Clinical Studies on Liv.52®

Liver/Hepatitis

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Chauhan and Kulkarni, 1991	Alcoholic liver disease	PC n=25	2 weeks	Two, 250 mg tablets, 2 times/day	Liv.52® tablets or placebo	The study was divided into 2 groups. Group A : (8 patients) measured ethanol absorption by comparing blood samples. Liv.52® treatment produced a marked increase in ethanol absorption vs. placebo in moderate drinkers, with no effect on occasional drinkers. Group B measured ethanol metabolism (9 moderate, 8 occasional drinkers), and found that Liv.52® reversed the effect of low blood ethanol and high acetaldehyde seen in heavy alcohol users. The study concluded that improved acetaldehyde elimination from the use of Liv.52® may reduce the harmful effect of ethanol on the liver and potentially the brain.
Mandal and Roy, 1983	Infective hepatitis (Group A), chronic active hepatitis (Group B) and cirrhosis (Group C)	DB, PC n=104 (Group A:30 treatment, 15 control; Group B: 24, 8; Group C: 19, 8)	Group A: 6 weeks; Group B: 12 months; Group C: 24 months	Four, 250 mg tablets, 3 times/day	Liv.52® tablets or placebo	Group A: patients with infective hepatitis showed a marked symptomatic improvement with Liv.52®, with lowered levels of serum bilirubin and alkaline phosphatase twice as quickly compared to control. Group B: patients with chronic active hepatitis demonstrated an immediate, significant drop in serum alkaline phosphatase, from 35 units (King-Armstrong or KA) to less than 10 within 12 months. Control group dropped from 35 to 25 units. Group C: 4 patients with cirrhosis showed clinical improvement in 12 months, 10 patients improved in 24 months compared to no improvement in control. Drop in serum alkaline phosphatase to 14 KA in 24 months vs. increase in control. Greater excretion of BSP in 80% of the treated group versus 20% in the control group. Histopathological examination revealed improvements in 4 cases and no progress in fibrosis in other treated cases versus fibrosis progression in control.
Saxena *et al*., 1980	Infective hepatitis	PC n=30	5 weeks	15 drops: 0–1 yr 2 tsp syrup: 1–3 yrs 2, 250 mg tablets: above 3 yrs, 3xday	Liv.52® drops, syrup, liquid, or tablets	Significant improvement observed after one week, with a reduction in symptoms compared to placebo at the end of the second week. Liver function tests returned to normal more quickly than with placebo.
Patney and Kumar, 1978	Serum B-hepatitis (Australian Antigen Positive)	PC n=20	6 months	6 tablets/day	Liv.52® tablets	Hematology studies indicated that Liv.52®, combined with steroids and other supportive therapy, significantly improved symptoms and sped up recovery time.
Singh *et al*., 1977	Infective hepatitis	PC n=50	8 weeks	6 tablets/day	Liv.52® tablets with B-complex and cortico-steroids vs. control of B-complex and cortico-steroids	Subjects with Liv.52® experienced symptom relief in 1/2 the time compared to control. Liver function tests showed improvement in both groups.
Sama *et al*., 1976	Infective hepatitis	R, DB, PC n=34	6 weeks with a 3-month follow-up	Six, 250 mg tablets/day	Liv.52® tablets	Subjects treated with Liv.52® showed a quicker clinical recovery and a 50% drop in bilrubin. The placebo group had a higher weight loss.

KEY: C – controlled, **CC** – case-control, **CH** – cohort, **CI** – confidence interval, **Cm** – comparison, **CO** – crossover, **CS** – cross-sectional, **DB** – double-blind, **E** – epidemiological, **LC** – longitudinal cohort, **MA** – meta-analysis, **MC** – multi-center, **n** – number of patients, **O** – open, **OB** – observational, **OL** – open label, **OR** – odds ratio, **P** – prospective, **PB** – patient-blind, **PC** – placebo-controlled, **PG** – parallel group, **PS** – pilot study, **R** – randomized, **RC** – reference-controlled, **RCS** – retrospective cross-sectional, **RS** - retrospective, **S** – surveillance, **SB** – single-blind, **SC** – single-center, **U** – uncontrolled, **UP** – unpublished, **VC** – vehicle-controlled.