IIPRD

IP LICENSING & COMMERCIALISATION

HIPATONE®

Plant Extracts Composition for Liver Dysfunction

Patent Application No.: 153/MUM/2011 (NBA Approval awaited)

US Patent No.: US8431167B2

Google patents: https://patents.google.com/patent/US8431167B2/en?oq=8431167

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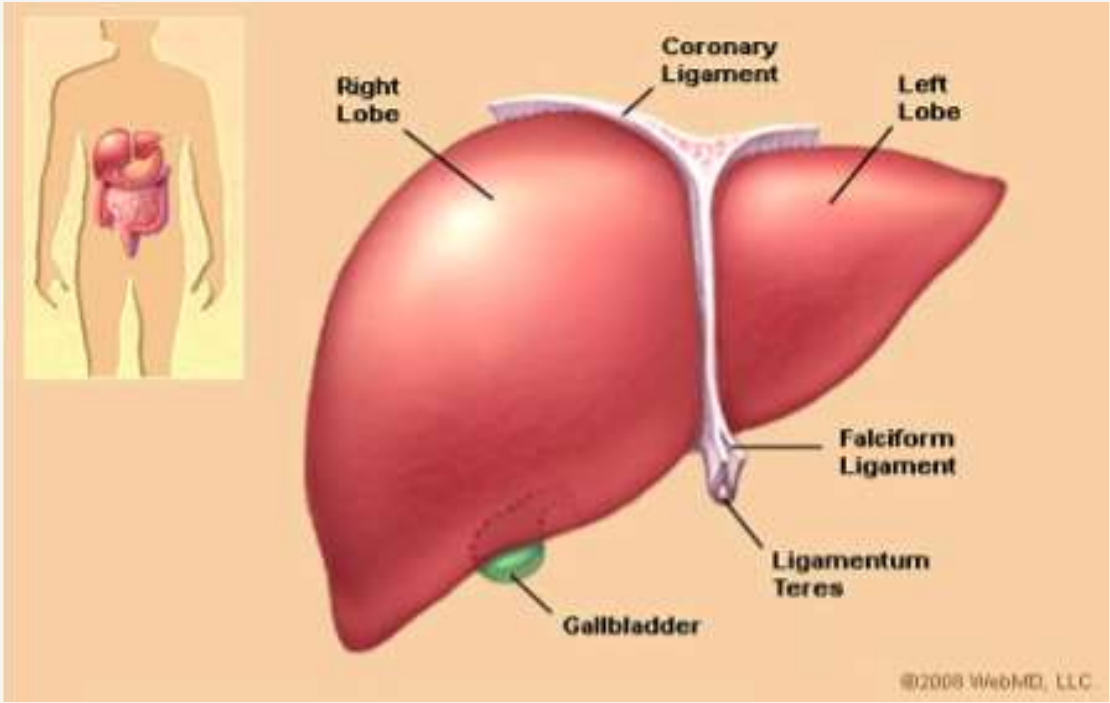
CLINICAL INDICATIONS

LIVER DYSFUNCTION & JAUNDICE

DETOXIFY LIVER THROUGH NATURAL SOURCE OF COMPOUNDS

- The liver is the principal organ that is capable of converting drugs into forms that can be readily eliminated from the body. Given the diversity in use today and the complex burden they impose upon the liver, it is not surprising that a broad spectrum of adverse drug's effects on liver functions and structures has been documented. The reactions range from mild and transient changes in the results of liver function tests to complete liver failure with death of the host. Many drugs may affect the liver adversely in more than one way, as cited below in several listings. The use of the following drugs requires careful monitoring of their effects on the liver during the entire course of treatment
- This list is just a general guideline. Many drugs affect the liver to one degree or another and we can't list all of them here; new drugs are always being approved for general use. “Liver Malfunction-Jaundice” – novel research composition signifies that HIPATONE® is analytically and clinically proven safe and effective.


Coronary
Ligament
Right
Lobe
Left
Lobe
Falciform
Ligament
Ligamentum
Teres
Gallbladder
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PATHOPHYSIOLOGICAL FACTORS

(TARGET OF NEW DRUG) – HYPOTHESIS AND PROGNOSIS (COMPOSITION OF BIOACTIVE COMPOUNDS)

Novel Hepatoprotective Drug Targets Liver Damage: Insights from CCl4-Induced Changes

Hepatoprotective activity by noting its effect on carbon tetrachloride (CC14)-indiced changes in liver cytoarchitecture and alterations in certain biochemical parameters as where transminase activity, lipid constituents of serum and liver, orosomucoid level in serum and liver glycogen, and phospholipids contents, besides, significant changes in the liver cytoarchitecture.

Multi-faceted Compound: Antagonist Activity and Diverse Pharmacological Effects

The compound has been well defined and established as an antagonist activity against genotoxic chemicals, anticlastogenecity in vitro , antimicrobial activity in vitro, anti oxidant activity in vitro, anti inflammatory activity in viva and vitro, prevention of hepatocarciogenesis in vitro and in viva, enhancer of natural killer (NK) cell activity in vitro, inhibition of HIV-1 reverse transcriptase in vitro, prevention of experimental acute pancreatitis, protection against radiation induced chromosome damage in vitro.

PATHOPHYSIOLOGICAL FACTORS

(TARGET OF NEW DRUG) – HYPOTHESIS AND PROGNOSIS (COMPOSITION OF BIOACTIVE COMPOUNDS)

Augmenting T-Cell Response

The selective, antigen specific augmentation of human T-cell response suggests that compound would be promising as an adjunct to chemotherapy or as a short term prophylactic agent- Immunomodulatory effect.

Targeting Cancer Pathways: Suppression of NF-KB and Beyond with Promising Compound

Suppressing nuclear factor kappa beta (NF-KB). Cancer cells often over express NK-KB and use this as a means to proliferate. Hepatone has shown to suppress NK-KB.It further blocks estrogen and estrogen-mimicking chemicals that promote cell mutation and proliferation. Hepatone also inhibits cyclooxigenase (COX) and lipoygebinase (LOX), two enzymes that promote inflammation which play significant role in the development and progression of cell carcinoma and colon cancer. The compound is strong antioxidant and further protects cells against free radicals that promote cancer and cause aging by damaging DNA and activating genes. Destroying abnormal pre-cancereous cells stop certain forms of cancer by inducing ‘aptosis’, a process that identifies cancereous cells and instructs them to self-destruct. Enhancing immunity shown to stimulate both, localized and general immunity cells. Also inhibiting angiogenesis.

ABOUT HIPATONE® & IT'S ROLE THEREOF

ABOUT

Hipatone is a plant extract composition specifically formulated to address liver dysfunction, particularly conditions like jaundice. It is composed of extracts from three key plants: Curcuma longa, Phyllanthus emblica, and Gymnosporea montana, along with additional carriers. The formulation and preparation process of Hipatone aim to provide a safe, natural, and effective solution for liver-related ailments.

- Jaundice Treatment: Hipatone acts as a therapeutic supplement for jaundice, lowering bilirubin levels and relieving symptoms like skin and eye yellowing, itching, and fatigue.
- Liver Detox Support: Hipatone aids natural liver detoxification by helping remove toxins and metabolic waste, promoting liver health and function.
- Hepatitis Adjunctive Therapy: In hepatitis cases, Hipatone complements standard treatments, reducing liver inflammation and safeguarding liver cells from damage.

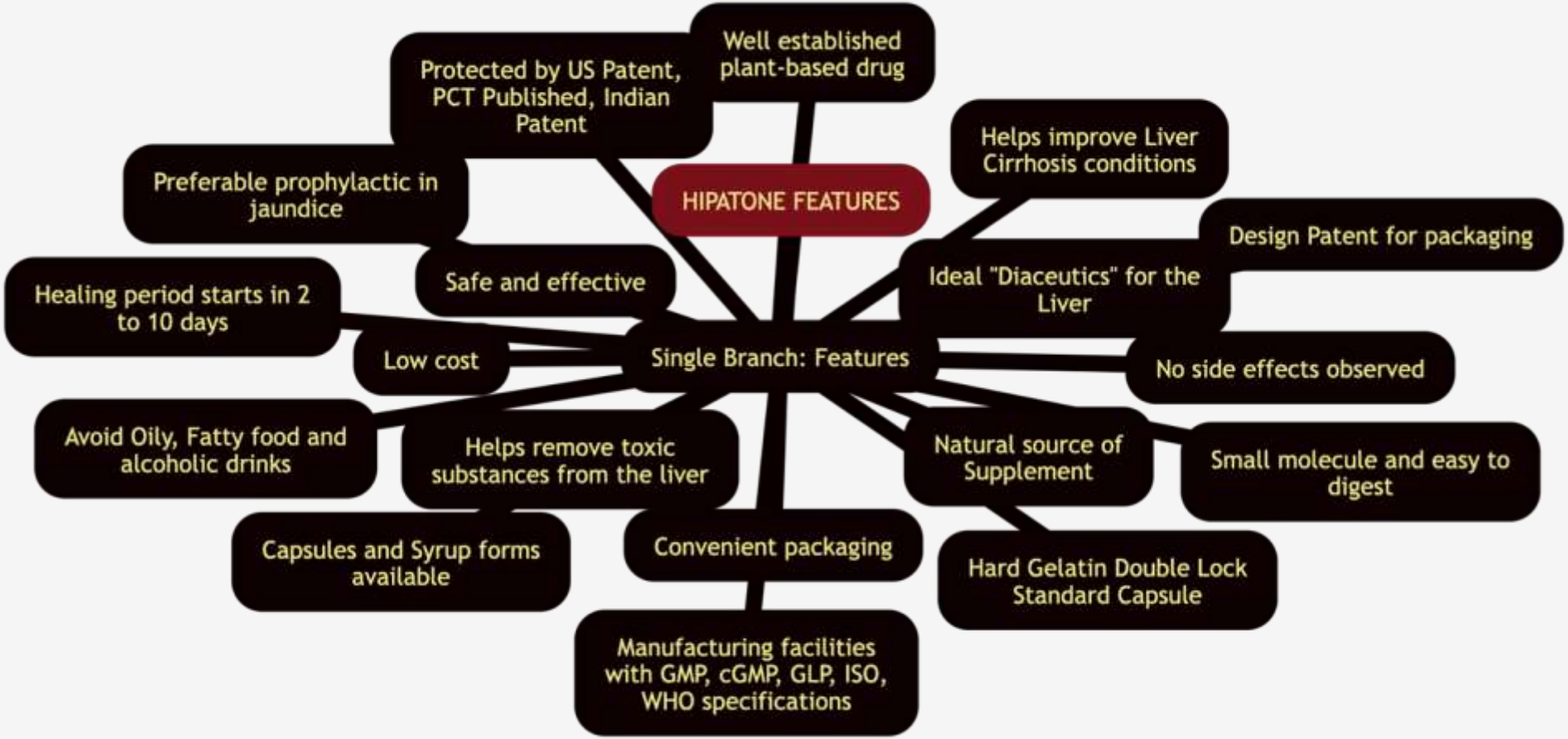
ROLE

Liver Dysfunction Treatment: Hipatone is primarily designed to treat liver dysfunction, with a specific focus on jaundice. The combination of plant extracts in Hipatone is targeted to alleviate symptoms associated with liver malfunctioning, such as yellowing of the skin and eyes due to bilirubin accumulation.

Therapeutic Properties: The active compounds derived from Curcuma longa, Phyllanthus emblica, and Gymnosporea montana are known for their hepatoprotective, antioxidant, and anti-inflammatory properties. These properties help in detoxifying the liver, reducing inflammation, and protecting liver cells from damage caused by various toxins and oxidative stress.

Natural Source of Compounds: Unlike conventional medications, Hipatone derives its therapeutic agents from natural sources, namely medicinal plants. This natural origin often appeals to individuals seeking alternative or complementary treatments for liver ailments, as it is perceived to be gentler on the body with fewer side effects.

HIPATONE FEATURES:



MARKET OPPORTUNITY

INDUSTRY OVERVIEW

- Global liver diseases market totaled nearly $21.10 billion and was projected to reach $34.78billion by 2030 with an CAGR of 7.4% through 2030.
- According to WHO, liver disease deaths in India reached 259,749 or 2.95% of total death.
- The age adjusted death rate is 22.93% per 100,000 of population ranks #63 in the world.

ESTIMATION OF MARKET GROWTH

- Expected to garner $43.47 Billion by 2030 with an expected CAGR of 7.6% for forecast period of 2024-2031

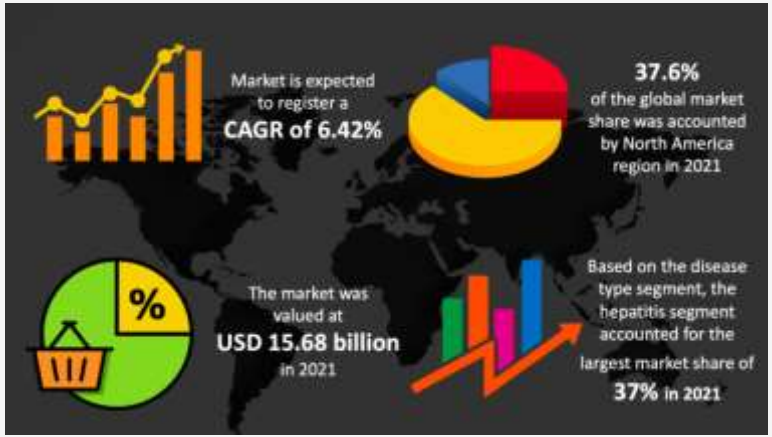
INVESTMENT OPPORTUNITY

- The idea behind is that it wants to create social impact.
- It aims to help people by providing with high quality medicine.
- It aims to help people by providing with affordability.
- These medicines are made from herbal and/or plants extracts.
- It is based on new advanced technology.
- Nowadays, people are prone to the usage of allopathic medicine despite of they having multiple side effects. This are biotech products which minimize the range of side effects and are beneficial to cure severe diseases like malaria, Liver dysfunction and Cholesterol.

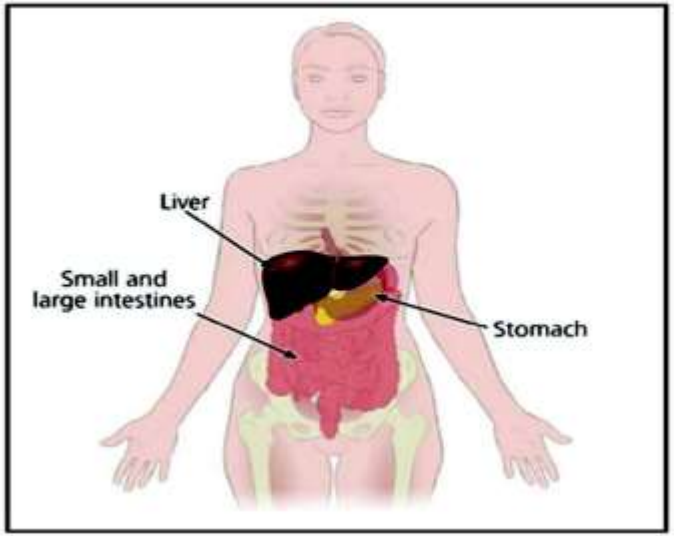
MARKET OPPORTUNITY

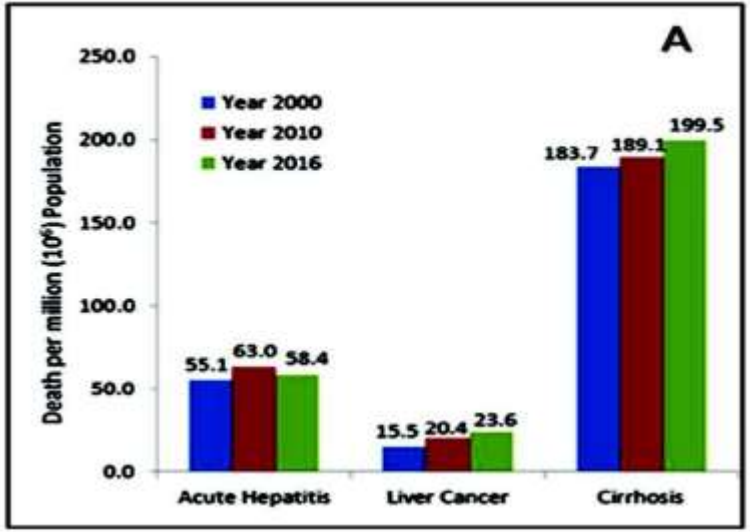
- With the increased demand for liver disease treatments, major players have invested capital in researching and developing better drugs, devices, and treatment options. For example, in December 2020, the American biopharmaceutical corporation Gilead Sciences, Inc. announced the acquisition of MYR GmbH, a German healthcare organization focused on discovering and commercializing therapies for treating chronic liver disease. Gilead declared its intention to buy MYR for approximately USD 1.36 billion in cash. Other such developments and advancements in the liver disease treatment market will make the industry competitive and help it become more efficient, providing the necessary impetus to its growth and lucrative opportunities for the market players.

- By 2030, it is anticipated that the India Liver Disease Therapeutics market will reach a value of $818 Mn from $420 Mn in 2022, growing at a CAGR of 8.7% during 2022-2030. Liver Disease Therapeutics in India is dominated by domestic pharmaceutical companies such as Dr. Reddy's Laboratories, Cadila Healthcare, and Sun Pharmaceutical.



MARKET OPPORTUNITY: STATISTICS





B

Syndromes of Liver Disease	Etiology	Prevalence (%)	Contribution to Mortality (%)
Acute liver disease	HAV	1.7-33	5-6.3
	HEV	30-50	30-40
	HBV	13.9-27.6	55-60
	Non-A-E virus	14.6-43.9	0.5-2
	Drugs (AID and others)*	0-15	
CLD including cirrhosis	HBV	17.6-47.9	30-60
	HCV	5.2-44.9	10-22
	Alcohol	10.9-31.9	20-25
	NAFLD/NASH	2.6-43.6	10-15
	Others*	9.7-23.2	5-10
Liver cancer	HBV	46.8	40-60
	HCV	14.8	10-20
	Alcohol	9.6	15-20
	NAFLD/NASH	4.6-19	5-10

Fig. Liver Disease Related Deaths in India. A. Changes in mortality over time. B. Etiology of different clinical syndromes and contribution to mortality. [*Mondal et al. Clinical Liver Disease 2022:19;114-117*]

WHY HIPATONE®?

Hipatone stands out as a revolutionary solution in the landscape of liver treatment for several compelling reasons. Firstly, it harnesses the power of nature through a meticulous blend of extracts from Curcuma longa, Phyllanthus emblica, and Gymnosporea montana, each renowned for their hepatoprotective and medicinal properties. These natural compounds have been traditionally used for centuries in various cultures for liver ailments, demonstrating a rich history of efficacy and safety.

What truly sets Hipatone apart is its comprehensive approach to liver health. Not only does it address the symptoms of liver dysfunction like jaundice, but it also targets the underlying causes with its potent anti-inflammatory and antioxidant properties. By reducing liver inflammation and protecting liver cells from oxidative damage, Hipatone not only alleviates current symptoms but also prevents further deterioration of liver function.

Moreover, Hipatone's formulation is backed by rigorous research and development, ensuring consistency, potency, and safety. Its adherence to stringent quality control standards, including Good Manufacturing Practices (GMP), cGMP, GLP, and ISO, instills confidence in its reliability and effectiveness. Additionally, its convenient dosage forms, such as capsules and syrups, cater to diverse patient needs and preferences, enhancing compliance and treatment outcomes.

For industries focused on liver treatment, Hipatone presents a compelling proposition: a natural, evidence-based solution with proven efficacy, minimal side effects, and a track record of patient satisfaction. As the demand for safe and holistic liver care continues to rise, Hipatone emerges as a frontrunner, offering a beacon of hope for those seeking lasting relief from liver ailments.

EXEMPLARY CLINICAL DATA UNDER HIPATONE'S OBSERVATION

Sr. No.	Name of Patient	Age	Liver Function Test Date of Diagnosis	Normal: Direct : **0.2-1.0** - Indirect:**0.0-0.8** -S.G.P.T: **0.45** Urine Bile Salts:***Absent*** -Urine bile Pigments: ***Absent***					Initial and with conventional drugsComplaints	Observation of **HIPATONE®**	COMPOSITION
				Total (mg/dl)	Indirect (mg/dl)	S.G.P.T.(u/L)	Urine Bile Salts	Urine Bile Pigments			**HIPATONE® Course Duration**
				Direct : 0.2-1.0 - Indirect:0.0-0.8 -S.G.P.T: 0.45 Urine Bile Salts:Absent-Urine bile Pigments: Absent							**TEN DAYS FOR ALL PATIENTS**
1	R. T.	14/M	01/05/11	6.8	1	1550			Loss of app-	Symptomatic Relief	
									etite and		
									vomiting		
	HIPATONE		14/05/11	2.2	0.2	80	-		**Nil**		1 Cap. b.i.d. X 10 days
2	A. P.	27/M	02/05/2011	12.8	3.4	2520			Vomiting,	Symptomatic Relief	
									Nausea		
	HIPATONE		13/05/2011	3.8	1.3	390			**Mild Gut-**		2 Cap. b.i.d.X 10 days
									Disturbance		
3	S.K.	25/F	02/05/11	9.2	2.4	2440			Weakness,		
									Vomiting,		
									backpain		
	HIPATONE		16/05/11	4	0.9	280			**Nil**	Symptomatic	2 cap. b.i.d. X 10 Days
										Relief	
4	D. P.	21/M	02/05/11	4	1	1870			Vomiting,		
									Uneasyness		
	HIPATONE		16/05/11	2.1	0.8	190			**Nausea**	Symptomatic	1 Cap. t.d.s. X 10 Dyas
										Relief	
5	D.J.	7/M	03/05/11	3.3	1	1900			Vomiting,		
									Uneasyness		
									Weakness		
	HIPATONE		17/05/11	1.9	0.9	160			**Nil**	Symptomatic Relief	1 Cap. b.i.d. X 10 Days

EXEMPLARY CLINICAL DATA - PART-II: After Consuming

7	M. V.	40/M	03/05/11	12.4	1.4	2140			Vomiting,		
									Bodyache		
	HIPATONE		24/05/11	5.5	2.3	102			**Nil**	Symptomatic -	
										Relief	2 Cap. b.i.d. X 10 days
8	D.P.	20/F	02/05/11	10.5	1.1	84			Vomiting,		
									Fever,		
									Backpain		
	HIPATONE		16/05/11	3.1	0.7	21			Mild Gut-		
									Disturbance	Symptomatic -	
										Relief	2 Cap. b.i.d. X 10 Dyas
9	D.V.	26/M	01/05/11	12.5	9.7	2100			Chest pain,		
									Vomiting,		
									Weakness,		
									Bodyache		
	HIPATONE		15/05/11	2.8	0.9	170			**Nil**	Symptomatic -	
										Relief	2 Cap. b.i.d. X 10 Days
10	R. S.	33/M	02/05/11	7.8	1	2080			Nausea		
									Neck Pain		
	HIPATONE		29/05/11	1.7	0.4	510			**Nil**	Symptomatic -	
										Relief	1 Cap. t.d.s. X 10 Days.

Physician's Comment: The voluntary clinical trial of HIPATONE had been observed and taken by me. The drug has shown most significant efficacy with safety.

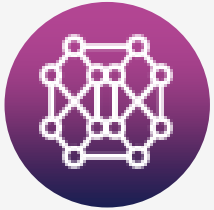
safety. I am at opinion that the H indicated for "Liver Malfunction-jaundice" has very prospective future.

The novel drug from plant origin has tendency to detoxify the damaged liver.

DOSES REGIME & PRECAUTIONS

DOSAGE

2 Caps. b.i.d. or as directed by the physician followed by Water. After principal meals



CONTRAINDICATION/ PRECAUTION

- Alcoholic Drinks
- No Adverse Effects in open label and controlled clinical surveillance.
- Observed Safe during Pregnancy
- No Interaction found in case to be taken with conventional drug(s)

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