Olmetor®

Olmesartan Medoxomil USP

COMPOSITION

Olmetor® 10 tablet: Each film coated tablet contains Olmesartan Medoxomil USP 10 mg.
Olmetor® 20 tablet: Each film coated tablet contains Olmesartan Medoxomil USP 20 mg.
Olmetor® 40 tablet: Each film coated tablet contains Olmesartan Medoxomil USP 40 mg.

PHARMACOLOGY

Olmesartan Medoxomil is a selective angiotensin-II receptor antagonist (AT1 subtype). Olmesartan Medoxomil a prodrug, is hydrolyzed to Olmesartan during absorption from the gastrointestinal tract.

INDICATION

For the treatment of hypertension.It may be used alone or in combination with other antihypertensive agents.

DOSAGE & ADMINISTRATION

The starting dose is 10 mg once daily and maximum dose is 40 mg once daily. In patients whose blood pressure is not adequately controlled at the starting dose, the dose of Olmesartan medoxomil may be increased to 20 mg once daily as the optimal dose.

CONTRAINDICATION

Olmesartan is contraindicated in patients who are hypersensitive to any component of this product.

PRECAUTION AND WARNING

As a consequence of inhibiting the renin-angiotensin- aldosterone system, changes in renal function may be anticipated in susceptible individuals treated with olmesartan medoxomil. In patients whose renal function may depend upon the activity of the renin-angiotensin- aldosterone system (e.g.patients with severe congestive heart failure), treatment with angiotensin converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Similar results may be anticipated in patients treated with olmesartan medoxomil.

SIDE EFFECTS

Common

The most common side effects include Back pain, bronchitis, creatine phosphokinase increased, diarrhea, headache, hematuria, hyperglycemia, hypertriglyceridemia, influenza-like symptoms, pharyngitis, rhinitis and sinusitis.

Rare

Chest pain, peripheral edema, arthritis.

USE IN PREGNANCY AND LACTATION

Pregnancy

When pregnancy is detected, discontinue this product as soon as possible. When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.

Nursing Mothers

It is not known whether Olmesartan is excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric use

Safety and effectiveness in paediatric patients have not been established.

Drug interaction with other medicine & Food

With medicine

No significant drug interactions were reported in which SevitanTM was co-administered.

With food & others

Food does not affect the bioavailability of Olmesartan.

OVERDOSE EFFECTS

Symptoms:

There is no experience of overdose with **Olmetor®**. The most likely effects of olmesartan medoxomil overdosage are hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurred.

Treatment

If intake is recent, gastric lavage or induction of emesis may be considered. Clinically significant hypotension due to an overdose of **Olmetor®** requires active support of the cardiovascular system, including close monitoring of heart and lung function, elevation of the extremities, and attention to circulating fluid volume and urine output.

STORAGE

Store in cool and dry place below 30°C, protect from light & moisture.
Keep out of reach of children.

COMMERCIAL PACK

Olmetor® 10 tablet: Each box contains 3x10's tablet in Alu-Alu blister pack.
Olmetor® 20 tablet: Each box contains 3x10's tablet in Alu-Alu blister pack.
Olmetor® 40 tablet: Each box contains 3x10's tablet in Alu-Alu blister pack.

Manufactured by
EURO Pharma Ltd.
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