Korrekturabzug

Package Leaflet: Information for the user

Benetor® 10 mg, 20 mg, 40 mg Film-Coated Tablets

olmesartan medoxomil

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

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 in children and adolescents aged 6 to less than 18 years. High blood pressure can damage blood vessels in organs such as the heart, kidneys, 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 also 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 have urged 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 are more than 3 months pregnant. (It is also better to avoid Benetor tablets in early pregnancy – see pregnancy section).
- if you suffer from yellowing of the skin and eyes (jaundice) or problems with drainage of the bile from the gallbladder (biliary obstruction e.g. gallstones).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor before using Benetor.

Tell your doctor if you are taking any of the following medicines used to treat high blood pressure:
- an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Benetor".

Tell your doctor if you have any of the following health problems:
- Kidney problems
- Liver disease
- Heart failure or problems with your heart valves or heart muscle.
- 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.
- Problems with your adrenal glands.

Contact your doctor if you experience diarrhoea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

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 taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Black patients
As with other similar drugs the blood pressure lowering effect of Benetor is somewhat less in black patients.

Elderly people
If you are 65 years or over and your doctor decides to increase your dose of olmesartan medoxomil to 40 mg daily, then you need to have your blood pressure regularly checked by your doctor to make sure that your blood pressure does not become too low.

Children and adolescents
Benetor has been studied in children and adolescents. For more information, talk to your doctor. Benetor is not recommended for children from 1 year to less than 6 years and should not be used in children under the age of 1 year as no experience is available.

Other medicines and Benetor
Tell 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:
  If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Benetor" and "Warnings and precautions").
- 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 (medicines used to relieve pain, swelling 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.
- Colesevelam hydrochloride, 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 colesevelam hydrochloride.
- Certain antacids (indigestion remedies), as the effect of Benetor can be slightly decreased.

Benetor with food and drink
Benetor can be taken with or without food.

Pregnancy and breast-feeding

Pregnancy
You must tell your doctor if you think you are (or 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 will advise you to take another medicine instead of Benetor. Benetor is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Benetor is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.
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.

Driving and using machines
You may feel sleepy or dizzy while being treated for your high blood pressure. If this happens, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

Benetor contains lactose
This medicine contains lactose (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 BENETOR

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

The recommended starting dose is one 10 mg tablet once a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose up to 20 or 40 mg once a day, or prescribe additional medicines.
In patients with mild to moderate kidney disease, your dose will not be higher than 20 mg once a day.

The tablets can be taken with or without food. Swallow the tablets with a sufficient amount of water (e.g. one glass). If possible, take your daily dose at the same time each day, for example at breakfast time.

Children and adolescents from 6 to less than 18 years of age:
The recommended starting dose is 10 mg once daily. If the patient's blood pressure is not adequately controlled, the doctor may decide to change the dose up to 20 or 40 mg once a day. In children who weigh less than 35 kg, the dose will not be higher than 20 mg once a day.

If you take more Benetor than you should
If you take more tablets than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

If you forget to take Benetor
If you forget a dose, take your normal dose on the following day as usual. Do **not** take a double dose to make up for a forgotten tablet.

If you stop taking Benetor
It is important to continue to take Benetor unless your doctor tells you to stop.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If they do occur, they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following two side effects can be serious:

On rare occasions (may affect up to 1 in 1,000 people) the following allergic reactions that may affect the whole body have been reported:

Swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Benetor. **If this happens stop taking Benetor and contact your doctor immediately**.

Rarely (but slightly more often in elderly people) Benetor can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. This could cause severe light-headedness or fainting. **If this occurs stop taking Benetor, contact your doctor immediately and lie down flat**.

These are the other side effects known about so far with Benetor:

Common side effects (may affect up to 1 in 10 people):
Dizziness, headache, nausea, indigestion, diarrhoea, stomach ache, gastroenteritis, tiredness, sore throat, runny or stuffy nose, bronchitis, flu-like symptoms, cough, pain, pain in the chest, back, bones or joints, infection of the urinary tract, swelling of ankles, feet, legs, hands, or arms, blood in the urine.

Some changes in blood test results have also been seen and include the following:
increased fat levels (hypertriglyceridaemia), increased uric acid levels (hyperuricaemia), rise in blood urea, increases in tests of liver and muscle function.

Uncommon side effects (may affect up to 1 in 100 people):
Quick allergic reactions that may affect the whole body and may cause breathing problems as well as a rapid fall of blood pressure that may even lead to fainting (anaphylactic reactions), swelling of the face, vertigo, vomiting, weakness, feeling unwell, muscular pain, skin rash, allergic skin rash, itching, exanthema (skin eruption), skin lumps (wheals), angina (pain or uncomfortable feeling in the chest).

In blood tests a reduction of the numbers of a type of blood cell, known as platelets has been seen (thrombocytopenia).

Rare side effects (may affect up to 1 in 1,000 people):
Lack of energy, muscle cramps, impaired kidney function, kidney failure.

Some changes in blood test results have also been seen. These include increased potassium levels (hyperkalaemia) and increased levels of compounds related to kidney function.

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

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
Earlsfort Terrace, IRL – Dublin 2
Tel.: +353 1 676 4971
Fax: +353 1 676 2517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BENETOR

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister strip after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Benetor contains

The active substance is olmesartan medoxomil. Each film-coated tablet contains 10 mg, 20 mg or 40 mg olmesartan medoxomil.

The other ingredients are microcrystalline cellulose, lactose monohydrate, hydroxypropylcellulose, low substituted hydroxypropylcellulose, magnesium stearate, titanium dioxide (E171), talc and hypromellose (See section 2 "Benetor contains lactose").

What Benetor looks like and contents of the pack

Benetor 10 mg film-coated tablets are white, circular with C 13 on one side.
Benetor 20 mg film-coated tablets are white, circular with C 14 on one side.
Benetor 40 mg film-coated tablets are white, oval with C 15 on one side.

Benetor film-coated tablets are available in packs of 14, 28, 30, 56, 84, 90, 98 and 10 x 28 film-coated tablets and in packs with perforated unit dose blisters of 10, 50 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
DAIICHI SANKYO IRELAND LTD.,
Riverside One, Sir John Rogerson's Quay,
Dublin 2, Ireland

Manufacturer
DAIICHI SANKYO EUROPE GmbH
Luitpoldstrasse 1
85276 Pfaffenhofen, Germany

This medicinal product is authorized in the Member States of the EEA under the following names:

Austria:	Olmetec
Belgium:	Olmetec
Denmark:	Olmetec
Germany:	Olmetec
Greece:	Olmetec
Finland:	Olmetec
France:	Olmetec
Iceland:	Olmetec
Ireland:	Benetor
Italy:	Olmetec
Luxembourg:	Olmetec
The Netherlands:	Olmetec
Norway:	Olmetec
Portugal:	Olmetec
Spain:	Olmetec
UK:	Olmetec

This leaflet was last revised in March 2017.

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The following pack sizes are currently marketed: 28 film-coated tablets.

Daiichi-Sankyo