine that improves breathing by opening air passages in the lungs.
- Other beta-adrenergic agonists (e.g. fenoterol): medicines used to relax the muscles of the airways, resulting in widening of the airways.
- Corticosteroids (e.g. prednisone, prednisolone): medicines that lower inflammation in the body.
- Diuretics (e.g. furosemide): Also known as ‘water tablets,’ medicines used to treat high blood pressure.
- As using the above with IPRABUT can result in increased risk of lowered potassium levels in your blood (hypokalaemia). Symptoms can manifest as tiredness, muscle cramps and abnormal heartbeat and/or increase of side effects.

- Beta-blockers (e.g. propranolol): medicines used to treat high blood pressure.

As using the above IPRABUT can cause a reduced effect of these types of medications.

- Monoamine-oxidase inhibitors (MAOIs) (e.g. linezolid, moclobemide, selegiline): medicines used to treat depression.
- Tricyclic antidepressants (e.g. imipramine): medicines used to treat depression.
- Halogenated hydrocarbon anaesthetics (e.g. halothane): medicines used to make you sleepy for an operation.
- Digoxin: A medicine used to treat heart conditions.

As using IPRABUT with the above-mentioned medicines can result in an increased or irregular heart rate.

Pregnancy, breastfeeding

The safety and efficacy of the use of IPRABUT in pregnancy and breastfeeding have not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

You should not use IPRABUT if you are pregnant. You should not breastfeed your baby when you are on treatment with IPRABUT.

Driving and using machines

IPRABUT may cause dizziness, difficulty focusing the eyes and blurred vision which may affect your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent IPRABUT may interfere with your daily activities as patient. You should not engage in the above activities until you are aware of the measure to which IPRABUT affects you (see section 4).

3. How to use IPRABUT

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

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

The usual dose of IPRABUT is:

Acute attack: 1 (vial) single dose unit

*Maintenance therapy:*1 (vial) single dose unit three or four times a day.

Instructions for use:

1. Prepare the nebuliser for filling, according to the instructions provided by the manufacturer or your doctor.
2. Tear one unit dose vial from the strip.
3. Open the unit dose vial by firmly twisting the top.
4. Squeeze the contents of the unit dose vial into the nebuliser reservoir. Your doctor will tell you if you need to use a different amount.
5. If your doctor has told you that your medicine needs to be diluted, you will be given ‘sterile sodium chloride 0.9% solution. Your doctor will tell you how to do this.
6. Assemble the nebuliser and use as directed.

After use throw away any solution left in the reservoir and clean the nebuliser, following the manufacturer’s instructions.

Since the unit dose vials contain no preservative, it is important that the contents are used soon after opening and that a fresh vial is used for each administration to avoid microbial contamination. Partly used, opened or damaged unit dose vials should be discarded.

It is strongly recommended not to mix IPRABUT solution for inhalation with other medicines in the same nebuliser reservoir.

Your doctor will tell you how long your treatment with IPRABUT will last. If you have the impression that the effect of IPRABUT is too strong or too weak, tell your doctor or pharmacist.

If you use more IPRABUT than you should

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

Signs and symptoms of overdose can be increased rate of heartbeat, irregular heartbeat, unintentional muscle movement involving to-and-fro movements (oscillations) of one or more parts of the body, increased blood pressure or low blood pressure, chest pain, reddening of the face and/or neck, dry mouth, blurred vision or tired, strained eyes.

If you forget to use IPRABUT

If you have missed a dose of IPRABUT, use the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to use several doses, contact your doctor without delay.

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

4. Possible side effects

IPRABUT can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat (angioedema, pharyngeal oedema), which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to IPRABUT. 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:

- build-up of lactate in the body (lactic acidosis) symptoms could include exhaustion, muscle cramps, weakness, diarrhoea,
- changes in the way your heart beats, for example, if you notice it beating faster (palpitations, tachycardia, atrial fibrillation, dysrhythmia, extrasystoles),
- hypotension and collapse,
- reduced blood flow to your heart preventing the heart muscle from receiving enough oxygen (myocardial ischaemia) resulting in symptoms like neck or jaw pain, shoulder or arm pain, fast heartbeat, nausea and vomiting, sweating,
- chest pain, tightness and a feeling of constriction in the chest and back causing difficulty breathing (paradoxical bronchospasm),
- inability to empty bladder (urinary retention).

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:

- dry mouth.

Less frequent side effects:

- hypokalaemia (low levels of potassium in the blood),
- high blood sugar levels (hyperglycaemia), symptoms can be increased thirst and/or hunger, blurred vision, frequent urination (peeing), headache.
- nervousness, mental disorder,
- agitation, restlessness, anxiety, sleep disturbances,
- dizziness, headache, shaking movements in one or more body parts (tremor),
- change in focus of the eye from seeing at a distance to seeing at near (accommodation disorder), fluid filling up in the eye (corneal oedema), eye pain, blocked drainage canals in the eye resulting in a sudden rise in eye pressure (intraocular pressure increased, angle closure glaucoma), increasing the size of the pupil of the eye (mydriasis), blurred vision, increase in blood flow to eye (conjunctival hyperaemia), changes in the way you see things (halo vision),
- increased blood pressure when the heart is contracting (systolic blood pressure), decreased pressure when the heart refills with blood (diastolic blood pressure),
- cough, difficulty speaking due to a disorder of mouth, throat or vocal cords (dysphonia), throat irritation, dry throat, spasm of the vocal cords (laryngospasm),
- nausea, loose stools (diarrhoea), constipation, vomiting, swelling in the mouth (mouth oedema), inflammation of the mouth and lips (stomatitis),
- abnormal increased sweating (hyperhidrosis),

- muscle spasms, muscle weakness, pain in the muscles (myalgia),
- lack of energy (asthenia),
- heartburn; indigestion (dyspepsia) and Intestinal colic: gripes (abdominal pain),
- sweating.

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

Side effects with an unknown frequency:

- State of being unusually or abnormally active (hyperactivity),
- mouth and throat irritation.
- redding of skin (peripheral vasodilatation)

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: https://www.sahpra.org.za/health-products-vigilance/ and to

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of IPRABUT.

5. How to store IPRABUT

Store at or below 30 °C.

Always keep unopened units in the original package and PET/Al/PE pouch so they are well protected from light.

Units in an open PET/Al/PE pouch must be used within 7 days.

Do not freeze.

Store all medicines out of reach of children.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 IPRABUT contains

The active substances are 0,5 mg of ipratropium bromide and 2,5 mg of salbutamol (as sulphate).

The other ingredients are hydrochloric acid (for pH adjustment), sodium chloride, water for injection.

What IPRABUT looks like and contents of the pack

IPRABUT is packed in strips of 5 unit-dose, LDPE containers. Sheets of 5 units are packed into a PET/Al/PE pouch. The pouches are packed into an outer cardboard carton.

Pack size: 30’s or 60’s

Not all packs and pack sizes are necessarily marketed.

Each labelled unit-dose, LDPE container contains 2,5 ml solution.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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