

RIBAVIRIN (AEROSOLISED): VARIETY WARD CHW PRACTICE GUIDELINE[®]

DOCUMENT SUMMARY/KEY POINTS

- Aerosolised ribavirin can only be administered on Variety Ward.
- Personal Protective Equipment (PPE) must be worn when preparing ribavirin, during administration and when cleaning the room or equipment post administration.
- Ribavirin is a potential teratogen and must be:
 - Prepared in pharmacy;
 - Handled with extreme care;
 - Administered by an accredited RN.
- **Staff** who are pregnant, trying to conceive or breast feeding **should not:**
 - prepare or administer ribavirin,
 - enter the patients' room during ribavirin administration or
 - care directly for patients who are receiving ribavirin.
- **Parent/visitors** who are pregnant or trying to conceive or breast feeding, should not enter the patients' room during ribavirin administration.
- Ribavirin must be checked by two accredited RN's or one accredited RN and one medical officer.
- Ribavirin must be prepared, administered and disposed of in accordance with NSW Work Cover guide "[Cytotoxic Drugs and related Waste risk Management Guide 2008](#)"
- Staff must adhere to waste management and spill management processes according to NSW Health Policy Directive.
- Hazardous and Cytotoxic Drugs – Administration and Handling – CHW:
<http://chw.schn.health.nsw.gov.au/o/documents/policies/procedures/2011-8019.pdf>

CHANGE SUMMARY

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guidelines Committee	
Date Effective:	1 st September 2016	Review Period: 3 years
Team Leader:	CNS	Area/Dept: Variety ward

- N/A – new document.

READ ACKNOWLEDGEMENT

- The following staff working in Variety Ward are to **read and acknowledge** they understand the contents of this guideline:
 - Nursing and medical staff
 - And any other staff who the manager deems necessary.
- **Training/Assessment Required:**
 - Attend annual in service for ribavirin administration and undertake PPE training as required
 - Training in the use of SPAG unit as required

Document all training and accreditation

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

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1 Introduction

Bronchiolitis is the most common lower respiratory tract infection in infancy and childhood. Respiratory Syncytial Virus (RSV) is the most common cause of bronchiolitis in infants and young children. High-risk populations include: infants born prematurely, those with chronic lung disease, congenital heart disease, and children with immunodeficiencies. The peak incidence of the disease is in infants less than 12 months of age.

In general, acute bronchiolitis is a self-limiting disease and the overall mortality rate is low (<1%), although it may be as high as 3% in high-risk groups of infants with chronic lung disease. Long-term morbidity is considerable with more than half of the patients with bronchiolitis having recurrent episodes of virus-induced wheezing and asthma up to the age of 7 to 11 years and lung function abnormalities that are even more protracted.

RSV is spread by direct contact with infected secretions and contaminated objects, thus hand-washing is important in containing the spread.

Antiviral therapy with ribavirin as well as symptomatic therapy has been the main treatment option to date.

1.1 Rationale

- To safely and effectively administer aerosolised ribavirin (Virazole) to clinically identified patients in Variety Ward. Aerosolised ribavirin is a red agent must be approved prior by the Antimicrobial Stewardship team (pager 7092).

2 Treatment

Ribavirin is a guanosine analogue with good in-vitro activity against a number of viruses including RSV. It is a virus static agent and prevents viral replication. At present, an indication for ribavirin in the treatment of RSV infections is (pre-emptive) therapy in immunocompromised individuals, e.g. pre and post bone marrow transplantation. Ghosh, Champlin and Englund (2000) treated paediatric bone marrow transplant patients with ribavirin at the first signs of RSV related upper respiratory tract infection, in order to prevent the development of pneumonia, which has a high mortality rate in this group.

3 Indications

- Immunocompromised children, particularly those with severe T cell deficiency, may get severe or persistent RSV infection.
- The marginal benefit of ribavirin may be important in severe and/or persistent RSV infection in children with T cell deficiency, particular if T cell function is likely to improve, for example in oncology patients pre and post bone marrow transplant & severe combined immunodeficiency (SCIDS).
- Ribavirin is virtually never indicated outside the above rare circumstances.

4 Safety

- Ribavirin is a potential teratogen; staff and parents/carers who are pregnant or are considering pregnancy within a 6 month period or breastfeeding should be made aware of the potential risks from inhaling aerosolized ribavirin (which can occur during drug preparation, administration or post administration cleaning).

In a study done by Ghosh *et al* (2000), of 358 adverse events reported by 152 healthcare personnel exposed to ribavirin, the most common were: headache, conjunctivitis, rhinitis, nausea, rash, dizziness, pharyngitis, and lacrimation. Several cases of bronchospasm and/or chest pain were also reported, usually in individuals with known underlying reactive airway disease. Most signs and symptoms resolved themselves in minutes to hours of discontinuing exposure to aerosolized ribavirin.

- Staff and parents/visitors should be advised that exposure to ribavirin can cause damage to **contact lenses**. Contact lens wearers are at greater risk of ocular adverse effects on exposure.

Ribavirin must be prepared, administered and disposed of in accordance with NSW Work Cover guide **Hazardous and Cytotoxic Drugs – Administration and Handling – CHW**: <http://chw.schn.health.nsw.gov.au/o/documents/policies/procedures/2011-8019.pdf>

Important Safety Notes:

- **Personal Protective Equipment (PPE) must** be worn when preparing ribavirin, during administration and when cleaning the room or equipment post administration.(see section 4.1)
- Ribavirin is a potential teratogen and must be prepared in pharmacy, handled with extreme care and administered by an accredited RN.
- **Staff** who are pregnant, trying to conceive or breast feeding **should not** mix or administer ribavirin, enter the patients' room during ribavirin administration or care directly for patients who are receiving ribavirin.
- **Parents/visitors** who are pregnant or trying to conceive or breast feeding, should not enter the patients' room during ribavirin administration.

4.1 Personal Protective Equipment (PPE)

- All **staff** entering the room whilst the aerosolised ribavirin is in progress or involved in the cleaning and disposal of the equipment used must wear:
 - i. All in one suit with hood and disposable cytotoxic gown.
 - ii. Nitrile Gloves
 - iii. Versaflo hood and respirator (Versaflo S-655 is the disposable component, Versaflo S-950, is the non- disposable component and requires sterilisation)

- If after discussion **parents wish to remain in/enter the room**, a P2 Mask, gown and goggles are to be worn

4.2 Staff Safety Precautions

Staff who are pregnant, to conceive within a 6 month period or breast feeding should not administer ribavirin, enter the patients' room during ribavirin administration or care directly for patients who are receiving ribavirin. Staff should discuss the family planning document with the NM/NUM and complete the following form:

http://chw.schn.health.nsw.gov.au/o/forms/ohs/staff_health/family_planning_document.pdf

- Other staff who administer/care for the patient/enter the room should record:
 - administration of ribavirin on *personal exposure sheet*;
 - side effects from exposure of ribavirin in IIMS and report them to NUM.

4.3 Parent/Carer Safety Precautions

- Parent/visitors who are pregnant or trying to conceive within a 6 month period or breast feeding, **should be advised not enter** the patients' room during ribavirin administration. The risks should be fully explained.
- If the parent chooses to remain in or enter the room, they are to wear PPE (see section 4.1) and it **must** be documented that the risks were fully explained to the parent and that the parent understood the risks. Document that the factsheet has been provided to the parent. The Team Leader or nurse attending the child is responsible.
- A parent fact sheet should be given to the parents explaining the risks. See [Appendix 3](#).

4.4 Environment

- The child should be nursed in a in a single hepa filtrated room with 100% exhaust air conditioning with at least 6 air changes per hour bed (17/18 or 19 Variety ward)
- Minimal equipment and/or personal effects are to remain in the room.
- The door to the room must remain closed whilst the ribavirin is being aerosolised.
- A sign stating that "Ribavirin is in progress in this room" must be placed on the door to the patient room. Signs are kept in the "Ribavirin Folder" in the ante room.
- Ribavirin aerosol scavenging devices must be used.
- The SPAG unit should be turned off one hour prior to handling the patient.

In Variety Ward, the mode of administration is generally via a tent or head-box.

Refer to [Appendix 2 for Equipment Set Up](#).

5 Dosage and administration

The usual dosage for **aerosolised ribavirin is 2g administered three times a day** via a small particle aerosol generator (SPAG) unit.

The solution for aerosolisation is prepared by in the Pharmacy.

Two syringes each containing 3g ribavirin in 50mL are prepared in the cytotoxic suite.

The contents of both syringes (6g) is transferred to the SPAG unit and it is turned on for 2 hours three times a day. This is expected to deliver 2g over 2 hours. When the next dose is due (after 8 hours) the SPAG unit is turned on for 2 hours to deliver another 2g.

Fresh solution (ribavirin 6g in 100mL) is to be placed in the unit each day after it is cleaned.

Note: This concentration is not suitable for use in patients with endotracheal tubes due to potential for crystallisation.

After each dose is administered the scavenging system needs to be run for 1 hour to remove the aerosols from the environment. See sections 4.4 Environment and Appendix 2.

The duration of therapy is to be decided in consultation with the infectious diseases team but may be between 3-7 days.

6 Spill Management

- All cytotoxic spillages should be managed in accordance with the management of spillages in the **Hazardous and Cytotoxic Drugs: Administration and Handling - CHW**: <http://chw.schn.health.nsw.gov.au/o/documents/policies/procedures/2011-8019.pdf>
- All spillages/equipment failures must be reported using IIMS (Safety at Kids). The incident should also be reported to Work Health and Safety department.
- Spill kits must be allocated to the patient's room and staff must be educated on how to use it.

7 Waste Management

- A cytotoxic sharps bin must be provided in the patient's room. On completion of treatment or when full the sharps bin should be sealed and removed.
- Any ribavirin solution remaining in the flask must be discarded in the cytotoxic sharps bin.
- Discard old tent in cytotoxic bin.
- Disposable gowns and gloves should be disposed of into contaminated waste bags.

8 Cleaning

8.1 Cleaning of PPE

- Face mask should be cleaned with warm water and a neutral detergent after each use.

8.2 Cleaning of equipment

- Protective clothing should be worn when cleaning items that may have been contaminated with condensed ribavirin aerosol.
- Double bag the equipment for cleaning and sterilizing; label clearly CYTOTOXIC and call Inhalation Therapy (ext no:52831).
- The trolley on which the SPAG unit is located whilst in use needs to be cleaned down with a neutral detergent daily, as do all equipment and audiovisual equipment that enters the room at any time.

8.3 Cleaning of the room

- Bed linen should be changed twice per day as per: [Linen Management – CHW](#).
- All surfaces, including the locker, drip stands and bed should be wiped over with a damp disposable cloth twice per day.
- The room should be cleaned using a mop and hot soapy water twice per day. Dry brushing should **not** be performed.
- The ventilation grill within the room should be wiped with a damp disposable cloth to remove deposits.
- Cleaning materials should be disposed of in the following way
 - i. Paper towels and disposable cloths should be placed in a yellow clinical waste bin
 - ii. Mop heads should be laundered after use
 - iii. Used water should be poured into the sink/toilet in the patient's room.

9 References

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3. Edell, D., Bruce, E., Hale, K., and Khoshoo, V. (1998) Reduced long-term respiratory morbidity after treatment of respiratory syncytial virus bronchiolitis with Ribavirin in previously healthy infants: a preliminary report. *Paediatrics Pulmonary*, Vol 25, pages 154 – 158.
4. Ghosh, S., Champlin, R.E., Englund, J., Giralt, S.A., Rolston, K., Raad, I., Jacobson, K., Neumann, J., Ippoliti, C., Mallik, S. and Whimbey, E. (2000) Respiratory syncytial virus upper respiratory tract illness in adult blood and marrow transplant recipients: combination therapy with aerosolised Ribavirin and intravenous immunoglobulin. *Bone Marrow Transplantation*, Vol 25, No 7, pages 751 – 755.
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7. Randolph, A.G. and Wang, E.E.L. (2004) Ribavirin for respiratory syncytial virus lower respiratory tract infection – update in Cochrane database Systematic Review 2004. *Archives of Pediatrics and Adolescent Medicine*.
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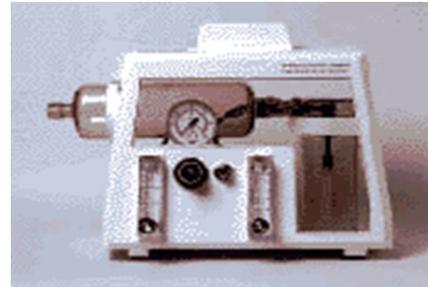
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Appendix 1: Modes of Aerosolised Ribavirin Administration

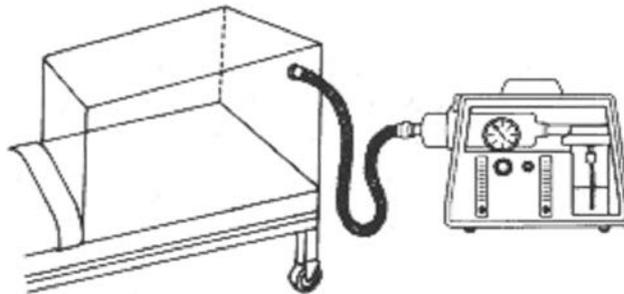
In Variety Ward, the mode of administration is generally via a tent or head-box.

Refer to Appendix 2 for Equipment Set Up.

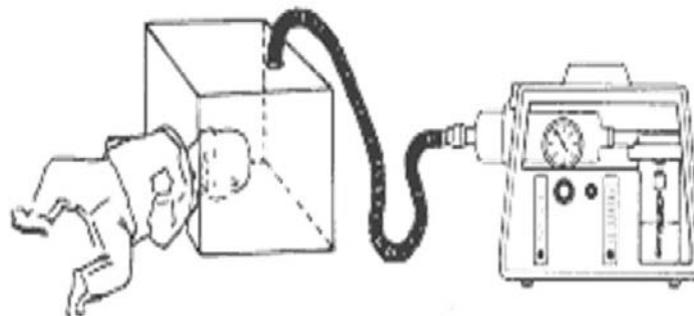
Most experience is with aerosolised Ribavirin administered using the small particle aerosol generator (SPAG).



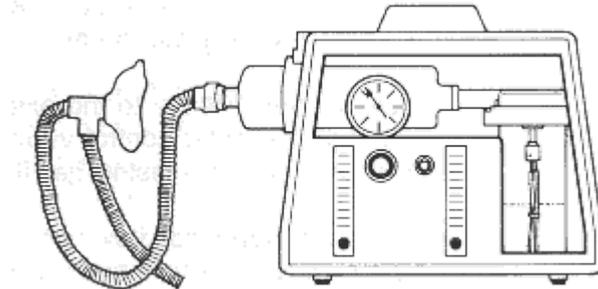
- via tent (very wasteful)



- via head-box



- Via Face Mask

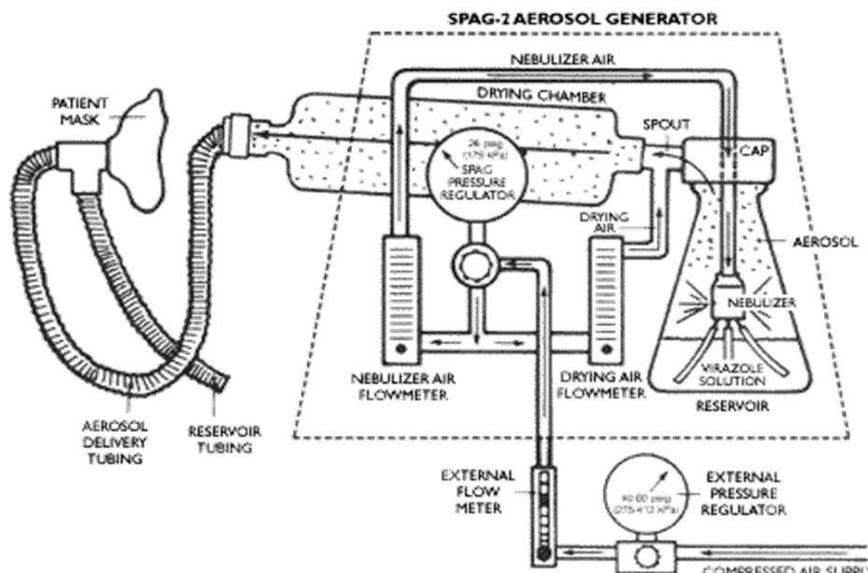


Appendix 2: Equipment set up and use

1. Prepare equipment required for ribavirin therapy prior to administration of drug, including the safety equipment.
2. Prepare room for ribavirin use, i.e. move bed or cot out from wall and put Ohio tent behind it.
3. Put SPAG unit next to bed on trolley so corrugated hose can reach into tent.

Equipment	Comment
Ribavirin medication	Reconstituted in Pharmacy
SPAG Unit (Small particle aerosol generator)	from Inhalation Therapy
Hosing from SPAG unit to air outlet (usually comes with SPAG unit)	from Inhalation Therapy
Hosing to scavenger outlet from inside the tent (blue corrugated hosing) with adaptation to connect to scavenger outlet on wall	from Inhalation Therapy
Corrugated tubing attached to spag unit and patient mask (usually comes with SPAG unit)	(from Inhalation Therapy)
Patient mask and head attachment	size according to patient - from Inhalation Therapy
Ohio Machine	from Inhalation Therapy
Plastic Tent (replaced weekly)	from Inhalation Therapy
Hosing from Ohio machine to air outlet (usually comes with Ohio machine)	from Inhalation Therapy
Mixing valve (only used if on oxygen therapy)	from Inhalation Therapy
Double adaptor for air outlet (if patient is on room air)	Ward Stock
Tyvek gowns and 3M all in one white suits	Ward stock
Gloves- Nitrile	Ward stock
Versaflo hood and respirator (Versaflo S-655 disposable component, Versaflo S-950, non-disposable component – requires sterilisation)	Ward stock

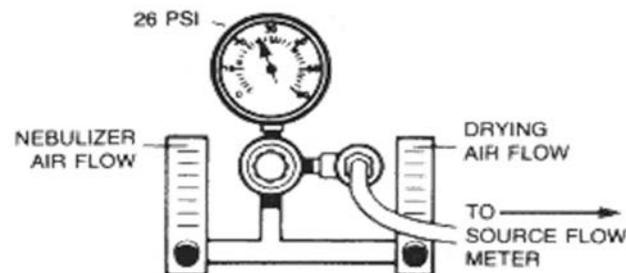
Setting up equipment



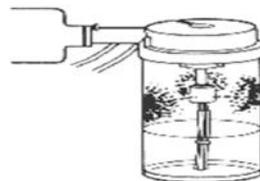
4. Don all safety equipment.
5. Set up Ohio tent onto the oxydome, connect and set the air outlet to 15L/min. Turn on the cooling fan at the back of the oxydome.
6. The drug will be reconstituted by pharmacy cytotoxic suite, into two 50mL syringes each containing 3g ribavirin. Gently syringe contents of each syringe into the flask.
7. Place the flask beneath the centre of the cap. Tighten the screw clamp firmly ensuring a tight and secure fit.
8. Insert the drying chamber through the side hole in the SPAG unit. Attach corrugated tubing from the drying chamber, placing the other end of tube inside Ohio tent.
9. Attach air outlet from the SPAG unit to wall air outlet directly to ensure adequate pressure.

Set machine as required. The operating parameters should stabilize into the following ranges:

- Regulator pressure = 26 PSI
- Nebuliser flowmeter = 8-9 LPM
- Drying air flowmeter = 2-3 LPM



- To verify that the SPAG machine is providing adequate aerosolisation, the flask of the machine should be checked to ensure that when the spray from the nebuliser contacts with the wall of the flask, three "circles" approximately half an inch in diameter are formed on the side of the flask.



Cessation

- To turn off the spag unit, turn off air flow and cooling system to Ohio Tent remove patient from tent pushing back towards head the bed.
- Start scavenging system for one hour after cessation of ribavirin.

Appendix 3: Ribavirin Information - Parent/Carer Education

Ribavirin

How does the medicine work?

Ribavirin is an antiviral drug used for severely immunosuppressed patients

How is it given?

- Ribavirin is administered to the patient via a Tent
- Treatment is delivered for two hours, three times each day.

What are the common side effects?

- Nausea, headaches, rashes and eye irritation (contact lens cannot be worn)
- Pregnant women, persons actively trying to conceive and those breastfeeding should not enter the room as the drug may effect an unborn child or the breastfeeding infant.

Special Instructions

- Parents are advised not to enter the patient's room whilst the ribavirin is being given
- The drug is given at 6am 2pm and 10pm to coincide with rest and sleep times
- Nursing staff aim to settle your child before commencing the ribavirin with your assistance
- You will be given a Parent Room on Variety Ward for the duration of your child's treatment
- Your child's room will be thoroughly cleaned twice per day however we recommend you minimize the items left in the patient room
- Please let staff know if you are experiencing any side effects

- **We strongly advise pregnant woman and persons actively trying to conceive not enter the room.**
- **If you enter the room you will be given goggles, mask, gloves and a gown to wear.**
- **Staff will be wearing special equipment to protect themselves from side effects.**
- **Please speak to the Nursing Unit Manager or Team Leader if you have any concerns.**