

PATIENT INFORMATION LEAFLET

DUBLEVENT 0,5 mg + 2,5 mg/2,5 mL Nebulization Solution

This medicine is used by mouth or nose inhalation

- **Active Substance:** *Ipratropium bromid and salbutamol sulfate.*
Each 2.5 mL single-dose ampoule contains 0.5 mg ipratropium bromide (as 0.52 mg ipratropium bromide monohydrate) and 2.5 mg salbutamol (as 3 mg salbutamol sulfate).
- **Excipients:** Sodium chloride, hydrochloric acid, water for injection.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher** or **lower** doses other than what is recommended to you.*

In this leaflet:

- 1. What is DUBLEVENT and what is it used for?***
 - 2. What you need to know before use DUBLEVENT***
 - 3. How to use DUBLEVENT?***
 - 4. Possible side effects***
 - 5. How to store DUBLEVENT***
- headlines are included.**

1. What is DUBLEVENT and what is it used for?

The name of your medicine is DUBLEVENT. You use this medicine with a device called a 'nebuliser'. This changes your medicine into a mist for you to breathe in. DUBLEVENT contains two different medicines called:

- Ipratropium bromide
- Salbutamol sulfate

Both belong to a group of medicines called "bronchodilators". They are used to make breathing easier in an illness called "chronic obstructive pulmonary disease" or COPD. They work by opening up your airways.

DUBLEVENT Inhalation Solution is offered to the market in packages containing 20 pieces glass ampoules of 3 mL (containing 2.5 mL of solution), each of which is prepared to be used at once.

2. What you need to know before use DUBLEVENT

DO NOT USE DUBLEVENT under the following circumstances:

If;

- You are allergic (hypersensitive) to ipratropium bromide or salbutamol or any of the other ingredients in DUBLEVENT. (See “*excipients*” part above)
 - You are allergic to similar medicines which contain atropine or medicines like atropine
 - 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.
 - You have a very fast heart beat (called tachyarrhythmia)
 - You are pregnant, likely to get pregnant or are breast-feeding

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using DUBLEVENT.

USE DUBLEVENT with CAUTION in following cases

Check with your doctor or pharmacist before using this medicine if any of the following conditions apply to you:

- You have glaucoma, or have been told that you may develop glaucoma,
- You have heart or circulation problems, or have had a recent heart attack,
- You have diabetes,
- You have an over-active thyroid gland,
- You have problems passing water urine,
- You are a man who has prostate problems,
- You have cystic fibrosis,
- You have ever had something called “pheochromocytoma”. This is a rare tumour which is not malignant. Using your inhaler can make the symptoms of this worse,
- 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 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.

If you are not sure if any of these apply to you above, talk to your doctor or pharmacist before using DUBLEVENT.

Please consult your doctor even if these warnings valid to you at any time in the past.

Using DUBLEVENT with food and drink

Since DUBLEVENT is administered by inhalation, it is not affected by food and drink.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

Do not use DUBLEVENT if you are pregnant, likely to get pregnant.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation

Please consult your physician or pharmacist before taking the drug.

Do not use DUBLEVENT if you are breast-feeding.

Ability to drive and use machines

You may feel dizzy, or have difficulty in focusing, or blurred vision whilst taking DUBLEVENT. If this happens do not drive or use tools or machines.

Vital information regarding some of the excipients contained in DUBLEVENT

DUBLEVENT does not contain any excipients that require special warning.

Use in combination with other drugs

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription during treatment with DUBLEVENT. This includes herbal medicines. This is because DUBLEVENT can affect the way some other medicines work. Also some other medicines can affect the way DUBLEVENT works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines such as prednisolone
- Water pills (diuretics)
- Medicines for depression
- Medicines to help your breathing
- Medicines called “anti-cholinergic” (These can be used to treat colic pain, Parkinson’s Disease, problems passing water or lack of control of your bladder or bowels)
- Beta blockers such as propranolol (These can be used to treat heart problems, high blood pressure, anxiety or migraine)
- Medicines called “beta mimetics” such as fenoterol for breathing problems
- Digoxin (used for a fast heart beat or heart failure)

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

Operations

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 taking DUBLEVENT to the doctor, dentist or anaesthetist.

Tests

If you have to provide an urine sample as part of a routine sport drug test, tell the person giving the test that you are taking this medicine. This is because DUBLEVENT contains salbutamol and this may lead to a positive result

If you are taking or have recently taken any other medicines, including medicines with a prescription or without a prescription, tell your doctor or pharmacist.

3. How to use DUBLEVENT?

- **Instructions for appropriate use and dose / frequency of administration:**

Always use your medicine exactly as your doctor's instructions. You should check with your doctor or pharmacist if you are not sure. Follow these instructions to get the best results. If anything is unclear after reading this leaflet, ask your doctor or pharmacist.

Dose:

For adults (including the elderly) and children over 12 years the usual dose is the contents of 1 single dose unit, 3 or 4 times a day.

DUBLEVENT is not recommended for children under 12 year.

Do not swallow or give this medicine by injection.

Do not use more than your doctor has told you.

See your doctor straight away:

- If you feel that your medicine is not working as well as usual
- If you need to use the nebuliser more than your doctor has recommended

Your doctor may need to check how well your medicine is working.

In some cases your doctor may need to change your medicine.

- **Use of administration and method:**

DUBLEVENT Inhalation Solution can be administered with a suitable nebulizer or intermittent positive pressure breathing apparatus (ventilator). For the correct use of DUBLEVENT, see the administration instructions at the end of this leaflet. If you are still not sure, consult your doctor or pharmacist.

• Different age groups:

Use in children:

DUBLEVENT is not recommended for children under 12 year due to insufficient information in children.

In elderly:

Elderly patients can use DUBLEVENT without a special dose adjustment.

• Special conditions of use:

Kidney/Liver failure

Since DUBLEVENT has not been studied in patients with hepatic or renal impairment, it should be used with caution in such patients.

If you have the impression that the effect of DUBLEVENT is too strong or weak, talk with your doctor or pharmacist.

If you have taken more DUBLEVENT than you should have:

If you use DUBLEVENT more than the recommended dose, some effects such as dry mouth and eye adjustment disorders may occur in a short time, depending on the ipratropium bromide it contains. These effects are mild and temporary. Because absorption in the body is low after inhalation or oral administration.

Symptoms of overdose with salbutamol, the other active ingredient in the formula of this drug, include: increased heart rate (tachycardia), palpitations, tremors, increased blood pressure, decreased potassium level in the blood, decreased blood pressure, increased pulse pressure, changes in heart rate, anginal pain and flushing. A medical condition called metabolic acidosis has also been reported with excessive intake of salbutamol.

In case of an overdose of salbutamol, your doctor will give you the necessary treatment. However, if you have a history of bronchospasm (contraction of the bronchi), your doctor will take this into account.

If you used more DUBLEVENT than was prescribed, tell your doctor or pharmacist.

If you forget to take DUBLEVENT

If you forget a dose, do not worry and take one of the dose of DUBLEVENT as soon as you remember it. However, if it is time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you have any further questions, ask your doctor or pharmacist.

Possible effects once DUBLEVENT treatment is concluded

Premature discontinuation of DUBLEVENT treatment may cause aggravation of your disease. Therefore, even if your complaints have disappeared, continue to use DUBLEVENT for as long as your doctor prescribes. If you want to stop this treatment, be sure to consult your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, side effects can occur in people sensitive to the ingredients of DUBLEVENT. These side effects may not be seen in everyone.

If any of the following reactions happen, stop taking DUBLEVENT and tell your doctor IMMEDIATELY or contact the emergency department at your nearest hospital:

- If after taking DUBLEVENT you are wheezy or have other difficulties in breathing, do not take any more unless you have been told to by your doctor.
- Allergic reactions - the signs may include skin rash, itching and nettle rash. In severe cases the signs include swelling of your tongue, lips and face, sudden difficulties in breathing and a fall in your blood pressure that may cause dizziness.

See your doctor straight away if you have any of these side effects.

These are all very serious side effects.

If you have one of these, you have a serious allergy to DUBLEVENT. You may need an emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor immediately or go to the nearest hospital emergency department:

The side effects described below have been experienced by people taking DUBLEVENT

Side effects are listed as shown in the following categories:

Other side effects are classified as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Not known: Cannot be estimated from the available data.

Uncommon:

- Feeling nervous, shaky or dizzy
- Dry mouth
- Cough, headache
- Nausea
- Throat irritation
- Increase in blood pressure
- Increased heart rate or uneven heart beats (palpitations)
- Voice problems (dysphonia)
- Skin reactions

Rare

- Anaphylactic reaction, hypersensitivity, angioedema (swelling of tongue, lips and face)
- Irregular heart beat
- Regular but abnormally fast heart rate
- Chest pain (due to heart problems such as angina). Tell your doctor or pharmacist if this occurs but do not stop taking this medicine unless told to do so.
- Blurred vision, dilated pupils, glaucoma, eye pain, stinging and red eyes, swelling of the eyes, see colours or lights, problems in adapting the eye to different distances (accommodation disorders)
- Increased sweating
- Unexpected tightening of the chest immediately after inhaling the medicine
- Dry throat, swelling of the throat
- Difficulty in breathing or speaking due to a brief spasm of your vocal muscles
- Difficulty in breathing due to narrowing of the bronchia
- Diarrhoea, constipation, vomiting or other problems with your digestive system
- Swelling in the mouth and inflammation of the oral mucosa
- Muscle cramps, muscle weakness and pain
- Difficulty in passing water
- Feeling weak (asthenia)
- Fall in blood pressure
- Mood changes
- Mental disorder (Dysfunction of the brain that may occur with a disease or other secondary factors)

You may also get unusually low levels of potassium in your blood (called 'hypokalemia'). If this happens, your doctor will keep checking your potassium levels

Unknown:

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. Consult your doctor or pharmacist if any of these side effects bother you or get worse, or if you experience any side effects not listed in this leaflet.

If any of the liquid or mist accidentally gets into your eyes you may get painful, stinging or red

eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

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

5. How to store DUBLEVENT

Keep DUBLEVENT out of the sight and reach of children, and in its packaging.

Store at room temperature below 25°C. Do not freeze. Do not use if the liquid is discoloured.

Keep vials in the outer carton in order to protect from light.

Do not use if there is a change in the color of the drug.

Use in accordance with expiration dates.

Do not use DUBLEVENT after the expiry date on the package.

Do not use DUBLEVENT if you notice any damage to the product and/or its packaging.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder: POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
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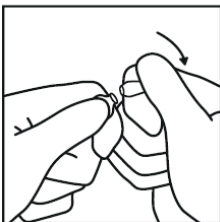
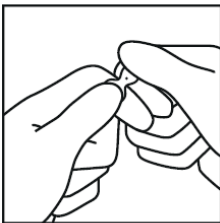
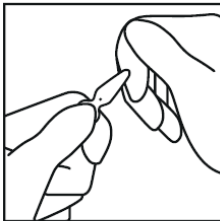
THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

Administration Instruction:

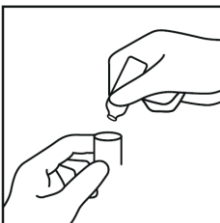
Single-dose ampoules are for inhalation use only with a suitable nebulizer device and should not be taken orally or administered parenterally.

Read through numbers 1 to 5 first, before starting to use your nebuliser.

1. Get your nebuliser ready by following the manufacturer's or physician's instructions. Ask your doctor if you are not sure how to use it.
 - Do not use if it is already open or if the liquid inside is discoloured.
2. Break the ampoule at the marked ringed/dotted area.
 - Always hold it upright while you do this.



3. Pour all the contents of single dose ampoule into the nebuliser reservoir (storage area)



- Your doctor will tell you if you need to use a different amount
 - 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. It is used immediately after dilution.
4. Assemble the parts of the nebuliser and inhale as directed by your doctor.
 5. After use, discard any solution that may have remained in the reservoir and nebuliser;
 - Follow the manufacturer's instructions on how to clean.
 - It is important to keep your nebulizer clean.

If any of the liquid or mist accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

Since single-dose ampoules do not contain preservatives, it is important to use the ampoule immediately after opening and to open a new ampoule for each application in order to prevent contamination with microbes. Partially used, opened or damaged single-dose ampoules should be discarded.

You should be especially careful not to mix DUBLEVENT with other medicines in the same nebulizer.