

NEBILET™

(nebivolol hydrochloride) oral tablets

PATIENT INFORMATION LEAFLET

INFORMATION FOR PEOPLE TAKING NEBILET™ ORAL TABLETS

Before you start to take your medicine, please read this leaflet carefully all the way through as it contains important information. This leaflet does not contain the complete information. If there is anything that you do not understand or if you need further information or advice, you should ask your doctor or pharmacist. This leaflet applies to Nebilet tablets. ***Please do not throw it away until you have finished taking the full course of your medicine. You may need to refer to it again.***

What is your medicine?

The name of your medicine is Nebilet and its active ingredient is nebivolol hydrochloride. Nebilet tablets are white, round, cross-scored tablets. Each tablet contains nebivolol hydrochloride corresponding with 5 milligrams of nebivolol. The tablets also contain polysorbate, hypromellose, lactose, maize starch, croscarmellose sodium, microcrystalline cellulose, colloidal silica and magnesium stearate.

The licence of this medicine is held by Berlin Chemie AG, Glienicke Weg 125, D-12489, Berlin, Germany, under licence of Janssen Pharmaceutica N.V., Beerse- Belgium.

Nebilet tablets are manufactured by Berlin Chemie AG, Glienicke Weg 125, D-12489, Berlin, Germany.

What is your medicine used for?

Nebilet is used to treat an increased blood pressure (hypertension). Nebilet is also used to treat chronic heart failure in patients aged 70 or over.

REMEMBER - This medicine has been prescribed for you only. ***Never give it to anyone else.*** It may harm them even if their symptoms are the same as yours.

WHAT SHOULD YOU KNOW BEFORE YOU START YOUR TREATMENT BEFORE TAKING ANY MEDICINE - always inform your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

When not to use your medicine

Do not use Nebilet if you are allergic to any of its ingredients, which can be found under "What is Nebilet?".

Do not use Nebilet if you are pregnant or breast-feeding.

Do not use Nebilet if you have one or more of the following disorders:

- liver function disorder;
 - low blood pressure, poor circulation in the arms or legs, very slow heartbeat (less than 60 beats per minute) or certain other heart problems;
 - your heart failure has just occurred or worsened recently, or you are receiving treatment into a vein (by intravenous "drip") to help your heart work;
 - asthma or wheezing (now or in the past);
 - certain tumours in the adrenal glands;
 - a metabolic disorder (metabolic acidosis) characterized by too much acid in your body (and blood).
- If in doubt, contact your doctor or pharmacist.

SPECIAL PRECAUTIONS

Pregnancy and Nebilet

It is not yet clear whether Nebilet can be harmful during pregnancy. To date, animal studies have not shown any harmful effects.

Nebilet should not be used during pregnancy. If you are pregnant or plan to become pregnant while on Nebilet, you should discuss with your doctor whether you can take Nebilet.

If you do find that you are pregnant after starting a course of Nebilet tablets, stop taking it and tell your doctor straight away.

Breast-feeding and Nebilet