Accurate Clinic
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www.AccurateClinic.com

Metanx® Tablets

Metanx® is an orally administered prescription medical food for the dietary management of patients with diabetic peripheral neuropathy.

Each round coated purple colored tablet contains**:**

Active Ingredients:

L-methylfolate Calcium (as Metafolin®)* 3 mg
Pyridoxal 5'-phosphate 35 mg
Methylcobalamin 2 mg

***Inactive ingredie*nts:**
Dibasic Calcium Phosphate Dihydrate, Microcrystalline Cellulose 90, Microcrystalline Cellulose HD 90, Pyridoxal-5'-Phosphate, Opadry II Purple 40L10045 (Polydextrose, Titanium Dioxide, Hypromellose 3cP, Hypromellose 6cP, Glycerol Triacetate, Hypromellose 50cP, FD&C Blue #2, FD&C Red #40, Polyglycol 800), Microcrystalline Cellulose 50, Opadry II Clear Y-19-7483 (Hypromellose 6cP, Maltodextrin, Hypromellose 3cP, Polyglycol 400, Hypromellose 50cP), L-methylfolate Calcium, Magnesium Stearate, Methylcobalamin, and Carnauba Wax.
Metanx® tablets do not contain sugar, lactose, yeast or glut**en.**

Metafolin® (L-methylfolate calcium) is a substantially diastereoisomerically pure source of L-methylfolate containing not more than 1% D-methylfolate which results in not more than 0.03 milligrams of D-methylfolate in Metanx®.

D-methylfolate or 6(R)-5-methyltetrahydrofolate [6(R)-5-MTHF] is the other diastereoisomer of folate. Studies administering doses of 2.5 mg per day or higher resulted in plasma protein binding of D-methylfolate higher than L-methylfolate causing a significantly higher renal clearance of L-methylfolate when compared to D-methylfolate.8 Further, D-methylfolate is found to be stored in tissues in the body, mainly in the liver. D-methylfolate is not metabolized by the body and has been hypothesized to inhibit regulatory enzymes related to folate and homocysteine metabolism and reduces the bioavailability of L-methylfo*late.9*

***Pyridoxal-5'-phospha*te (PLP)** is the active form of vitamin B6 and is used as the prosthetic group for many of the enzymes where this vitamin is involved. PLP is readily absorbed by the intestine by a process which is preceded by dephosphorylation to form pyridoxal. The phosphate group is regained during passage through the intestine. Pyridoxine, the parent compound of PLP and the most frequently used form of vitamin B6, requires reduction and phosphorylation before becoming biologically active. The PLP in Metanx® contains 25mg of pyridoxal (the active component o*f PLP).*

***Methylcobalamin** (Me*thyl-B12) is one of the two forms of biologically active vitamin B12. Methyl-B12 is the principal form of circulating vitamin B12, hence the form which is transported into peripheral tissue. Methyl-B12 is absorbed by the intestine by a specific mechanism which uses the intrinsic factor and by a diffusion process in which approximately 1% of the ingested dose is absorbed. Cyanocobalamin and hydroxycobalamin are forms of the vitamin that require conversion to methylco**balamin.**

INDICATION AND USAGE
Metanx® tablets are indicated for patients with loss of protective sensation and neuropathic pain associated with diabetic peripheral neuropathy.

Metanx® tablets are indicated for patients with lower extremity ulceration(s).

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DOSAGE AND ADMINISTRATION
The recommended dose is one tablet twice daily (B.I.D.) or as directed.
Metanx® must be used under medical supervision.

CONTRAINDICATIONS
There have been rare reports of hypersensitivity (allergic-like reactions) to Metanx®. Therefore, a known hypersensitivity to any of the components in the product is a contraindication to its use for any indication.

PRECAUTIONS
General:
Folic acid, when administered as a single agent in doses above 0.1mg daily, may obscure the detection of B12 deficiency (specifically, the administration of folic acid my reverse the hematological manifestations of B12 deficiency, including pernicious anemia, while not addressing the neurological manifestations). L-methylfolate may be less likely than folic acid to mask vitamin B12 deficiency.22,23 Folate therapy alone is inadequate for the treatment of a **B12 deficiency.**

DRUG INTERACTIONS
Metanx® added to other Drugs: High dose folic acid may result in decreased serum levels for pyrimethamine and first generation anticonvulsants (carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, valproic acid, valproate).25,26 This may possibly reduce first generation anticonvulsants effectiveness and/or increasing the frequency of seizures in susceptible patients.25,26 While the concurrent use of folic acid and first generation anticonvulsants or pyrimethamine may result in decreased efficacy of anticonvulsants, no such decreased effectiveness has been reported with the use of L-methylfolate. Nevertheless, caution should be used when prescribing Metanx® among patients who are receiving treatment with first generation anticonvulsants or pyrimethamine. Pyridoxal 5'-phosphate should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxal 5'-phosphate. However, pyridoxal 5'-phosphate may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Capecitabine (Xeloda®) toxicity may increase with the addition of leucovorin (5-formyltetrahydr***ofolate) (folate).***

Drugs added to Metanx®: Antibiotics may alter the intestinal microflora and may decrease the absorption of methylcobalamin. Cholestyramine, colchicines or colestipol may decrease the enterohepatic re-absorption of methylcobalamin. Metformin, para-aminosalicylic acid and potassium chloride may decrease the absorption of methylcobalamin. Nitrous oxide can produce a functional methylcobalamin deficiency. Several drugs are associated with lowering serum folate levels or reducing the amount of active folate available. First generation anticonvulsants (carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone, valproic acid, valproate)25,26 and lamotrigine27 (a second-generation anticonvulsant) may decrease folate plasma levels. Information on other second-generation anticonvulsants impact on folate levels is limited and cannot be ruled out. Diavalproex sodium28, topiramate29, gabapentin30, pregabalin31, levetiracetam32, tiagabine33, zonisamide34, have not reported the potential to lower folate in their respective prescribing information. Methotrexate, alcohol (in excess), sulfasalazine, cholestyramine, colchicine, colestipol, L-dopa, methylprednisone, NSAIDs (high dose), pancreatic enzymes (pancrelipase, pancratin), pentamidine, pyrimethamine, smoking, triamterene, and trimethoprim may decrease folate plasma levels. Warfarin can produce significant impairment in folate status after **a 6-month therapy**.

ADVERSE REACTIONS
While allergic sensitization has been reported following both oral and parenteral administration of folic acid, allergic sensitization has not been reported with the use of Metafolin®. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxal 5'-phosphate. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated w**ith methylcobalamin.**

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