Non-steroidal anti-inflammatory medicinal products
NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the diuretic, natriuretic and antihypertensive effects of thiazide diuretics and the antihypertensive effects of Angiotensin II receptor antagonists. In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function) the co-administration of Angiotensin II receptor antagonists and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.

Pressor amines (e.g. noradrenaline)
The effect of pressor amines may be decreased.

Nondepolarizing skeletal muscle relaxants (e.g. tubocurarine)
The effect of nondepolarizing skeletal muscle relaxants may be potentiated by hydrochlorothiazide.

Medicinal products used in the treatment for gout (e.g. probenecid, sulfinpyrazone and allopurinol)
Dosage adjustment of uricosuric medications may be necessary as hydrochlorothiazide may raise the level of serum uric acid. Increase in dosage of probenecid or sulfinpyrazone may be necessary. Co-administration of thiazide may increase the incidence of hypersensitivity reactions of allopurinol.

Calcium salts
Thiazide diuretics may increase serum calcium levels due to the decreased excretion. If calcium supplements or calcium sparing medicinal products (e.g. vitamin D therapy) must be prescribed, serum calcium levels should be monitored and calcium dosage adjusted accordingly.

Beta-blockers and diazoxide
The hyperglycemic effect of beta-blockers and diazoxide may be enhanced by thiazides.

Anticholinergic agents (e.g. atropine, biperiden)
The bioavailability of thiazide-type diuretics may be increased by decreasing gastrointestinal motility and stomach emptying rate.

Amantadine
Thiazides may increase the risk of adverse effects caused by amantadine.

Cytotoxic agents (e.g. cyclophosphamide, methotrexate)
Thiazides may reduce the renal excretion of cytotoxic medicinal products and potentiate their myelosuppressive effects. Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensives including Telmisartan: Baclofen, amifostine.
Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants.

Statement on Usage during Pregnancy and Lactation

Pregnancy
The use of angiotensin II receptor antagonists is not recommended during the first trimester of pregnancy. The use of angiotensin II receptor antagonists is contraindicated during the second and third trimesters of pregnancy.
There are no adequate data from the use of TELSTRAN PLUS® in pregnant women. Studies in animals have shown reproductive toxicity.

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive; however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of drugs. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of re function and skull is recommended.

Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension.

There is limited experience with hydrochlorothiazide during pregnancy, especially during the first trimester. Animal studies are insufficient. Hydrochlorothiazide crosses the placenta. Based on the pharmacological mechanism of action of hydrochlorothiazide its use during the second and third trimester may compromise foeto-placental perfusion and may cause foetal and neonatal effects like icterus, disturbance of electrolyte balance and thrombocytopenia.

Hydrochlorothiazide should not be used for gestational oedema, gestational hypertension or preeclampsia due to the risk of decreased plasma volume and placental hypoperfusion, without a beneficial effect on the course of the disease.

Hydrochlorothiazide should not be used for essential hypertension in pregnant women except in rare situations where no other treatment could be used.

Breast-feeding
Because no information is available regarding the use of TELSTRAN PLUS® during breast-feeding, it is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant. Hydrochlorothiazide is excreted in human milk in small amounts. Thiazides in high doses causing intense diuresis can inhibit the milk production. The use of TELSTRAN PLUS® during breast feeding is not recommended. If it is required to be used during breast feeding, doses should be kept as low as possible.

Side Effects/ Adverse Reactions:
Summary of the safety profile
The most commonly reported adverse reaction is dizziness. Serious angioedema may occur rarely.
Tabulated list of adverse reactions
Adverse reactions reported in all clinical trials and occurring more frequently with telmisartan plus hydrochlorothiazide than with placebo are shown below according to system organ class. Adverse reactions known to occur with each component given singly but which have not been seen in clinical trials may occur during treatment with Telmisartan/Hydrochlorothiazide.
Adverse reactions have been ranked under headings of frequency using the following convention: very common ; common; uncommon; rare; very rare, not known.
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Infections and infestations
Rare: Bronchitis, pharyngitis, sinusitis
Immune system disorders
Rare: Exacerbation or activation of systemic lupus erythematosus
Metabolism and nutrition disorders
Uncommon: Hypokalaemia
Rare: Hyperuricaemia, hyponatraemia
Psychiatric disorders
Uncommon: Anxiety
Rare: Depression
Nervous system disorders
Common: Dizziness
Uncommon: Syncope, paraesthesia
Rare: Insomnia, sleep disorders
Eye disorders
Rare: Visual disturbance, vision blurred
Ear and labyrinth disorders
Uncommon: Vertigo
Cardiac disorders
Uncommon: Tachycardia, arrhythmias
Vascular disorders
Uncommon: Hypotension, orthostatic hypotension
Respiratory, thoracic and mediastinal disorders
Uncommon: Dyspnoea
Rare: Respiratory distress (including pneumonitis and pulmonary oedema)
Gastrointestinal disorders
Uncommon: Diarrhoea, dry mouth, flatulence
Rare: Abdominal pain, constipation, dyspepsia, vomiting, gastritis
Hepatobiliary disorders
Rare: Abnormal hepatic function/liver disorder
Skin and subcutaneous tissue disorders
Rare: Angioedema (also with fatal outcome), erythema, pruritus, rash, hyperhidrosis, urticaria
Muscoloskeletal, connective tissue and bone disorders
Uncommon: Back pain, muscle spasms, myalgia
Rare: Arthralgia, muscle cramps, pain in limb
Reproductive system and breast disorders
Uncommon: Erectile dysfunction
General disorders and administration site conditions
Uncommon: Chest pain
Rare: Influenza-like illness, pain
Investigations
Uncommon: Blood uric acid increased
Rare: Blood creatinine increased, blood creatine phosphokinase increased, hepatic enzyme increased

For further description, please see sub-section "Description of selected adverse reactions"

Additional information on individual components

Adverse reactions previously reported with one of the individual components may be potential adverse reactions with Telmisartan/Hydrochlorothiazide, even if not observed in clinical trials with this product.

Telmisartan:
Adverse reactions occurred with similar frequency in placebo and telmisartan treated patients.
The overall incidence of adverse reactions reported with telmisartan was usually comparable to placebo in placebo controlled trials. The following adverse reactions listed below have been accumulated from all clinical trials in patients treated with telmisartan for hypertension or in patients 50 years or older at high risk of cardiovascular events.

Infections and infestations
Uncommon: Upper respiratory tract infection, urinary tract infection including cystitis
Rare: Sepsis including fatal outcome
Blood and lymphatic system disorders
Uncommon: Anaemia
Rare: Eosinophilia, thrombocytopenia
Immune system disorders
Rare: Hypersensitivity, anaphylactic reactions
Metabolism and nutrition disorders
Uncommon: Hyperkalaemia
Rare: Hypoglycaemia (in diabetic patients)
Cardiac disorders
Uncommon:Bradycardia

Nervous system disorders
Rare: Somnolence
Respiratory, thoracic and mediastinal disorders
Uncommon: Cough
Very rare: Interstitial lung disease
Gastrointestinal disorders
Rare: Stomach discomfort
Skin and subcutaneous tissue disorders
Rare: Eczema, drug eruption, toxic skin eruption
Musculoskeletal, connective tissue and bone disorders
Rare: Arthrosis, tendon pain
Renal and urinary disorders
Uncommon: Renal impairment (including acute renal failure)
General disorders and administration site conditions
Uncommon: Asthenia
Investigations
Rare: Haemoglobin decreased
For further description, please see sub-section *"Description of selected adverse reactions"*

Hydrochlorothiazide:
Hydrochlorothiazide may cause or exacerbate hypovolaemia which could lead to electrolyte imbalance.
Adverse reactions of unknown frequency reported with the use of hydrochlorothiazide alone include:
Respiratory, thoracic and mediastinal disorders
Frequency 'very rare': Acute respiratory distress syndrome (ARDS)
Infections and infestations
Not known: Sialadenitis
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Not known: Non-melanoma skin cancer (Basal cell carcinoma and Squamous cell carcinoma)
Blood and lymphatic system disorders
Rare: Thrombocytopenia (sometimes with purpura)
Not known: Aplastic anaemia, haemolytic anaemia, bone marrow failure, leukopenia, neutropenia, agranulocytosis

Immune system disorders
Not known: Anaphylactic reactions, hypersensitivity
Endocrine disorders
Not known: Diabetes mellitus inadequate control
Metabolism and nutrition disorders
Common: Hypomagnesaemia
Rare: Hypercalcaemia
Very rare: Hypochloraemic alkalosis
Not known: Anorexia, appetite decreased, electrolyte imbalance, hypercholesterolaemia, hyperglycaemia, hypovolaemia
Psychiatric disorders
Not known: Restlessness
Nervous system disorders
Rare: Headache
Not known: Light-headedness
Eye disorders
Not known Xanthopsia, acute myopia, acute angle-closure glaucoma, choroidal effusion
Vascular disorders
Not known: Vasculitis necrotizing
Gastrointestinal disorders
Common: Nausea
Not known: Pancreatitis, stomach discomfort
Hepatobiliary disorders
Not known: Jaundice hepatocellular, jaundice cholestatic
Skin and subcutaneous tissue disorders
Not known: Lupus-like syndrome, photosensitivity reactions, skin vasculitis, toxic epidermal necrolysis, erythema multiforme
Musculoskeletal, connective tissue and bone disorders
Not known: Weakness
Renal and urinary disorders
Not known: Nephritis interstitial, renal dysfunction, glycosuria
General disorders and administration site conditions
Not known: Pyrexia
Investigations
Not known: Triglycerides increased
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Not known Skin and lip cancer (Non-melanoma skin cancer)

Description of selected adverse reactions
Hepatic function abnormal / liver disorder:
Most cases of hepatic function abnormal / liver disorder from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience these adverse reactions.

Sepsis:
An increased incidence of sepsis was observed with telmisartan compared with placebo. The event may be a chance finding or related to a mechanism currently not known.

Interstitial lung disease:
Cases of interstitial lung disease have been reported from post-marketing experience in temporal association with the intake of telmisartan. However, a causal relationship has not been established.
Neoplasms benign, malignant and unspecified (incl cysts and polyps): Frequency not known: non melanoma skin cancer (Basal cell carcinoma and Squamous cell carcinoma)

Non-melanoma skin cancer:
Based on available data from epidemiological studies, cumulative dose-dependant association between HCTZ and NMSC has been observed.

Signs & Symptoms of overdose and Treatment
There is limited information available for Telmisartan with regard to overdose in humans. The degree to which hydrochlorothiazide is removed by hemodialysis has not been established.

Symptoms
The most prominent manifestations of Telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, vomiting, increase in serum creatinine, and acute renal failure have also been reported. Overdose with hydrochlorothiazide is associated with electrolyte depletion (hypokalaemia, hypochloraemia) and hypovolaemia resulting from excessive diuresis. The most common signs and symptoms of overdose are nausea and somnolence.
Hypokalaemia may result in muscle spasms and/or accentuate arrhythmia associated with the concomitant use of digitalis glycosides or certain anti-arrhythmic medicinal products.

Treatment
Telmisartan is not removed by hemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms.
Suggested measures include induction of emesis and/or gastric lavage. Activated charcoal may be useful in the treatment of overdose. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacements given quickly.

Storage Conditions
Do not store above 30ºC.
Store in the original package in order to protect from moisture.

Shelf Life
36 months

Dosage forms and packaging available
TELSTRAN PLUS® tablets are available in Alu-Alu blister pack of 10 Tablets. Each printed carton contains 3 such blisters. (3 X 10 Tablets).

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