

Package leaflet: Information for the user

Bambec® Tablets 10 mg and 20 mg bambuterol hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Bambec Tablets are and what they are used for

Bambec Tablets contain bambuterol hydrochloride. They belong to a group of medicines called bronchodilators.

- Bronchodilators work by relaxing the airways of your lungs, making them wider.
- Bambec Tablets are used to treat breathing problems in people with asthma and similar conditions. Bambec Tablets are used as regular treatment to prevent expected breathing problems. Bambec Tablets should not be used alone for the regular treatment of asthma or other breathing conditions. Bambec tablets must only be used when your doctor has prescribed you another type of medication such as an “inhaled corticosteroid”, which helps reduce the swelling and inflammation in your lungs. **However, Bambec Tablets will not relieve an acute asthma attack that has already started.**

2. What you need to know before you take Bambec Tablets

Do not take Bambec Tablets:

If you are allergic to bambuterol hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Bambec Tablets if:

- You are diabetic. You may need some additional blood sugar tests when you start taking Bambec Tablets.
- You have a history of heart disease, irregular heart rhythm or chest pains (angina).
- You have an overactive thyroid gland.
- You have problems with your liver or kidneys.
- You are going to have a general anaesthetic for an operation, including for dental work.
- You have a family history of glaucoma (increased pressure in the eye).

Other medicines and Bambec Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular, tell your doctor before taking Bambec Tablets if you are taking:

- Steroid medicines (such as prednisolone).
- Theophylline or aminophylline medicines (for breathing problems).
- Beta-blocker medicines (e.g. medicines for high blood pressure or heart conditions such as propranolol and eye drops for glaucoma such as timolol).
- Water tablets (diuretics).
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- Medicines containing ipratropium.

There may also be effects on the salt balance in the blood (low potassium levels) when Bambec Tablets are used at the same time as certain other medicines. Usually this is of no importance, but in some cases there can be effects on the heart rhythm.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- If you get pregnant when taking Bambec Tablets, talk to your doctor straight away.
- Bambec Tablets should be used with caution at the end of pregnancy since it relaxes the womb.
- It is not known if Bambec Tablets pass into breast milk. Talk to your doctor before breast-feeding if you are taking Bambec Tablets.

Driving and using machines

Bambec Tablets are not likely to affect you being able to drive or use any tools or machines.

Bambec Tablets contain lactose

Bambec Tablets contain lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Bambec Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Bambec Tablets must only be used with medication such as Inhaled corticosteroids.
- The recommended dose is one tablet just before bedtime.
- Do not chew or crush the tablets.
- Swallow the tablets whole with a drink of water.
- If necessary, the tablets can be broken in half.

Contact your doctor straight away if:

- Your breathing is getting worse.
- You often wake up at night with wheezing or difficulty in breathing.
- You start to get a tight chest.
- The Bambec Tablets do not make your breathing any easier.

If any of these happen, it could mean your asthma is not being controlled. You may need different treatment or extra treatment straight away.

Use in children

Bambec Tablets should not be taken by children.

If you take more Bambec Tablets than you should

If you have taken more Bambec Tablets than prescribed by your doctor, tell the doctor or go to the nearest hospital straight away. Take the Bambec Tablets with you.

If you forget to take Bambec Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bambec Tablets

Do not stop taking your medicine without first talking to 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, Bambec Tablets can cause side effects, although not everybody gets them.

Allergic (hypersensitive) reactions:

An allergic reaction may happen with medicines like Bambec Tablets. It is not known exactly how often this happens. If you think Bambec Tablets are causing an allergic reaction, **stop taking your tablets and contact your doctor straight away.**

An allergic reaction could cause:

- A swollen face.
- Skin rash.
- Breathing problems, low blood pressure (feeling faint) and collapse.

You may experience Bronchospasm (tightening of the muscles in the airways which causes wheezing). It is not known exactly how often this happens. If the wheezing comes on suddenly after taking your dose of Bambec Tablets **stop taking your tablets and contact your doctor straight away.**

Contact your doctor if you notice any of the following:

- Muscle weakness, thirst or pins and needles. This may mean that you have low levels of potassium in your blood. It is not known exactly how often this happens. It is more likely to happen if you have severe asthma or if you are taking steroid medicines, theophylline or aminophylline, or water tablets (diuretics).
- Heart problems, such as an irregular heart beat. These have occurred with medicines of this type in susceptible patients.

Other possible side effects:

Very common (may affect more than 1 in 10 people)

Trembling or shaking.

Headache.

Being restless.

Common (may affect up to 1 in 10 people)

Awareness of your heart beating (palpitations).

Sudden painful muscle tightness (cramp).

Difficulty in sleeping.

Uncommon (may affect up to 1 in 100 people)

Feeling agitated.
Faster heartbeats.
Irregular heartbeats.

Not known (frequency cannot be estimated from the available data)

Feeling sick (nausea).
Feeling hyperactive.
High levels of sugar in your blood.
Feeling dizzy.

Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor if you develop these symptoms whilst receiving treatment with Bambec, but do not stop using this medicine unless told to do so.

Some of the side effects listed above may go away within 1 or 2 weeks of starting Bambec tablets.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bambec Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.

6. Contents of the pack and other information**What Bambec Tablets contain**

- The active substance is bambuterol hydrochloride. Each tablet contains 10 or 20 mg of the active ingredient.
- The other ingredients are lactose monohydrate, maize starch, povidone, microcrystalline cellulose, magnesium stearate and purified water.

What Bambec Tablets look like and contents of the pack

Bambec Tablets are off-white in colour and are available in packs containing 28 or 30 tablets. The tablets are packed in blister strips. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Bambec Tablets are held by AstraZeneca UK Ltd., 600 Capability Green, Luton, LU1 3LU, UK.

Bambec Tablets are manufactured by AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK and AstraZeneca GmbH, Tinsdaler Weg 183, 22880, Wedel, Germany.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Bambec 10 mg Tablets Bambec 20 mg Tablets
Reference number	17901/0103 or 17901/0104

This is a service provided by the Royal National Institute of the Blind.

This leaflet was last revised in May 2018.

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