1. WHAT BENETOR IS AND WHAT IT IS USED FOR

Benetor belongs to a group of medicines called angiotensin-II receptor antagonists. They lower blood pressure by relaxing the blood vessels.

Benetor is used for the treatment of high blood pressure (also known as ‘hypertension’) in adults and elderly patients and adolescents aged 6 to less than 18 years. High blood pressure can damage blood vessels in organs such as the heart, kidney, brain and eyes. In some cases this may lead to a heart attack, heart or kidney failure, stroke or blindness. Usually high blood pressure has no symptoms. It is important to have your blood pressure checked to prevent damage occurring.

High blood pressure can be controlled with medicines such as Benetor tablets. Your doctor has probably already recommended that you make some changes in your lifestyle to help lower your blood pressure (for example losing weight, giving up smoking, reducing the amount of alcohol you drink and reducing the amount of salt in your diet). Your doctor may also recommend you to take regular exercise, such as walking or swimming. It is important to follow this advice from your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BENETOR

Do not take Benetor:

- If you are allergic to olmesartan medoxomil or any of the other ingredients of this medicine (listed in section 6).
- If you have a history of diabetes and you are taking an olmesartan medoxomil preparation.
- If you have more than 3 months pregnant. (It is important to follow this advice from your doctor."

If you are pregnant or breast-feeding, think you might become pregnant. Your doctor will normally advise you to stop taking Benetor before you become pregnant or as soon as you know you are pregnant and you will advise you to take another medicine instead. Benetor is not recommended for mothers who are breast-feeding, and it is not recommended in early pregnancy, and must not be used in women who are breast-feeding during the third month of pregnancy."

Breast-feeding

You must tell your doctor if you think you are (or might become) pregnant. Benetor is not recommended in early pregnancy, and must not be used in women who are breast-feeding."

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.

3. HOW TO TAKE BENETOR

Follow your doctor’s instructions. Take your tablet(s) with a full glass of water.

Your doctor will probably recommend that you take Benetor 1 tablet(s) a day.

If you have any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

4. POSSIBLE SIDE EFFECTS

- Problems with your adrenal glands.
- Increased levels of potassium in your blood.
- Severe vomiting, diarrhoea, treatment with high doses of water tablets (diuretics) or if you are on a low salt diet.
- Increased levels of potassium in your blood.
- Potassium supplements, a salt substitute which contains potassium, water tablets (diuretics) or heparin (for thinning the blood). Using these medicines at the same time as Benetor may raise the levels of potassium in your blood.
- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Benetor may increase the toxicity of lithium. If you have to take lithium, your doctor will measure your lithium blood levels.
- Non-Steroidal Anti-Inflammatory (NSAIDs) medicines used to relieve swelling, pain and other symptoms of inflammation, including arthritis used at the same time as Benetor may increase the risk of kidney failure and the effect of Benetor can be decreased by NSAIDs.
- Captopril, a diuretic, a drug that lowers the level of cholesterol in your blood, as the effect of Benetor may be decreased. Your doctor may advise you to take Benetor at least 4 hours before capohelemide hydrochloride.
- Certain antacids (indigestion remedies), as the effect of Benetor can be slightly decreased.
- Benzodiazepines or any other medicines and Benetor experience is available.

Your doctor may check your blood pressure, kidney function, liver function, and certain blood tests to make sure that your blood pressure does not become too low.

Do not take more than the recommended dose of Benetor."

5. HOW TO STORE BENETOR

Keep this leaflet. You may need to read it again.

Do not take any more tablets than you need, save them for another patient. It may harm them, even if their signs of illness are the same as yours.

Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

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.

7. ADDITIONAL INFORMATION

Children and adolescents

Benetor is not recommended in children and adolescents. For more information, talk to your doctor.

Other medicines and Benetor

Talk to your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist about any of the following:

- Other blood pressure lowering medicines, as the effect of Benetor can be increased. Your doctor may need to change your dose and/or to take other precautions.
- Any of the other ingredients of this medicine (listed in section 6).

If you have any further questions, ask your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
Common side effects (may affect up to 1 in 10 people):

- Rash, itching, exanthema (skin eruption), skin rash, allergic skin reactions, facial swelling (angioedema), rash which may occur as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions), swelling of the face, mouth and/or larynx (voice box), increased fat levels (hypertriglyceridaemia), some changes in blood test results have also been seen. These include increased potassium levels, ketone bodies, pyruvate, increased levels of compounds related to kidney function.

- Additional side effects in children and adolescents:
In children, side effects are similar to those in adults. However, dizziness and headache are seen more often in children, and nose bleeding is a common side effect seen only in children.

- 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 HPRA Pharmacovigilance.

- 6. CONTENTS OF THE PACK AND OTHER INFORMATION:
Benetor contains lactose. This leaflet was last revised in March 2017.