

**Safety Data Sheet**  
**RIBAVIRIN TABLETS**

**Strength:** 200mg.

**Pack Size:** 168 Tablets per bottle

**Revision No.:** 02

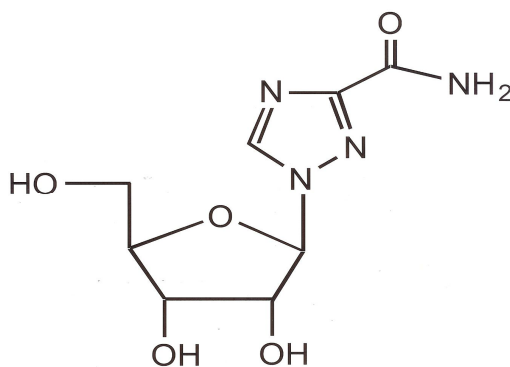
**EMERGENCY OVERVIEW**

Each Ribavirin Tablets intended for oral administration contains Ribavirin and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

**Section 1. Identification**

**Identification of the product**

**Product name:** Ribavirin Tablets  
**Formula:** C<sub>8</sub>H<sub>12</sub>N<sub>4</sub>O<sub>5</sub>  
**Chemical Name:** 1-β-D-ribofuranosyl-1H-1,2,4-triazole-3-carboxamide



**Manufacturer / supplier identification**

**Company:** Cadila Healthcare Ltd. Ahmedabad, India  
**Address:** Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.  
Dist. Ahmedabad – 382210. State: Gujarat. India  
**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319  
**Emergency Telephone No.** Tel.: +91 79 6868100  
**Recommended use / Therapeutic Category** A nucleoside analogue with antiviral activity.

**Restriction on Use /  
Contraindications**

Ribavirin tablet is contraindicated in:

- Patients with known hypersensitivity to ribavirin tablets or to any component of the tablet.
- Women who are pregnant.
- Men whose female partners are pregnant..

- Patients with hemoglobinopathies (e.g., thalassemia major or sickle-cell anemia).
- Ribavirin tablets and peginterferon alfa-2a combination therapy is contraindicated in patients with Autoimmune hepatitis and Hepatic decompensation (Child-Pugh score greater than 6; class B and C) in cirrhotic CHC monoinfected patients before or during treatment.

## Section 2. Hazard(s) Information

**Dose and Administration** The daily dose of ribavirin tablet is 800 mg to 1200 mg administered orally in two divided doses. The dose should be individualized to the patient depending on baseline disease characteristics, response to therapy, and tolerability of the regimen.

**Adverse Effects** The most common life-threatening or fatal events induced or aggravated By peginterferon alfa-2a and ribavirin tablets were depression, suicide, relapse of drug abuse/ overdose, and bacterial infections.

In all studies, one or more serious adverse reactions occurred in 10% of CHC monoinfected patients receiving peginterferon alfa-2a alone or in combination with ribavirin tablets.

The most common serious adverse event (3% in CHC) was bacterial infection (e.g., sepsis, osteomyelitis, endocarditis, pyelonephritis, pneumonia).

**Over Dose Effect** No cases of overdose with ribavirin tablets have been reported in clinical trials.

**Medical Conditions** Birth defects and fetal death with ribavirin: Patients must have a negative pregnancy test prior to therapy; use at least 2 forms of contraception and undergo monthly pregnancy tests.

Patients exhibiting the following conditions should be closely monitored and may require dose reduction or discontinuation of therapy:

- Monotherapy with ribavirin is not permitted.
- Hemolytic anemia may occur with a significant initial drop in hemoglobin.
- Pancreatitis.
- Pulmonary infiltrates or pulmonary function impairment.
- New or worsening ophthalmologic disorders
- Severe decreases in neutrophil and platelet counts, and hematologic, endocrine (e.g., TSH), and hepatic abnormalities.
- Dental/periodontal disorders reported with combination therapy.
- Weight loss and growth inhibition reported during combination therapy in pediatric patients. Long-term growth inhibition (height) reported in some patients.

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**Pregnancy Comments**

Ribavirin may cause birth defects and/or death of the exposed fetus. Extreme care must be taken to avoid pregnancy in female patients and in female partners of male patients. Ribavirin has demonstrated significant teratogenic and/or embryocidal effects in all animal species in which adequate studies have been conducted. These effects occurred at doses as low as one twentieth of the recommended human dose of ribavirin.

RIBAVIRIN TABLETS THERAPY SHOULD NOT BE STARTED UNLESS A REPORT OF A NEGATIVE PREGNANCY TEST HAS BEEN OBTAINED IMMEDIATELY PRIOR TO PLANNED INITIATION OF THERAPY.

**Pregnancy Category** X

**Section 3. Composition / information on ingredients**

<b>Component</b>	<b>Exposure Limit</b>	<b>CAS No.</b>
<b>Principle Component :</b>		
Ribavirin	Not Found	36791-04-5
<b>Inactive Ingredients :</b>		
Crospovidone,	Not Found	9003-39-8
Hypromellose,	Not Found	9004-65-3
Iron oxide red	Not Found	51274-00-1
Iron oxide yellow	Not Found	51274-00-1
Microcrystalline cellulose	Not Found	9004-34-6
Polyethylene glycol	Not Found	25322-68-3
Povidone	Not Found	9003-39-8
Silicon dioxide	Not Found	7621-86-9
Talc	Not Found	14807-96-6
Titanium dioxide.	Not Found	13463-67-7

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**Section 4. First - aid measures**

**General** Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention

**Overdose Treatment** No case of overdose

**Section 5. Fire - fighting measures**

**Flash point** Not Found **Upper Flammable Limit:** Not Found

**Auto-Ignition Temperature:** Not Found **Lower Flammable Limit:** Not Found

**Extinguishing Media** Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material. **Fire and Explosion Hazard** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.

**Fire Fighting Procedure** As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

**Section 6. Accidental Release Measures**

**Spill Response** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

**Section 7. Handling and Storage**

**Storage** Store at 20° to 25°C (68° to 77°F).  
Keep bottle tightly closed.

**Incompatibilities:** No data available.

**Section 8. Exposure controls / personal protection**

**Respiratory Protection** Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

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<b>Skin Protection</b>	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
<b>Eye protection</b>	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
<b>Protective Clothing</b>	Protective clothing is not normally necessary, however it is good practice to use apron.
<b>Engineering Control</b>	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Section 9. Physical and chemical properties**

<b>Appearance</b>	Ribavirin Tablets, 200 mg are light pink to pink, round, biconvex, beveled, film-coated tablets debossed with the logo of 'ZC19' on one side, other side plain.		
<b>Solubility in water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
		<b>Vapour pressure</b>	No Data Available
<b>Other information</b>	The molecular formula of Ribavirin is $C_8H_{12}N_4O_5$ and the molecular weight is 244.2. Ribavirin is a white crystalline powder. It is freely soluble in water and slightly soluble in anhydrous alcohol. Ribavirin tablet is available as a light pink to pink, round, biconvex, beveled, film-coated tablet for oral administration.		

**Section 10. Stability and Reactivity**

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities:</b>	No Data available.		

**Section 11. Toxicological information**

<b>General</b>	Handling of formulated product is not expected to cause any toxicological effects. The data pertains to the ingredient in formulations, rather than this
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specie formulation.

**Target organ**

Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

**Other**

The primary clinical toxicity of ribavirin is hemolytic anemia. The anemia associated with ribavirin therapy may result in worsening of cardiac disease that has led to fatal and nonfatal myocardial infarctions.

Significant teratogenic and/or embryocidal effects have been demonstrated in all animal species exposed to ribavirin. In addition, ribavirin has a multiple dose half-life of 12 days, and it may persist in non-plasma compartments for as long as 6 months.

**Section 12. Ecological information**

Do not allow product to enter drinking water supplies, waste water or soil

**Section 13. Disposal Consideration**

Dispose the waste in accordance with all applicable Federal, State and local laws.

**Section 14. Transport Information**

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

**Section 15. Regulatory Information**

Generic Medicine. Approved by USFDA & the ANDA Number is 77-094

**Section 16. Other information**

None

**Date of issue:** 28/05/2015

**Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.