

**Brand Name:** Copegus

**Generic:** ribavirin

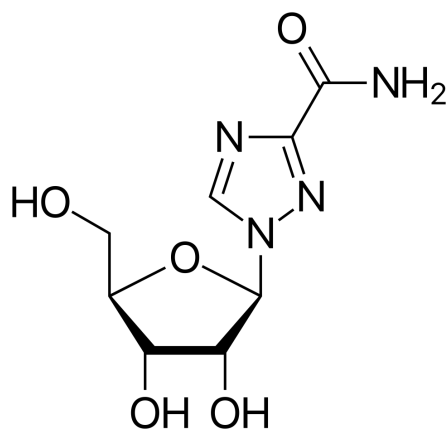
**Type:** small molecule

**Year Accepted/Phase:** 2002

### **Mechanism:**

Ribavirin is a nucleoside analog that inhibits viral RNA synthesis and viral mRNA capping. Its precise mechanism of action in treating hepatitis C is not completely understood, but it is known to enhance the antiviral effects of interferons and DAAs.

### **Chemical Structure:**



### **Indication:**

Copegus (ribavirin) is indicated for use in combination with peginterferon alfa-2a or alfa-2b for the treatment of chronic hepatitis C in patients with compensated liver disease. It is also used with certain DAAs for specific HCV genotypes and treatment scenarios.

## **Clinical trials:**

### **Combination Therapy with Interferon (Phase III)**

**Purpose:** Evaluate the efficacy and safety of ribavirin in combination with interferon alfa-2b in patients with chronic hepatitis C.

**Dates:** Results published in 1998; FDA approval for combination therapy with interferon alfa-2b in 1998.

**Results:** The combination of ribavirin and interferon alfa-2b significantly improved sustained virologic response (SVR) rates compared to interferon alfa-2b alone, leading to its FDA approval for use in combination therapy.

### **Combination Therapy with Peginterferon Alfa-2a (Phase III)**

**Purpose:** Assess the efficacy and safety of ribavirin in combination with peginterferon alfa-2a in patients with chronic hepatitis C.

**Dates:** Results published in 2002; FDA approval for combination therapy with peginterferon alfa-2a in 2002.

**Results:** The combination of ribavirin and peginterferon alfa-2a demonstrated significantly higher SVR rates compared to peginterferon alfa-2a alone, establishing it as a standard treatment for chronic HCV infection.

### **Combination Therapy with Peginterferon Alfa-2b (Phase III)**

**Purpose:** Evaluate the efficacy and safety of ribavirin in combination with peginterferon alfa-2b in patients with chronic hepatitis C.

**Dates:** Results published in 2001; FDA approval for combination therapy with peginterferon alfa-2b in 2001.

**Results:** Ribavirin in combination with peginterferon alfa-2b significantly improved SVR rates compared to peginterferon alfa-2b alone, supporting its use in combination therapy.

### **Direct-Acting Antivirals (DAAs) Combination Therapy (Various Phase III Trials)**

**Purpose:** Assess the efficacy and safety of ribavirin in combination with various DAAs for the treatment of chronic hepatitis C.

**Dates:** Various results published between 2011 and 2015.

**Results:** Studies demonstrated that adding ribavirin to DAA regimens can enhance SVR rates in certain patient populations, particularly those with difficult-to-treat genotypes or prior treatment failures. The role of ribavirin became

more specific, often used in tailored regimens for certain HCV genotypes and patient conditions.