Normisar Tablets

(Telmisartan Tablet USP)

COMPOSITION:
Each film coated tablet contains:
Telmisartan USP … 20mg, 40mg & 80mg.
USP Specs.

MECHANISM OF ACTION: Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. There is also an AT_2 receptor found in many tissues, but AT_2 is not known to be associated with cardiovascular homeostasis. Telmisartan has much greater affinity (>3,000 fold) for the AT_1 receptor than for the AT_2 receptor. Blockade of the renin-angiotensin system with ACE inhibitors, which inhibit the biosynthesis of angiotensin II from angiotensin I, is widely used in the treatment of hypertension. ACE inhibitors also inhibit the degradation of bradykinin, a reaction also catalyzed by ACE. Because Telmisartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Whether this difference has clinical relevance is not yet known. Telmisartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation. Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increased plasma renin activity and angiotensin II circulating levels do not overcome the effect of Telmisartan on blood pressure.

PHARMACOKINETICS: Telmisartan is rapidly absorbed from the gastrointestinal tract; the absolute oral bioavailability is dose-dependent and is about 42% following a 40mg dose and 58% following a 160mg dose. Peak plasma concentrations of Telmisartan are reached about 0.5 to 1 hour after an oral dose. Telmisartan is over 99% bound to plasma proteins. It is excreted almost entirely in the faeces via bile, mainly as unchanged drug. The terminal elimination half-life of Telmisartan is about 24 hours.

INDICATIONS: Normisar (Telmisartan) is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

DOSAGE & ADMINISTRATION: Adults: Dosage must be individualized. The usual starting dose of Normisar (Telmisartan) tablets is 40mg once a day. Blood pressure response is dose related over the range of 20-80mg.
Renal impairment: In patients with severe renal impairment or haemodialysis a lower starting dose of 20mg is recommended.
Hepatic impairment: In patients with mild to moderate hepatic impairment the dose should not exceed 40mg once daily.
Elderly: No dosing adjustment is necessary.
Children and adolescents: Normisar (Telmisartan) is not recommended for children and adolescents up to 18 years.

CONTRA-INDICATION: Telmisartan is contra-indicated in patients who are hypersensitive to any component of this product.

DRUG INTERACTIONS:
Digoxin: When Telmisartan was co-administered with digoxin, median increase in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed.
Warfarin: Telmisartan administered for 10 days slightly decreased the mean warfarin trough plasma concentration.
Other Drugs: Co-administration of Telmisartan did not result in a clinically significant interaction with acetaminophen, amlodipine, glibenclamide, simvastatin, hydrochlorothiazide or ibuprofen. Telmisartan is not metabolized by the cytochrome P450 system and had no effects in vitro on cytochrome P450 enzymes, except for some inhibition of CYP2C19. Telmisartan is not expected to interact with drugs that inhibit cytochrome P450 enzymes; it is also not expected to interact with drugs metabolized by cytochrome P450 enzymes, except for possible inhibition of the metabolism of drugs metabolized by CYP2C19.

PREGNANCY: Telmisartan have been found to cause fetal and neonatal toxicity and death when taken by pregnant women. Pregnant mothers should discontinue use of Telmisartan as soon as they know they are pregnant.

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NURSING MOTHERS: It is not known if Telmisartan is secreted into milk. Since most medicines are secreted into breast milk, potential risks and benefits need to be assessed in women who are nursing to determine if breast feeding or Telmisartan need to be discontinued.

PRECAUTIONS: Telmisartan should be used with caution in patients with renal artery stenosis. Telmisartan is excreted in urine and in bile and reduced doses, may therefore be required in patients with renal impairment and should be considered in patients with hepatic impairment or biliary obstruction. Patients with volume depletion (for example those who have received high dose diuretic therapy) may experience hypotension; volume depletion should be corrected before starting therapy, or a low initial dose should be used. Since hyperkalemia may occur, serum potassium concentrations should be monitored, especially in the elderly and patients with renal impairment, and the concomitant use of potassium sparing diuretics should generally be avoided.

ADVERSE EFFECTS: Adverse effects of Telmisartan have been reported to be usually mild and transient, and include dizziness, headache and dose related orthostatic hypotension. Hypotension may occur particularly in patients with volume depletion (for example those who have received high dose diuretics). Impaired renal function and, rarely, rash, urticaria, pruritus, angioedema, and raised liver enzyme values may occur. Hyperkalemia, myalgia and arthralgia have been reported. Telmisartan appears less likely than ACE inhibitors to cause cough. Other adverse effects that have been reported wtih angiotensin II receptor antagonists include respiratory tract disorders, back pain, gastrointestinal disturbances, fatigue and neutropenia.

INSTRUCTIONS: Store below 30°C. Protect from heat, light & moisture. Keep out of the reach of children.

AVAILABILITY:
Normisar (Telmisartan) 20mg tablets are available in Alu Alu blister pack of 10'sx1 tablets.
Normisar (Telmisartan) 40mg tablets are available in Alu Alu blister pack of 10'sx1 tablets.
Normisar (Telmisartan) 80mg tablets are available in Alu Alu blister pack of 10'sx1 tablets.

نورمی سار گولیاں

(ٹیلمیسارٹن)

اجزائے ترکیب: نورمی سار کی ہر فلم کوٹڈ گولی میں ۲۰ ملی گرام، ۴۰ ملی گرام یا ۸۰ ملی گرام ٹیلمیسارٹن موجود ہے۔

علامات: نورمی سار (ٹیلمیسارٹن) بلند فشارِ خون میں استعمال کی جاتی ہے۔ نورمی سار کو دوسری دافع بلند فشارِ خون دوائیوں کے ساتھ بھی استعمال کیا جا سکتا ہے۔

خوراک: عمومی ابتدائی خوراک ۴۰ ملی گرام ایک مرتبہ روزانہ ہے مریض پر دوائی کے اثرات کے مطابق خوراک ۲۰ ملی گرام سے ۸۰ ملی گرام تک تجویز کی جا سکتی ہے۔ ناقص جگر کی کارکردگی والے مریضوں کو ۴۰ ملی گرام سے تجاوز کردہ خوراک نہیں دینی چاہیے۔ ناقص گردوں کی کارکردگی والے مریضوں کو ۲۰ ملی گرام کی خوراک تجویز کی جاتی ہے۔

ممانعت: دوا کے کسی جزو سے حساسیت۔

دورانِ حمل اور رضاعت: دورانِ حمل ٹیلمیسارٹن تجویز نہیں کی جاتی۔ دودھ پلانے والی مائیں دوا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

بچوں میں دوا کا استعمال ممنوع ہے۔

ہدایات: ۳۰° ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: نورمی سار (ٹیلمیسارٹن) ۲۰ ملی گرام گولیاں ۱۰ گولیوں کے ایلو ایلو بلسٹر پیک میں دستیاب ہیں۔
نورمی سار (ٹیلمیسارٹن) ۴۰ ملی گرام گولیاں ۱۰ گولیوں کے ایلو ایلو بلسٹر پیک میں دستیاب ہیں۔
نورمی سار (ٹیلمیسارٹن) ۸۰ ملی گرام گولیاں ۱۰ گولیوں کے ایلو ایلو بلسٹر پیک میں دستیاب ہیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area,
Karachi-Pakistan.
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