

Formoterol Neutec 12mcg Capsair Hard Capsule Inhalation Powder

Formoterol Fumarate Dihydrate (12 mcg)

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What *Formoterol Neutec 12 mcg Capsair* is used for

- Prophylaxis and treatment of bronchoconstriction (tightening of the muscle surrounding the airways) in patients with asthma.
- Prophylaxis of bronchospasm (tightening of the muscle surrounding the airways in lungs) induced by inhaled allergens, cold air, or exercise.
- Prophylaxis and treatment of bronchoconstriction in patients with obstructive airways disease (Chronic Obstructive Pulmonary Disease - COPD) including chronic bronchitis (inflammation of the breathing tubes) and emphysema (lung problem that causes shortness of breath). Formoterol Neutec has been shown to improve quality of life in COPD patients.

How *Formoterol Neutec 12 mcg Capsair* works

Formoterol is a potent selective β_2 -adrenergic stimulant. It works by relaxing the muscles in your airway. It has rapid effect that are seen within 1-3 minutes till 12 hours after inhalation.

Before you use *Formoterol Neutec 12 mcg Capsair*

- When you must not use it

Do not take *Formoterol Neutec 12 mcg Capsair* if you are allergic to *formoterol*, lactose or any other ingredients of this medicine.

Pregnancy and lactation

Do not take *Formoterol Neutec 12 mcg Capsair* if you are pregnant, trying to get pregnant or think you may be pregnant unless to control asthma in all stages of pregnancy, and if the expected benefit to the mother is greater than any possible risk to the fetus.

Do not take *Formoterol Neutec 12 mcg Capsair* if you are breast-feeding unless the expected benefit to the mother is greater than any possible risk to the child. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor or pharmacist or nurse before using *Formoterol Neutec 12 mcg Capsair*, if you have any of the following:

- Diabetes Mellitus
- High blood pressure
- Heart related problem
- Thyroid gland related problem
- Serious liver problems (eg. Liver cirrhosis)
- Low levels of potassium in blood

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using *Formoterol Neutec 12 mcg Capsair*.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular you need to tell your doctor, if you are taking:

- Monoamine oxidase (MAO) inhibitors e.g. moclobemide for depression. Do not take *Formoterol Neutec 12 mcg Capsair*, if you have taken MAO inhibitors within the last 14 days.
- Tricyclic antidepressants e.g. amitriptyline or imipramine.
- Medicines for Parkinson's disease e.g. selegiline and levodopa
- Medicines for heart conditions

- Medicines for hypertension e.g. beta blockers
- Medicines for infection e.g. erythromycin
- Medicines for water excretion e.g. diuretics
- Corticosteroids tablets e.g. prednisolone
- Medicines for allergies such as antihistamines
- Medicines for thyroid disorders e.g. levothyroxine
- If you are going to have an anaesthetic tell your doctor

How to use *Formoterol Neutec 12 mcg Capsair*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Formoterol Neutec 12 mcg Capsair should only be taken as an additional to an inhaled corticosteroid.

Adults

Asthma

Regular maintenance therapy:

1 to 2 inhalation capsules twice daily.

For more severe cases: 2 inhalation capsules twice daily.

Maximum daily dose: 4 inhalations.

Prophylaxis against exercise induced bronchospasm or before exposure to a known unavoidable allergen

1 inhalation capsule to be inhaled 15 minutes prior to exercise or exposure.

For more severe cases: 2 inhalation capsules

Chronic Obstructive Pulmonary Disease

Regular maintenance therapy:

1 to 2 inhalation capsules twice daily.

Pediatrics (Children aged 5 years or older)

Asthma

Regular maintenance therapy: 1 inhalation capsule to be inhaled twice daily.

Maximum daily dose: 24 micrograms per day

Prophylaxis against exercise induced bronchospasm or before exposure to a known unavoidable allergen

1 inhalation capsule to be inhaled 15 minutes prior to exercise or exposure.

Adults and children aged 5 years or older

Maintenance therapy: Twice-daily, both during day and at night.

Children under 5 years

Not recommended.

Special populations:

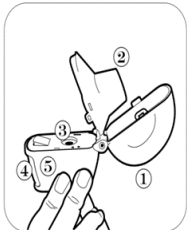
Renal and hepatic impairment

The pharmacokinetics of Formoterol has not been studied in patients with hepatic or renal impairment.

Geriatrics (older than 65 years)

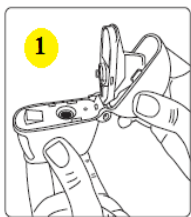
The pharmacokinetics of formoterol has not been studied in the elderly population.

Instruction for Use:

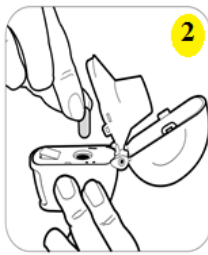


1. Powder cap
2. Mouthpiece
3. Central reservoir
4. Drill button
5. Bottom reservoir

1. Pulling the dust head up ensure that the mouthpiece is fully opened.



2. Take a capsule from blister package (It is important that you take the capsule from the blister pack only immediately before you use it.) and as shown at figure 2, place it in the central reservoir. It does not matter direction of the capsule in the reservoir.



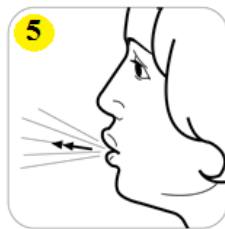
3. Close the mouthpiece tightly until it clicks. Leave the powder cap open.



4. Keep the inhaler device upright and push the drilling button only a single motion and leave. Thus holes will be opened in the capsule and will allow the drug to be released when you breathe.



5. Breathe out fully. Important: please never breathe into the mouthpiece.



6. Lift the inhalation device up to your mouth and close your lips tightly around the mouthpiece. Take a slow and deep breath by holding your head upright; adjust your breathing rate to hear or feel the capsule vibrating. Inhale until your lungs are full; hold your breath for a period of time and remove the inhalation device from your mouth. Then breathe normally. Repeat steps 5 and 6 to empty capsule.



7. Open the mouthpiece again. Turn the device and throw the used capsule. To clean powders in the inside, use a dry soft tissue or a clean soft brush. Close the mouthpiece and powder cap and leave your device.



NOTE: DO NOT USE WATER to clean the inhaler device. The capsules should not be exposed to extreme temperatures. Formoterol Neutec inhaler capsules contain a small amount of powder, so capsules are only partially filled.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Formoterol Neutec 12 mcg Capsair* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of

this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause effects similar to β 2-adrenergic agonists including nausea, vomiting, headache, tremor, feeling drowsy, abnormal and fast heartbeat, body produces too much acid, low level of potassium in blood, high blood sugar, prolonged QTc interval, hypertension.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Formoterol Neutec 12 mcg Capsair*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Formoterol Neutec 12 mcg Capsair* to anyone else, even if they have the same symptoms or condition as you.

Do not try to inhale them using another inhaler. It must only be used with the inhaler provided.

Do not put other types of capsules into the inhaler supplied.

- Things to be careful of

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effect

If you experience any of the following side effects, stop taking *Formoterol Neutec 12 mcg Capsair* and seek immediate medical attention:

- itching, rash, reddened skin
- swelling of the eye lids, lips, face or throat
- low blood pressure or collapse

- increase in wheezing, and shortness of breath shortly after dosing

Common:

- tremor
- fast heartbeat
- headache

Like all medicines, *Formoterol Neutec 12 mcg Capsair* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Formoterol Neutec 12 mcg Capsair*

- Storage

Keep out of the reach and sight of children.

Store at room temperature below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Cover; transparent

Body; in natural transparent capsule, white powder

- Ingredients

- Active ingredient
Formoterol Fumarate Dihydrate

- Inactive ingredients
Lactose (Respitose ML001)

- MAL number:

MAL*****

Manufacturer

Neutec İnhaler İlaç Sanayi ve Ticaret. A.Ş.
Turkey, Sakarya, Arifiye, 1. Organize Sanayi Bölgesi,
2 Nolu Yol, No:3

Product Registration Holder

Medispec (M) Sdn Bhd.
55 & 57, Lorong Sempadan 2,
11400, Ayer Itam, Penang,
Malaysia.

Date of revision

30/03/2021

Serial number

NPRA (R2) 20/016