PACKAGE LEAFLET: Information for the patient

MESACOR

Film-coated tablets – 20 mg

(Olmesartan medoxomil)

Read this leaflet carefully before you start taking this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. WHAT MESACOR IS AND WHAT IT IS USED FOR

Mesacor contains the active substance olmesartan medoxomil, which is an angiotensin II-receptor antagonist with a similar action to that of losartan.

Mesacor is used in the control of hypertension.

2. BEFORE YOU TAKE MESACOR

Do not take Mesacor if you:

- suffer from severe renal disorders,
- suffer from severe hepatic disorders,

- have biliary obstruction,
- are in the second and third trimester of pregnancy,
- are breastfeeding,
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Take special care with Mesacor

Talk to your doctor before taking Mesacor if you:

- are hypersensitive to olmesartan medoxomil or to any of the excipients of Mesacor tablets,
- have renal artery stenosis,
- have aortic or mitral valve stenosis,
- have hypertrophic cardiomyopathy,
- 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 Mesacor if you”.
Monitoring of plasma-potassium concentration is advised, particularly in the elderly and in patients with renal impairment; lower initial doses may be appropriate in these patients.
Patients with primary aldosteronism and Afro-Caribbeans (particularly those with left ventricular hypertrophy), may not benefit from the effect of the angiotensin-II receptor antagonists.
Olmesartan medoxomil should be avoided during the first trimester of pregnancy.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Mesacor.
Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor

for the treatment with Mesacor if you have been given any other medicine during treatment, especially the following:

- potassium salts, because they increase the risk of hyperkalaemia;
- ciclosporin, because it increases the risk of hyperkalaemia;
- diuretics (potassium - sparing diuretics and aldosterone antagonists), because they enhance the hypotensive effect and increase the risk of hyperkalaemia;
- lithium, because its excretion is reduced by angiotensin-II receptor antagonists;
- an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Mesacor if you” and “Take special care with Mesacor”).

Your doctor may need to change your dose and/or to take other precautions.

Pregnancy and lactation

Mesacor should be avoided in the first tremester of pregnancy.
Mesacor is contraindicated in the second and third tremester of pregnancy.
Mesacor is not recommended during lactation.

Driving and using machinery

Mesacor has minor or moderate influence on the ability to drive and use machinery. In some cases, in patients taking antihypertensive therapy, Mesacor causes dizziness or fatigue, which may impair the ability to react.

Important informations about some of the excipients of Mesacor

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE MESACOR

Always take Mesacor exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Mesacor is given orally for the treatment of hypertension. After the first dose, the hypotensive effect lasts for 24 hours. Most of the hypotensive effect is apparent within two weeks after starting the therapy and is maximal within about 8 weeks.

At the beginning of therapy, 10 mg olmesartan medoxomil is taken once daily. If it is necessary, the dose is increased to 20 mg once daily; the maximum is 40 mg daily.

In patients with *renal impairment*, it is not recommended the use of Mesacor in severe renal impairment (when creatinine clearance is below 20 mL/min.) since experience is limited, and the maximum dose in mild to moderate impairment (when creatinine clearance is 20 to 60 mL/min), is 20 mg daily.

Similarly, in patients with *hepatic impairment*, it is not recommended the use of Mesacor in severe hepatic impairment since there is no experience. Patients with moderate hepatic impairment should be given an initial dose of 10 mg daily and the maximal dose is 20 mg daily.

If you take more Mesacor than you should

If you take more Mesacor than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Mesacor

If you forget a dose (or more doses), take the following dose when it is time to take it usually. Do not take a double dose (or higher) to make up for a forgotten dose. If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Mesacor can cause side effects, which are usually mild, although not everybody manifests them. Tell your doctor for the following side effects that may appear to you:

- symptomatic hypotension including dizziness, particularly in patients with intravascular volume depletion (e.g. those taking high - dose diuretics);
- hyperkalaemia occurs occasionally;
- commonly: gastro-intestinal disturbances, chest pain, peripheral oedema, hypertriglyceridaemia, fatigue, influenza-like symptoms, cough, pharyngitis, rhinitis, urinary tract infection, haematuria, hyperuricaemia, arthritis, musculo-skeletal pain;
- less commonly: angina, vertigo, rush;
- very rarely: headache, thrombocytopenia, myalgia, pruritus, urticaria.

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

5. HOW TO STORE MESACOR

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 box.
Store below 25°C.
Keep in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION

What Mesacor 20 mg film-coated tablets contain

The **active substance** is olmesartan medoxomil.
Each film-coated tablet contains 20 mg olmesartan medoxomil.
The **excipients** are:
tablet core: lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate, stearic acid, colloidal anhydrous silica
film coat: polyvinyl alcohol, titanium dioxide, macrogol, talc.

Contents of the pack:

Carton box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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