Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

IPRATRIM
Inhaler

Each puff releases:
20 mcg ipratropium bromide

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

For relief of symptoms of reversible bronchospasm in case of asthma, chronic bronchitis, and emphysema.

Therapeutic group: anticholinergic.

IPRATRIM is an inhaler that dilates the airways in cases of constriction of the bronchial muscles (bronchospasm), so that you can breathe more easily and freely.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient ipratropium bromide, to atropine or atropine derivatives (anticholinergic substances with similar structure) or to any of the other ingredients in this medicine (see section 6).
- You are pregnant (particularly during the first trimester) or are breastfeeding, unless your doctor has recommended this treatment after weighing the risks and benefit.

Special warnings about using this medicine

- Consult your doctor or pharmacist before using this medicine.
- Make sure that the solution or medicine mist does not get in your eyes.
- Use IPRATRIM with caution if you have a tendency to narrow-angle glaucoma.
  If the medicine accidentally gets in your eyes during use, mild and reversible eye complications may occur. Especially patients with elevated intraocular pressure (narrow-angle glaucoma) may experience an acute glaucoma attack with the following characteristic symptoms: eye pain, blurred vision, cloudy vision, seeing halos around lights or perceiving colors incorrectly, eye redness and swelling of the cornea.
- If you have pupil dilation with moderate and transient problems adjusting to various distances (accommodation problems), this condition can be treated with eye drops that constrict the pupils. Contact an eye doctor as well if you experience serious eye complications. Since the inhaler is used with a mouthpiece and is manually controlled, the chance of spraying the medicine into the eye is small.
- Use with caution in patients with urinary bladder emptying disorders (for example in patients with an enlarged prostate or narrowed urinary bladder neck).
- Dysfunction and motility disorders of the digestive system may occur in patients with cystic fibrosis.
- If the respiratory distress acutely worsens while inhaling the medicine (paradoxical bronchospasm), stop treatment immediately and contact your doctor to change your treatment plan.
- Immediate allergic reactions may occur after using this medicine, such as rare cases of skin rash (exanthema), allergic rash (urticaria), anaphylactic shock and significant swelling (angioedema) of the tongue, lips and face, and tightening of the airway muscles (bronchospasm).

Children and adolescents
To ensure correct use of the inhaler, children should inhale IPRATRIM under an adult's supervision.
See section 3 - 'How to use this medicine?'.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medications, dietary supplements, and herbal preparations, tell your doctor or pharmacist. Particularly if you are taking:

- Long-term use of IPRATRIM with other medicines that are similar to ipratropium bromide (anticholinergic) has not been studied, and is therefore not recommended.
- Beta agonists and medicines that contain xanthine (such as theophylline) may enhance the effect of IPRATRIM.
- Other anticholinergics, such as pirenzepine-containing medicines, may enhance the effect of IPRATRIM and its side effects.

Please note that this information may also apply to medicines you have recently taken.

Using this medicine and food
No restrictions.

Pregnancy, breastfeeding, and fertility
Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
There is no information about using this medicine in humans during pregnancy and breastfeeding.
Although currently this medicine is not known to have any teratogenic effects, it should only be used during pregnancy, especially during the first trimester and during breastfeeding, if your doctor considers it necessary and has made a careful risk-benefit assessment.
The risk from inappropriate treatment should be considered.

Fertility
There is no clinical information about fertility in connection with ipratropium bromide (the active ingredient in IPRATRIM). Pre-clinical studies with ipratropium bromide did not show any negative effect on fertility.

Driving and using machines
There are no studies on the effect of this medicine on the ability to drive or operate machines.
During treatment with this medicine, you may experience side effects such as dizziness, problems with the eyes adjusting to various distances (accommodation problems), transient pupil dilation (mydriasis), and blurred vision. Therefore, exercise caution when driving or operating machines.
Caution children against riding a bicycle, playing near a road, etc.

Important information about some of this medicine's ingredients
This medicine contains 8.4 mg alcohol per dose. The amount per dose is equivalent to less than 0.3 ml of beer or less than 0.09 ml of wine. The small amount of alcohol in the medicine is unlikely to have any effect.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. It is important to follow the instructions for using IPRATRIM. Proper use of the inhaler is necessary for treatment success. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:
Adults:
1 or 2 puffs, four times a day, although some patients may need up to 4 puffs at a time at the beginning of treatment to achieve maximal benefit. Do not exceed the dosage of 12 puffs in 24 hours.

Children:
6-12 years old: 1 or 2 puffs, three times a day.
To ensure correct use of the inhaler, children should inhale IPRATRIM under an adult's supervision.
The same dose recommendation applies to children under 6 years of age. Since there is currently insufficient experience with using the medicine in this age group, inhalation of IPRATRIM should be performed under medical supervision.

Use in children is allowed only under an adult's supervision.

If additional treatment is needed in case of dosage elevation, do not exceed the daily dose of 12 puffs.

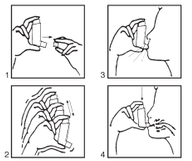
Do not exceed the recommended dose.

This medicine is administered by inhalation only.

How to use the IPRATRIM inhaler:
If possible, use this medicine while sitting or standing.
Correct use of the medicine is essential for treatment success.

Follow the instructions below with **every** use:

a. Remove the protective cap (Figure 1).
   If it is a new inhaler or an inhaler that has not been used for several days, shake the container (Figure 2) and press down once to ensure that the inhaler is working properly. If the inhaler is used regularly, skip to the following instructions:



b. Shake the inhaler (Figure 2).
c. Expel from your lungs as much air as possible.
d. Place the inhaler in your mouth as shown in the figure (Figure 3).
e. Inhale as deeply as possible.
   Press down on the device while you inhale, as shown in the figure (Figure 4).
f. Remove the inhaler from your mouth while trying to keep the air in your lungs for a few seconds and expel the air slowly.

Wash the plastic mouthpiece regularly. To do this, separate the plastic casing of the inhaler from the metal canister and rinse it with plenty of water. Shake the mouthpiece after cleaning and allow to air-dry. Once the mouthpiece is dry, re-insert the canister and replace the protective cap.
g. Store the inhaler with the protective cap in place to protect it from dust and dirt.
h. It is advisable to rinse your mouth with water after each inhalation.

Do not spray in or around the eyes.

It is easier to keep the mouthpiece clean if you do not breathe into the mouthpiece.
The mouthpiece was specially developed and adjusted for use with this inhaler to ensure that the correct dose is always released. Therefore, do not use this mouthpiece with other inhalers. Also, do not use any other mouthpiece with this medicine, except for the one supplied with the product.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally inhaled some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
Do not take more than 12 metered doses (puffs) a day. In addition, a daily dose of more than 12 puffs does not usually provide any additional therapeutic benefit. If you significantly exceed the prescribed dose, seek medical attention immediately. You may be at greater risk of experiencing side effects such as dry mouth, problems with the eyes adjusting to various distances (accommodation problems) and increased heart rate.

If you forget to take the medicine
Do not take a double dose to make up for a forgotten dose. Inhale the next dose at the regular time.
In case of continuous underdose, your shortness of breath may get worse.

Adhere to the treatment as recommended by your doctor.
Your doctor will determine the duration of treatment based on your medical condition and the severity of side effects. Do not change or stop treatment on your own mind.
Consult your doctor or pharmacist if you feel that the effect of the inhaler is too strong or too weak.
Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

If you stop taking this medicine
If you interrupt or end the treatment with IPRATRIM early, your shortness of breath may get worse. Therefore, do not stop the treatment with IPRATRIM without consulting your doctor first.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using IPRATRIM inhaler may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Common side effects (frequency range is 1:10 to 1:100):
Headache, dizziness, cough, throat irritation, dry mouth, taste disturbances, gastrointestinal motility disorders and nausea.

Uncommon side effects (frequency range is 1:100 to 1:1,000):
Immediate allergic reactions, hypersensitivity , blurred vision, temporary pupil dilation, increased intraocular pressure sometimes accompanied by eye pain, cloudy vision and seeing rainbow colors (in the shape of rainbow colored rings), increased circulation to the conjunctiva, corneal swelling, glaucoma, stronger heart beats (palpitations), supraventricular cardiac arrhythmia accompanied by increased heart rate (inhalation-related), bronchospasm (tightening of the bronchial muscles), tightening of throat muscles, swelling of the throat, dry throat, constipation, diarrhea, abdominal pain, vomiting, inflammation of the mouth, swelling of the mouth, rash, itching, significant swelling of the tongue, lips and face, urinary retention.

Rare side effects (frequency range is 1:1,000 to 1:10,000):
Problems with the eyes adjusting to various distances (accommodation problems), atrial fibrillation, hives.
As with all medicines for inhalation, some patients may experience signs of local irritation in the throat area.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il
You can also report by email to: safety@trima.co.il.

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and label. The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 30°C. Protect from direct exposure to sunlight. Do not freeze.
The medicine canister contains pressurized liquid. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn the canister, even when it seems to be empty.
Do not throw away the inhaler with the propellant via wastewater (e.g. down the toilet or washbasin) and do not dispose of it in the household waste. Ask at your pharmacy how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

- **In addition to the active ingredient, this medicine also contains:**
  1,1,1,2-tetrafluoroethane, absolute ethanol, purified water, anhydrous citric acid.
- **What the medicine looks like and contents of the pack:**
  10 ml (200 metered doses) metal canister as a part of a plastic inhaler with mouthpiece.
- **Registration holder's name and address:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- **Manufacturer's name and address:** Laboratorio Aldo-Union, S.L, Baronesa de Malda 73, 08950 Esplugues de Llobregat, Barcelona, Spain.

Revised in August 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: **169-62-35731-00**

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Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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