Teva Pharmaceuticals (Pty) Ltd.
CO-IPRASAL SOLUTION (solution for inhalation)
Each 2,5 ml unit dose vial contains 0,5 mg ipratropium bromide and
3,0 mg salbutamol sulphate, (equivalent to 2,5 mg salbutamol base).
Reg No: 41/10.2.1/0765

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CO-IPRASAL SOLUTION (solution for inhalation)

Read this entire leaflet carefully before you start using CO-IPRASAL SOLUTION.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CO-IPRASAL SOLUTION 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.

1. WHAT CO-IPRASAL SOLUTION CONTAINS:

Your medicine comes as an inhalation solution which contains a combination of two bronchodilators: 0,5 mg ipratropium bromide and 3,0 mg salbutamol sulphate (equivalent to 2,5 mg salbutamol base) in a volume of 2,5 ml.

Other ingredients are:

Hydrochloric acid, sodium chloride, water for injection.

2. WHAT CO-IPRASAL SOLUTION IS USED FOR:

CO-IPRASAL SOLUTION is used to treat the wheezing or shortness of breath caused by COPD (chronic obstructive pulmonary disease). CO-IPRASAL SOLUTION works by opening up your airways.

3. BEFORE YOU USE CO-IPRASAL SOLUTION:

Do not use CO-IPRASAL SOLUTION:

- if you are allergic (hypersensitive) to ipratropium or salbutamol or to any of the other ingredients in CO-IPRASAL SOLUTION
- if you are allergic (hypersensitive) to similar medicines which contain atropine

- 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 or irregular heartbeat
- if patients are younger than 12 years of age.

Take special care with CO-IPRASAL SOLUTION:

You must tell your doctor before using* CO-IPRASAL SOLUTION *if:

- you have any allergies or reactions to food or medicines
- you have or develop eye problems, such as glaucoma (high pressure in the eye), blurred vision, colour distortion or eye pain
- you have heart or circulation problems, or have had a recent heart attack
- you have any other health problems, including a thyroid condition, difficulty in urination, enlarged prostate, diabetes mellitus (too much sugar in the blood), raised blood pressure or a heart problem
- you have cystic fibrosis, a condition which causes the body to make thick, sticky mucus, which builds up in the lungs, the digestive system and other parts of the body
- you have ever had 'pheochromocytoma'. This is a rare tumour in the brain which is not malignant (non-cancerous). Using CO-IPRASAL SOLUTION can worsen the symptoms of this condition
- you are taking any other medicines including eye drops or any medicines you can buy without prescription.

You must not use any additional bronchodilators (e.g. medicines containing fenoterol or salbutamol) at the same time or together with CO-IPRASAL SOLUTION, unless instructed to do so by your doctor as doing so may have serious effects on your heart.

A condition known as lactic acidosis may occur with high therapeutic doses of CO-IPRASAL SOLUTION, mainly in patients being treated for an acute bronchospasm (tight chest). Lactic acidosis is caused by an increase in lactate levels which may lead to shortness of breath and hyperventilation even though there may be an improvement in your wheezing. If you feel that CO-IPRASAL SOLUTION is not working as well as usual and you need to use the nebuliser more than your doctor has recommended, tell your doctor immediately.

Pregnancy and breastfeeding:

The safety of CO-IPRASAL SOLUTION in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before using CO-IPRASAL SOLUTION.

Driving and using machines:

You may feel dizzy, have difficulty in focusing, experience dilated pupils or blurred vision whilst using CO-IPRASAL SOLUTION. If this happens do not drive or operate tools or machines.

Using other medicines with CO-IPRASAL SOLUTION:

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before using CO-IPRASAL.
(This includes complementary or traditional medicines.)

Some medicines can affect the way CO-IPRASAL SOLUTION works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines to help your breathing (e.g. theophylline), epinephrine (adrenaline) and medicines called ‘beta stimulants’ such as fenoterol
- medicines called ‘anticholinergics’. These can be used to treat colic pain, Parkinson’s disease, problems passing water or lack of control of your bladder or bowels
- steroid medicines such as prednisolone
- water tablets (also called ‘diuretics’)
- medicines for depression
- medicines called ‘beta blockers’. These can be used to treat heart problems, high blood pressure, anxiety or migraine
- digoxin - used for a fast heart rate or heart failure.

Some gases used in operations (anaesthetic gases) may affect how your medicine works. If you are about to have surgery, make sure you mention that you are using CO-IPRASAL SOLUTION to the doctor, dentist or anaesthetist.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using CO-IPRASAL

SOLUTION.

Do not mix CO-IPRASAL SOLUTION with other medicines in the same nebuliser.

4. HOW TO USE CO-IPRASAL SOLUTION:

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

Always use CO-IPRASAL SOLUTION exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is:

Adults (including elderly patients) and children over 12 years:

Treatment of acute attacks:

1 unit dose vial is usually sufficient for prompt symptom relief.

If your attack is severe and not relieved by one unit dose vial, two unit dose vials may be required. If this happens you should consult your doctor or go to the nearest hospital immediately.

Maintenance treatment:

1 unit dose vial three or four times daily.

There is no experience on the use of CO-IPRASAL SOLUTION in children under 12 years of age.

Do not exceed the recommended dose.

Your doctor or pharmacist will tell you how to prepare your CO-IPRASAL SOLUTION. If you are told to dilute CO-IPRASAL SOLUTION, you must do so immediately before you plan to use the solution.

Your doctor or pharmacist might instruct you to use sterile sodium chloride solution (0,9 %) to dilute the CO-IPRASAL SOLUTION if necessary.

Dilution instruction:

If necessary, before use, doses may be diluted to a total nebulisation volume of 3 to 5 ml with preservative-free 0,9 % sterile sodium chloride solution and used immediately. Discard any unused solution. Nebulise over 10 to 15 minutes at gas flow of 6 to 10 l/min. Repeat every six hours as necessary.

The unit dose vials are intended for inhalation with suitable nebulising devices and should not be taken orally or administered parenterally.

- Prepare the nebuliser for filling, according to the instructions provided by the manufacturer or your doctor.
- Tear one unit dose vial from the strip.
- Open the unit dose vial by firmly twisting the top.
- Squeeze the contents of the unit dose vial into the nebuliser reservoir.
- 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 CO-IPRASAL SOLUTION for inhalation with other medicines in the same nebuliser reservoir.

If dilution is necessary, this should be carried out using ONLY sterile sodium chloride 0,9 % solution and as instructed by your doctor.

If you have the impression that the effect of CO-IPRASAL SOLUTION is too strong or too weak, talk to your doctor or pharmacist.

If you use more CO-IPRASAL SOLUTION than you should:

You may experience side effects such as fast or irregular heartbeat, palpitations, tremors, low or high blood pressure, chest pain or flushing.

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

If you forget to take a dose of CO-IPRASAL SOLUTION:

If you forget to take a dose of your medicine, take it as soon as you remember. If you should be taking your next dose soon (within one hour) then do not take any medicine now, but wait until your next dose and carry out as before.

Do not mix CO-IPRASAL SOLUTION with other medicines in the same nebuliser.

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

5. POSSIBLE SIDE EFFECTS:

CO-IPRASAL SOLUTION can have side effects.

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

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

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching
- wheezing or tightness in the chest after having used CO-IPRASAL SOLUTION

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CO-IPRASAL SOLUTION. 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:

- heart problems (chest pain, irregular or rapid heartbeat, palpitations)
- increased or fast heartbeat (tachycardia)

- low blood pressure or fainting when getting up from a lying or sitting position
- high blood pressure
- difficulty in emptying your bladder (passing less water than is normal for you).

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

Tell your doctor if you notice any of the following:

- blurred vision or pain in the eyes, double vision or eye strain
- abnormal blood test results
- skin rash, excessive sweating
- nervousness, mood changes
- dry mouth, nausea, digestive system problems, vomiting
- muscle cramps, muscle weakness and pain
- physical weakness or lack of energy
- cough, throat irritation, spasm in the muscles around the voice box resulting in changes in your voice, inflammation of the salivary gland in the mouth
- dizziness, headache, tremors
- 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).

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

6. STORING AND DISPOSING OF CO-IPRASAL SOLUTION:

Store at or below 25 °C protected from light.

The ampoule should be opened immediately before use and any solution remaining after use should be discarded.

KEEP ALL MEDICINE OUT OF REACH OF CHILDREN.

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).

7. PRESENTATION OF CO-IPRASAL SOLUTION:

A carton containing 6 x 10 strips of 2,5 ml solution (packed in 3 ml ampoules).

10 strips of the 2,5 ml units are contained in aluminium overwraps.

8. IDENTIFICATION OF CO-IPRASAL SOLUTION:

Clear, colourless to pale yellow solution.

Free from visible particles.

9. REGISTRATION NUMBER:

41/10.2.1/0765

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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