Hydrotalcite

Agreed Core Safety Profile

4.3 CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients

- Serious renal impairment

- hypophosphatemia

- myasthenia gravis

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

In patients with impaired renal function (particularly patients on hemodialysis), in patients with M. Alzheimer or other forms of dementia, and in patients with hypophosphataemia or on a low-phosphate diet, high doses and long-term exposure should be avoided.

Hydrotalcite must not be taken simultaneously with acid-containing food (vine, fruit juice,…) because of increased intestinal resorption of aluminium hydroxide.

Talcid® 500 mg chewable pastilles

Contains 1.7 g of glucose and 1.1 g of sucrose per pastille. This should be taken into account in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsortion or sucrose-isomaltase insufficiency should not take this medicine.

4.5 INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

Hydrotalcite must not be taken simultaneously with drugs whose absorption may be affected when co-administered (i.e. glycosides, tetracyclines or quinolone derivatives like ofloxacin and ciprofloxacin, H_2 receptor blocking agents, coumarine derivates, natrium fluoride, chenodesoxy-cholate).

Generally other drugs should be administered at least 1-2 hours before or after the intake of Talcid®.

4.6 PREGNANCY AND LACTATION

As with any drug the advice of a physician should be sought if pregnant or nursing a baby. Whereas pharmacokinetic studies have shown that aluminium blood levels remain in the normal range, Talcid® should be used only for short periods of time during pregnancy to minimize potential aluminium exposure of the unborn child.

Generally, aluminium containing substances are excreted into the breast milk. There are no data available on the excretion of Talcid® into breast milk, however, due to low enteral resorption in the mother and child, no health risks must be expected for the newborn.

4.7 ABILITY TO DRIVE AND USE MACHINES:

No effects on ability to drive and use machines have been observed.

4.8 UNDESIRABLE EFFECTS

Gastrointestinal disorders: At high doses soft stools, increased stool frequency, vomiting, diarrhoea,

Investigation: decreased serum phosphor-levels, hypermagnesiemia

Immun system disorders: allergic reaction

Long-term treatment in patients with renal impairment can lead to aluminium intoxication with osteomalacia and encephalopathy.

4.9 OVERDOSE

No cases of overdose with hydrotalcite have been reported.