



Product Monograph

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Introduction:

The liver is a vital organ located in the upper right-hand side of the abdomen. It is as large as a football, weighs 3 pounds, and performs numerous functions for the body:

Converting nutrients derived from food into essential blood components, Storing vitamins and minerals,

Regulating blood clotting, Producing proteins and enzymes, Maintaining hormone balances, and

Makes bile, which is essential for digestion.

Metabolizing and detoxifying substances that would otherwise be harmful to the body.

Liver disease is categorized both by the cause and the effect it has on the liver. Causes may include infection, injury, and exposure to drugs or toxic compounds, an autoimmune process.

Epidemiology of liver problems:

It is estimated that liver diseases are among the top ten killer diseases in India, causing lakhs of deaths every year.

Nearly 20 per cent of the people in Southeast Asia are carriers of hepatitis B, one of the deadliest diseases of modern times.

In India, 4-4.75 per cent carry this virus.

Hepatitis B is one of the world's most common and serious infectious diseases.



Hepatitis B affects 2 billion people worldwide.

More than 350 million people have chronic or lifelong hepatitis B infections.

Hepatitis B virus causes a life-threatening liver infection that often leads to chronic liver disease and puts people at high risk of death from cirrhosis of the liver and liver cancer. Hepatitis B virus infection is a major global health problem. Worldwide, an estimated two billion people have been infected with the hepatitis B virus (HBV), and more than 350 million have chronic (long-term) liver infections. At least 15-25% of chronically HBV infected people will die due to liver disease caused by HBV and this constitutes nearly one million people each year. It is the most common cause of chronic liver disease

An effective vaccine is available for over two decades and has brought about remarkable changes in the global epidemiology of HBV infection.

alcohol consumption is steadily increasing among the Indian population, especially among the younger generation. Excessive drinking can lead to liver damage, involve other organs and could even be fatal.

Excessive consumption of alcohol can cause an acute or chronic inflammation of the liver and may even harm other organs in the body.

In India, even though there is a greater incidence of cirrhosis of the liver due to viral and other infectious types of hepatitis, alcohol induced liver disease remains a major problem.

The amount of alcohol that can cause liver damage seems to vary from person to person. But the following points are proven: A person may be genetically susceptible to the harmful effects of alcohol.

Women are more sensitive to the harmful effects of alcohol than men. Daily drinking is definitely more harmful than only drinking occasionally or at weekends.

There is clear evidence that the risk of developing Alcoholic Liver Disease increases proportionately with the amount of alcohol intake.

Alcoholic Liver Disease may progress in three stages, but the way in which the liver is affected may vary from person to person. The doctor can study this progress by studying a biopsy of the liver tissue.

8. Fatty liver with minimal changes: Heavy drinkers often develop fatty change in the liver. This may not be linked to deterioration in liver function, but abnormalities may be seen in Liver Function Tests (LFT's). If a person stops drinking alcohol, fatty liver changes may be reversed. Otherwise this can be considered as the first stage in the progression towards Cirrhosis of the Liver.



9. Alcoholic Hepatitis: This stage could be anything from mild to life threatening. The LFT's will almost always be abnormal, and the patient may develop jaundice. Just as with fatty liver changes, abstinence from alcohol can reverse the effects, but people who continue to drink heavily even after this stage are at high risk of developing cirrhosis.

10. Cirrhosis: This is the final, irreversible stage of Alcoholic Liver Disease. It is characterized by scarring of the liver and development of liver nodules. It severely affects liver function and reduces life expectancy. The LFT's are usually abnormal. There may be jaundice (yellow coloring of the eyes and skin) and sometimes bruising or bleeding caused by abnormalities of the blood clotting system. Complications of so-called 'decompensated cirrhosis' may develop (see below).

Medications & their limitations:

Allopathic medicines such as Interferons (IFNs) & Lamivudine have many limitations:

Treatment of hepatitis B carriers is expensive. An injection of Interferon costs Rs 6,000 and the patients have to take these every week for at least a year. Another option is Lamivudine tablet and a single one costs Rs 30. The treatment may go beyond five years. The efficacy is between 30-40 per cent and the treatment is reported to have many side effects.

An Indian medicine for hepatitis B; www.vaccinationnews.com, Shobha Warriar - Chennai

Side effects from drug therapy include

- Severe flu like symptoms insomnia,
- Anemia
- Decreased platelet counts Extreme fatigue, Anxiety,
- Irritability and Depression.
- A small percentage of people may experience psychosis or suicidal behavior.

Chronic side effects, which affect about half of those receiving treatment with interferon-ribavirin, include

- Extreme fatigue,
- Anxiety,
- Irritability and



- Depression.
- A small percentage of people may experience psychosis or suicidal behavior.

Interferon is not recommended for people who have:

A history of major depression Untreated thyroid disease, Low blood cell counts Autoimmune disease,

Who drink alcohol & use drugs are also not good candidates for this treatment.

- They are Expensive
- Have to be taken for long duration (1-5 yrs)
- Include many side effects
- Lesser efficacy rate & high recurrence factor
- Recommended among restricted patients only.

Therefore we can see the limitations in hepatic

as said

“A Valuable Tonic”

Composition:

| Sanskrit Name | Botanical Name | 10ml liquid contains (mg) | Each Tablet contains (mg) |
|---------------|--------------------------------|---------------------------|---------------------------|
| BHUMYAMALAKI | <i>Phyllanthus niruri</i> | 500 | 500 |
| GUDUCHI | <i>Tinospora cordifolia</i> | 350 | 150 |
| NIMBA | <i>Azadiracta Indica</i> | 165 | 150 |
| PUNARNAVA | <i>Boerhavia diffusa</i> | 250 | 150 |
| BHRINGARAJA | <i>Eclipta alba</i> | 200 | 150 |
| KATUKI | <i>Picrorhiza kurroa</i> | 165 | 100 |
| KALMEGHA | <i>Andrographis paniculata</i> | 165 | 100 |
| KUMARI GEL | <i>Aloe vera/barbadensis</i> | 100 | 75 |

Comparative study & Clinical reports:

Bhumyamalaki [*Phyllanthus niruri*]

This is a very bitter tasting small shrub that literally means ‘the Amalaki of the earth’ as this very low lying shrub. Leaves resemble the pattern and shape of Amalaki (*Emblica officinalis*).

Bhumyamalaki is a very effective liver remedy



Phyllanthus primarily contains lignans (e.g., phyllanthine and hypophyllanthine), alkaloids, and bioflavonoids (e.g., quercetin). Its action in the liver confirms its historical use as a remedy for jaundice.

In a 30-day double-blind, placebo-controlled trial of 60 people with chronic hepatitis B, treatment with Phyllanthus (200 mg 3 times daily) dramatically increased the odds of full recovery.³ In the treated group, almost 60% were hepatitis B –negative at follow-up, as compared to only 4% in the placebo group.

Thyagarajan SP, Subramanian S, Thirunalasundar T, et al. Effect of Phyllanthus amarus on chronic carriers of hepatitis B virus. *Lancet*. 1988;2:764–766.

Meixa W, Haowei C, Yanjin L, et al. Herbs of the genus Phyllanthus in the treatment of chronic hepatitis B: observation with three preparations from different geographic sites. *J Lab Clin Med* 1995;126: pp.350-2

EFFECT OF PHYLLANTHUS AMARUS ON CHRONIC CARRIERS OF HEPATITIS B VIRUS

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Abstract

In a preliminary study, carriers of hepatitis B virus were treated with a preparation of the plant Phyllanthus amarus for 30 days. 22 of 37 (59%) treated patients had lost hepatitis B surface antigen when tested 15-20 days after the end of the treatment compared with only 1 of 23 (4%) placebo-treated controls. Some subjects have been followed for up to 9 months. In no case has the surface antigen returned. Clinical observation revealed few or no toxic effects. The encouraging results of this preliminary study recommend continued evaluation of this plant and the active principles isolated from it.

Probable mode of action:

Phyllanthus amarus may block the spread (proliferation) of the virus by directly blocking, or preventing, replication of the virus' genetic material.



Efficacy of phyllanthus amarus treatment in acute viral hepatitis A, B and non A non B: an open clinical trial.

Efficacy of Phyllanthus treatment in acute viral hepatitis A, B and non A non B was evaluated by an open clinical trial. At the end of treatment period of 4 weeks with each respective drug regimen, it was seen that both P. amarus and Essentiale brought about significant biochemical and clinical normalcy among the HAV infected patients compared with the control group. In acute HBV group, P. amarus-treated patients recovered faster than the Essentiale-treated group and the controls. Essentiale helped the non-A non-B hepatitis patients to resume biochemical normalcy earlier than the other treatments. It was suggested that P. amarus seemed to accelerate the clearance of hepatitis B surface antigen in 86.9% of convalescing Acute Viral Hepatitis-B cases after 3 months time as against 48.0% in the Essentiale treated group and 50% in the controls.

BIBLIOGRAPHIC CITATION Indian-Journal-of-Virology. 997, 13: 1, 59-64; 12 references

The Chinese published a more recent (2001) study, which compared 30 chronic HBV patients taking a chanca piedra extract to 25 patients taking interferon (IFN-alpha 1B) for three months. Both treatments showed an equal effectiveness of 83%, but the chanca piedra group rated significantly higher in the normalization of liver enzymes (ALT, AG, and SB) and recovery of liver function than the interferon-treated group.

Finally, The Cochran Hepato-Biliary Research Group in Copenhagen reviewed all the HBV published research (22 randomized trials) and published an independent review of

the results. It stated that treatment with "Phyllanthus herb" (they acknowledged the confusion in nomenclature among the species) had "a positive effect on clearance of serum HBsAg" (HBV surface antigen) comparable to interferon and was better than nonspecific treatment or other herbal medicines for HBV and liver enzyme normalization

<http://www.rain-tree.com/chanca.htm>

Katuki - Picrorhiza kurroa

In Ayurveda Picrorhiza kurroa is a reputed remedy for the treatment of liver diseases. The chemical composition of the Picrorhiza has been studied and active constituents are group of iridoid glycosides known as picrosides and kutkosides. Modern clinical studies have confirmed the efficacy and safety of Picrorhiza kurroa for the treatment of liver disease. Most of the studies have shown Picrorhiza kurroa extract (standardized to kutkin content) has potential hepatoprotective activity as compared to placebo.

Kutkin vs. silymarin:

Silymarin is a well-known hepatoprotective agent. Silymarin is a flavonol- lignan mixture obtained from seeds of Silybum marianum. Randomized, controlled trials have proved efficacy of silymarin in liver diseases.



Picrorhiza kurroa, when compared with silymarin, the hepatoprotective effect of Picrorhiza kurroa was found to be similar, or in many cases, superior to the effect of Silybum marianum.

Single herbs have been tried as well. In a double-blind trial of 33 people with acute viral hepatitis, use of the herb Picrorhiza kurroa at a dose of 375 mg three times daily significantly speeded recovery time as compared to placebo.

Vaidya AB, Antarkar DS, Doshi JC, et al. Picrorhiza kurroa(Kutki) Royle ex Benth as a hepatoprotective agent—experimental & clinical studies. J Postgrad Med. 1996;42:105-108.

Picrorhiza's most important use may be in the support of liver health. Scientists think picrorhiza may benefit the liver. Studies suggest that it may actually be able to stimulate the growth and regeneration of damaged liver tissues.

Singh V, et al. Effect of Picroliv on Protein and

Nucleic Acid Synthesis. Indian J Exp Biol.
Jan1992;30(1):68-69.

Nimba – azadirachta indica

Azadirachta indica, a plant used widely in Ayurveda, has been reported to have anti-inflammatory, immunomodulatory and adaptogenic properties.

Tinospora Cordifolia

The hepatoprotective effect of T. Cordifolia has been studied in carbon tetrachloride induced liver damage in rats. While acute damage was enhanced by prior exposure to the drug, it proved effective in the prevention of fibrosis, and in stimulating regeneration of hepatic tissue.

Recently it has been evaluated the effect of aqueous extract of T. cordifolia (powdered stem) administered through oral route in patients with hepatic disorders with evidence of fibrosis & immunosuppression (obstructive jaundice, asymptomatic carriers of hepatitis B antigen & cirrhosis) .in all the three conditions, having different etiologies & pathogenesis, the drug has proven its potential. Oral efficacy of this immunostimulant. Coupled with wide therapeutic range, has provided a new weapon to fight uncontrolled fibrosis in the chronic liver disease and other connective tissue disorders.

Rege et al. (1999)

In hepatitis patients T.cordifolia has shown normalization of the liver function

Prakash S et al., J Res Ayurv Siddha, 1996: 17(1-2): pp 58.



Punarnava – Boerhavia diffusa

Treatment with PUNERNAVA (Boerhaavia diffusa) along with alcohol, showed a significant fall in serum ALT, triglycerides, cholesterol & lipids. In addition to this, significant reduction in tissue levels of lipids supports the finding that it has hepatoprotective activity as alcohol otherwise causes fatty liver.

(Ind. J. Pharmacol.18 (1986), 211-214:23(1991), 264-266)

Andrographis Paniculata – Kalamegh

Andrographis Paniculata Nees (Acanthaceae), the Kalmegh of Ayurveda is an erect The major constituents in andrographis are diterpene lactones known as andrographolides. These bitter constituents are believed to have immune-stimulating, anti-inflammatory, fertility-decreasing, liver-protective, and bile secretion-stimulating actions.

With regards to its liver-protecting abilities, andrographis was studied by scientists working at the Microbiology and Immunology Laboratory, Vidyasagar University in India. The scientists found that andrographolide is able to protect liver cells against alcohol-induced damage. They compared the effects of andrographis with silymarin, a well known herbal liver protector from milk thistle, and found that the two are equally as effective at protecting the liver from the effects of excess alcohol

(J Ethnopharmacol. 2007 Apr 20;111(1):13-21).

Indications:

Beliv Liquid & tablets are useful in Prevention & treatment of

Hepatitis B

Alcoholic liver disease & their complications

GIT problems (loss of appetite)

Recommend as a long-term supplement to restore the functional efficiency of the liver esp in long term diseases & treatments such as cancer, radiation therapy etc

Dosage:

Liquid – adults: 10 ml 2 – 3 times daily; children: 5 ml 2-3 times daily. Tablets - 2 Tablets 2-3 times daily

FAQ's:

Why Beliv?



Beliv is a liver protector with an effective combination of liver herbs used in ayurvedic preparations since ages. All the ingredients have been studied for their efficacy & found to be Safe, Fast, efficient, & Recommended to all above 10 yrs of age. Also it can be used safely for long durations.

Can Beliv be used singly in hepatitis B & Alcoholic liver diseases?

Beliv is a liver protector with an effective combination of liver herbs used in ayurvedic preparations since ages. All the ingredients have been studied & proven for their efficacy & found to be Safe, Fast & efficient in treating Hepatitis B & Alcoholic liver diseases.

Can beliv be used as a co therapy with other medications?

Yes Beliv liver protector can be used as co therapy with other medications such as interferon. To avoid side effects & reduce recurrence factor

How long Beliv should be taken in hepatitis B & alcoholic liver disease

Beliv liver protector should be taken until the traces of hepatitis B & alcoholic liver diseases are completely negative & the liver enzymes in the Liver function test are in normal limits. This may take about 3 months time, after that the patient can go on with the maintenance dose for about 2 months to avoid recurrence.

Is it safe to take Phyllanthus niruri / amarus in large quantity (500mg?)

The usual dose of P. niruri / amarus used in studies is 600 to 900 mg daily.

There are no incidences of P. niruri / amarus being toxic when used at recommended doses. Safety in pregnant or nursing women, or individuals with kidney disease, has not been established, hence has to be avoided among them.

Who are contraindicated for interferon / lamuvudine therapy?

Patients who are suffering from the following are contraindicated for interferon / lamuvudine therapy:

- Major depression
- Untreated thyroid disease,
- Low blood cell counts
- Autoimmune disease,&
- Who drink alcohol & use drugs



Who are contraindicated for Beliv?

Safety in pregnant or nursing women, or individuals with kidney disease, has not been established, hence has to be avoided among them.

Will beliv liver protector help a patient who is continuing alcohol intake?

It is advisable for a patient to discontinue taking alcohol in alcoholic liver diseases. However, it is easy said than done. In those patients who continue taking alcohol the use of Beliv liver protector may help in minimizing the adverse effect due to alcohol.