Material Safety data sheet

RIBAVIRIN CAPSULES

Strength: 200mg. **Pack Size: 42, 56, 70, 84, 140, 168** Tablets per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

RIBAVIRIN CAPSULES contain Ribaverin and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name:	Ribaverin Capsules
Formula:	C8H12N4O5
Chemical Name:	1-ß-D-ribofuranosyl- 1 H-1,2,4-triazole-3-carboxamide
Therapeutic Category	A nucleoside analogue with antiviral activity.

Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Ribavirin	Not Found	36791-04-5
Inactive Ingredients :		
crospovidone	Not Found	9003-39-8
magnesium stearate	Not Found	557-04-0
microcrystalline cellulose	Not Found	9004-34-6
povidone	Not Found	9003-39-8
silicon dioxide	Not Found	7621-86-9
Capsule Shell		
Gelatin	Not Found	9000-70-8
Titanium dioxide.	Not Found	13463-67-7

Section 3. Health Hazards Information

Dose and Administration

INTRON A Injection should be administered subcutaneously and ribavirin capsules should be administered orally. Ribavirin capsules may be administered without regard to food, but should be administered in a consistent manner

Body Weight	Ribavirin Capsules	INTRON A Injection
=75 kg	2 times 200 mg capsules AM, 3 times 200 mg capsules PM daily p.o.	3 million IU 3 times weekly s.c.
>75 kg	3 times 200 mg capsules AM, 3 times 200 mg capsules PM daily p.o.	3 million IU 3 times weekly s.c.

Adverse Effects

The primary toxicity of ribavirin is hemolytic anemia. Reductions in hemoglobin levels occurred within the first 1 to 2 weeks of oral therapy.

Cardiac and pulmonary events associated with anemia occurred in approximately 10% of patients.

Ribavirin capsules/INTRON A Combination Therapy:
In general, the selected treatment-emergent adverse events were are as under:

General Disorders
Headache, Fatigue, Rigors, Fever, Influenza-like symptoms ,Asthenia, Chest pain.

Central & Peripheral Nervous System Disorders
Dizziness

Gastrointestinal System Disorders
Nausea, Anorexia, Dyspepsia, Vomiting.

Musculoskeletal System Disorders
Myalgia, Arthralgia,
Musculoskeletal pain,

Psychiatric Disorders
Insomnia, Irritability, Depression, Emotional lability, Concentration impaired, Nervousness,

Respiratory System Disorders
Dyspnea,Sinusitis,

Skin & Appendages Disorders
Alopecia, Rash,Pruritus,Special Senses,

Other Disorders
In addition, the following spontaneous adverse events have been reported during the marketing surveillance of ribavirin capsules/INTRON A therapy: hearing disorder and vertigo.

Over Dose Effect	There is limited experience with overdosage. Acute ingestion of up to 20 grams of ribavirin capsules, up to 10 times the recommended doses have been reported.
Contraindications	Combination ribavirin capsules/INTRON A therapy is contraindicated in females who are pregnant and in the male partners of females who are pregnant. Extreme care must be taken to avoid pregnancy during therapy and for 6 months after completion of treatment in female patients, and in female partners of male patients who are taking combination ribavirin capsules/INTRON A therapy Ribavirin capsules monotherapy is not effective for the treatment of chronic hepatitis C and should not be used for this indication. Patients with persistently severe or worsening signs or sympoms of these conditions should be withdrawn from therapy. In many but not all cases these disorders resolve after stopping INTRON A therapy.
Pregnancy Comments	Ribavirin produced significant embryocidal and/or teratogenic effects in all animal species in which adequate studies have been conducted. Malformations of the skull, palate, eye, jaw, limbs, skeleton, and gastrointestinal tract were noted. The incidence and severity of teratogenic effects increased with escalation of the drug dose. Survival of fetuses and offspring was reduced.
Pregnancy Category	**X**

Section 4. First aid measures

General	Remove from exposure. Remove contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention
Overdose Treatment	There is no specific antidote for INTRON A or ribavirin capsules, and hemodialysis and peritoneal dialysis are not effective treatment of overdose of either agent.

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. Storage / Spill / Disposal Measures

Storage	Keep bottle tightly closed. Store at 25°C (77°F); excursions permitted to 15°C- 30°C (59°- 86°F).
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.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and 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.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	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.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 8. Physical and chemical properties

Appearance Ribavirin capsules, 200 mg are white to off-white granular powder filled in size '0' hard gelatin capsules with white colored cap printed with "ZA-12" in black ink and white colored body printed with "200mg" in black ink

Odour	Odourless	**Melting Point**	No Data Available
Solubility in water	No Data Available	**Vapour density**	No Data Available
Boiling point	No Data Available	**Evaporation rate**	No Data Available
Evaporation rate	No Data Available	**Specific gravity**	No Data Available
Reactivity in water	No Data Available	**Vapour pressure**	No Data Available
% Volatile by volume	No Data Available		

Other information The molecular formula of Ribavirin is C8H12N4O5 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 9. Physical Hazards

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

Section 10. Toxicological information

Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

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

other Long-term studies in the mouse and rat (18 to 24 months; doses of 20 to 75 and 10 to 40mg/kg/day, respectively [estimated human equivalent doses of 1.67 to 6.25 and 1.43 to 5.71 mg/kg/day, respectively, based on body surface area adjustment for a 60 kg adult; approximately 0.1 to 0.4 times the maximum human 24-hour dose of ribavirin]) have demonstrated a relationship between chronic ribavirin exposure and increased incidences of vascular lesions (microscopic hemorrhages) in mice. In rats, retinal degeneration occurred in controls, but the incidence was increased in ribavirin-treated rats.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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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.