# ADMINISTRATION OF NEBULISED RIBAVIRIN IN ADULTS (HAEMATOLOGY) PROCEDURE

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# ADMINISTRATION OF NEBULISED RIBAVIRIN IN ADULTS (HAEMATOLOGY) PROCEDURE

## CONTENTS

**The purpose of this procedure is to ensure compliance with the Control of Substances Hazardous to Health (COSHH) Regulations 1994, when administering nebulised Ribavirin.**

## 1.0 INTRODUCTION

The procedure outlines the control measures that must be adopted to comply with the requirements of the (COSHH) regulations 1994. The procedure exists to minimize the risk to staff health and **must** be complied with by all persons involved in the prescription and administration of nebulised ribavirin.

The procedure was drafted for use within the inpatient Haematology setting. Any area proposing to use nebulised ribavirin must be independently risk assessed.

Ribavirin is a broad spectrum antiviral agent which inhibits a wide range of DNA and RNA viruses by disrupting viral protein synthesis. Virazole® (ribavirin for inhalation) is licensed for treatment of infants and children with severe Respiratory Syncytial Virus (RSV) bronchiolitis. It is used off licence for treatment of viral chest infections including RSV and Para-influenza in adults, often within the bone marrow transplant setting in immunocompromised patients. Treatment with nebulised ribavirin is usually given for between 3 and 7 days.

## 2.0 HEALTH AND SAFETY CONSIDERATIONS

2.1 Ribavirin is classed as a “Substance Hazardous to Health” under the statutory requirements of the COSHH regulations 1994 and the Approved Code of Practice for Carcinogens. Under the regulations, the risk of exposure to ribavirin must be reduced to “as low a level as is reasonably practicable” where use cannot be eliminated.

2.2 The senior nurse on the ward must risk assess the patient and environment before treatment with nebulised ribavirin is commenced. If there is reasonable cause for concern, he/she may decline to allow the administration of nebulised ribavirin. For example if the patient requires regular nursing intervention such as intravenous medication, or is unable or unwilling to sit for 2 hours with nebuliser in situ.

2.3 The decision whether to administer ribavirin or not must be reviewed on a daily basis by the prescribing consultant and senior nurse on the ward.

2.4 In a number of studies, healthcare workers have reported experiencing increased headache, nausea, dizziness and eye irritation during **prolonged** exposure to nebulised Ribavirin, however other studies state that healthcare workers did not report any adverse reactions.

-Healthcare workers who suspect, or know, that they are pregnant or who are breastfeeding should not reconstitute or administer nebulised ribavirin. In addition, they must not enter the patient's room during administration of nebulised ribavirin or for 15 minutes following completion.
-Staff known to suffer from asthma should not enter the patient's room whilst the nebulised ribavirin is being administered or for 15 minutes following administration.

-Contact lens wearers should be aware that nebulised ribavirin has been reported as leaving deposits on contact lenses which may cause eye irritation. They are strongly advised to wear spectacles if nursing patients receiving nebulised ribavirin, both during the period of administration and for 15 minutes following administration. If contact lenses are worn, the company recommends that tight fitting goggles are used.

2.5 All staff involved in the direct care of patients receiving nebulised ribavirin must inform the senior nurse on duty if they experience any adverse effects attributable to ribavirin whilst caring for such patients. The senior nurse will

- complete a clinical incident form, and
- refer the staff member to the Occupational Health department for advice.

## 3.0 PLANNING THE USE OF NEBULISED RIBAVIRIN

3.1 Planning for the use of nebulised ribavirin is important due to the associated health and safety risks and the need for nurses trained in administration of ribavirin to care for these patients.

3.2 Ribavirin MUST be prescribed by a consultant, after discussion between the medical team and microbiology/virology when it is agreed that there is no clinically effective alternative. This must be documented in the patient health record.

3.3 The patient must be provided with information about the benefits and risks of this unlicensed treatment and provide informed consent prior to progressing. This must be documented in the patient health record.

3.4 The senior nurse on the ward must assess:

- ward staffing levels for the period of ribavirin administration
- availability of suitably trained staff for preparation and administration of treatment and cleaning of the room (note- staff can expect any health concerns to be treated in confidence by the senior nurse)
- availability of a single cubicle (which is NOT under positive pressure)
- ability of the patient to comply with restrictions required for treatment.

3.5 The following must be informed of use of nebulised ribavirin and, where appropriate, of the restrictions and instructed to get advice from the senior nurse on duty as to when it is safe to enter the room:

- the ward sister/charge nurse
- occupational health department
- all staff caring for the patient
- cleaning and catering staff
- visitors to the patient

Note- Patient confidentiality must be maintained at all times and no information offered which could compromise patient trust.

3.6 If the patient's condition is serious enough to require constant nurse assistance then the administration of nebulised ribavirin must be reviewed by the senior nurse on duty and attending consultant in line with health and safety requirements.

## 4.0 STAFF TRAINING

All ward staff involved in the administration of nebulised ribavirin must be familiar with this procedure, and trained in the correct use of equipment, including the Aiolos nebuliser for Virazole®(ribavirin).
Formal training sessions on the correct use of the equipment will be provided on a regular basis and coordinated by the ward sister/charge nurse.
Attendance at training sessions will be documented and a record held on a Health board database. Once staff have received appropriate training they will be expected to care for patients receiving nebulised ribavirin in the same way as any other patient. The only exception will be where there is a recognized documented health risk. .

## 5.0 PRESCRIBING INFORMATION

5.1 The licensed dose of nebulised ribavirin is 6g administered over 12-18 hours within a 24hour period. Within the haematology unit, Cardiff and Vale University Health Board the dose will be split into 3 x 2g doses, each over 2 hours period, leaving a minimum of 4-6 hours between each dose. Due to measurability the 2g dose is prescribed at 1980mg.

## Sample prescription (adults)

| Date → | | | | MEDICINE (approved Name) | SPECIAL INSTRUCTIONS | Prescriber's signature | Pharm |
|---|---|---|---|---|---|---|---|
| Route → | | Nebulised | | RIBAVIRIN | 1980mg in 33ml. Run nebuliser solution at 17.5ml/hr for 2 hours discard remaining solution. Air flow 7 Litres/min | *J Bloggs* (Consultant) | *JB* Supply |
| Specify Time required ↓ | | Dose ↓ | Sign / Dose Change ↓ | | | | |
| | | | | FOR NEBULISATION ONLY | | | |
| Morning | ✓ (6-8am) | 1980mg in 33ml | | | | | |
| Midday | ✓ (12-2pm) | 1980mg in 33ml | | | | | |
| Evening | | | | | | | |
| Bedtime | ✓ (9-11pm) | 1980mg in 33ml | | | | | |
| | | | | | | | |

### 6.0 PROCEDURE FOR TREATMENT PREPARATION AND ADMINISTRATION

6.1 Assemble required equipment:

- Ribavirin 6g in 100ml vial or Ribavirin 1980mg in 33ml prepared in pharmacy.
- Aiolos nebuliser
- Elephant tubing
- Baxter Control-A-Flo set (ref code EMC5908P)
- Oxygen mask and tubing or nebulizer mask and tubing
- Empty 125ml TPN infusion bag (kept with Aiolos device) (only required if nurse reconstituting)

6.2 Nebulised ribavirin should be prepared in pharmacy within working hours. Pharmacy will provide 1980mg in 33ml in an infusion bag.

6.3 Where treatment is required to start urgently **out of hours**, the following method may be used to prepare on the ward. Add 50mls of water for injection to a ribavirin vial (6g). Shake well until dissolved then inject into an empty infusion bag.

A further 50mls of water for injection should then be added to the infusion bag, making a total of 6g ribavirin in 100mls water for injection. Label bag clearly FOR NEBULISATION ONLY. It will be nebulised at a rate of 17.5ml/hr for 2 hours, any solution remaining (which will be approximately two thirds) at the end of the nebuliser period must be discarded IN A CYTOTOXIC BIN.

6.4 Assemble the Aiolos nebuliser as directed in Appendix (NB the insert tube at the top is not required) Attach the metal clamp to the blue part, also using a cable tie often provides solid support for the device

6.5 Remove the Baxter Control-A-Flo infusion set from its outer wrapping.

6.6 Insert the spike of the Baxter Control-A-Flo set into the polyfusor port of the ribavirin infusion bag (twist until in up to the ridge on the spike). Mix well. Hang on drip stand.

6.7 Squeeze the drip chamber until it is approx half full. Keep clamp on and remove luer lock end

6.8 Attach the end of the Baxter Control-A-Flo infusion set to the yellow reservoir on the nebuliser and fill to approx 1-2ml line by turning the rate to prime and opening and closing the clamp. Do not overfill the chamber as this is the most common cause of problems during treatment. Turn the rate down to 17.5ml/hr for the period of nebulisation.

6.9 Attach the nebuliser to the drip stand using the large metal clamp. **Avoid** attaching to an IV stand which is being used for IV infusions to ensure that IV and nebulisation equipment is kept separate.

6.10 Connect the elephant tubing (which will deliver the nebulised solution via the mask) to the blue vent at the top of the Aiolos nebuliser and attach the other end to a face mask. The elephant tubing should never be longer than 78 cm.

6.11 Connect the oxygen/air tubing to the red part of the Aiolos nebuliser device (silver coloured connection) by 1st opening the valve on the red lower part of the nebuliser by turning anticlockwise, then attach the thin clear plastic tubing to this valve and tighten by turning clockwise. Attach the other end to the oxygen or turbo air nebuliser on the ward. Set the flow to 7 L/min if using ward air or oxygen.

6.12 A warning notice must be placed on the cubicle door, informing staff and visitors of the exclusion criteria and that no-one should enter the room without the express permission of the senior nurse on duty.

6.13 Internal air vents from the room should not be covered or sealed. External windows must remain sealed at all times. Ribavirin should only be administered in a neutral pressure or negative pressure room, the only occasion you may consider a positive pressure room is with a scavenger system in use.

6.14 Entry to the room should be restricted to essential patient contacts only. Anyone entering the room must use a correctly-fitted disposable mask (see section 7 on protective clothing for further information).

6.15 Requirements for nurse assistance during the period of administration must be limited by ensuring that blood products and other drugs (where possible) are administered prior to the commencement of nebulised ribavirin. Ensure patient has access to call bell so that they can attract staff if they need to.

6.16 At the end of the treatment period a member of staff wearing appropriate protective clothing (see section 7) should enter the room and ensure that the nebuliser is switched off. It is also possible to educate the patient on the treatment and they can turn the treatment off themselves. Where possible, the member of staff should then leave the room for a further 15 minutes before re-entering. This will help minimize exposure to ribavirin particles which may remain in the air for a short while following administration.

Notes:
The administration of nebulised Ribavirin via the Aiolos nebuliser requires the continuous filling of the nebuliser reservoir. This is achieved by using an iv infusion bag, and an iv giving set. To minimize the risk of error, the nebuliser solution and line must be clearly labeled.
Label the bag containing the solution 'RIBAVIRIN FOR NEBULISED USE ONLY'
Label the giving set at the top and bottom. Labelling should be in capital letters, preferably in red ink.

The only infusion set which may be used is the Control-A-flow, a supply of which will be found with the Aiolos sets. If no Control-A-Flow sets are available, the advice of the senior nurse on duty MUST be sought.

None of the above recommendations should be seen as a substitute for nurse awareness and vigilance of the potential risks.

## 7. PROTECTIVE CLOTHING

7.1 For the duration of, and for at least 30 minutes following the treatment, all staff and visitors entering the patient's room must wear appropriate respiratory protective masks (3M 8835 "duck bill"), goggles, disposable apron and gloves.

7.2 Masks must be worn as per the instructions on the box. Also, when removing the mask the orange "respirator' part should not be touched. Rather, the retaining elastic band should be snapped.

7.3 When reconstituting Ribavirin staff must wear the mask, disposable apron, gloves and goggles.

7.4 After each administration surfaces should be wiped with the IMPI wipes available in cubicle. When cleaning the room, apron and gloves should be worn.

## 8. CLEANING OF EQUIPMENT, ROOM AND DISPOSAL OF LINEN

8.1 Until the area has been cleaned and cleared protective clothing should be worn (see section 7).

8.2 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 and disposed of as per the procedure for Cytotoxic waste. Any unused ribavirin must be disposed of in the cytotoxic sharps bin.

8.3 All protective clothing and equipment must be placed in a cytotoxic clinical waste bag which should be swan-necked and cable tied.

8.4 After 3 nebulisations, the Aiolos device must be thoroughly washed in copious amounts of soapy water and then rinsed in sterile water. This should take place in the patient's room. At the end of a treatment period (ie once Ribavirin is no longer required for that patient) the Aiolos must be discarded.

***NB The Aiolos is for single patient use only. It must be washed as stated above after every third use (or more if required) and discarded at the end of the course of treatment.***

8.5 Any spillage/leakage of Ribavirin must be cleared using the Cytotoxic spillage kit
available on the ward (see section 9). Any spillage must be reported on a Trust Clinical Incident Form.

8.6 All bed linen should be changed at least once daily, as should the patients clothing. The dirty linen should be placed in a red "dirty linen" bag.

8.7 The patient's room should be cleaned at least at least daily with hot soapy water and actichlor as per health board policy.

Housekeeping staff should not enter the room for at least 30 minutes after the Ribavirin nebulisation has been stopped.

- all surfaces, including the locker, drip-stands and bed should be wiped over with a damp disposable cloth.
- the room should be cleaned using a mop and hot soapy water.
- dry brushing should not be performed.
- the ventilation grill within the room should be wiped with a damp disposable cloth to remove any deposits.

8.8 Cleaning materials should be disposed of in the following way:
- paper towels and disposable cloths should be placed in a yellow clinical waste bag.
- mop heads should be laundered after use.
- used water should be poured down the sink/toilet in the patient's room.

## 9. PROCEDURE FOR DEALING WITH SPILLAGE

In the event of a spillage the cytotoxic spillage kit must be used and the Health Board's cytotoxic spillage procedure followed.

All spillages/equipment failures must be reported using the clinical incident report form. The incident should also be reported to the occupational health department and health & safety advisor.

Appendix

Aiolos Nebuliser for Virazole® (ribavirin) Aerosol

## 5. Assembly instructions and spare part list for Aiolos nebuliser for Virazole®

1. Press insert tube down into nebuliser upper part.
2. Press baffle cap firmly into nebuliser upper part.
3. Screw medicine reservoir into nebuliser upper part.
4. Assemble nozzle. The two parts snap together.
5. Check that the black O-ring is properly located.
6. Press the nozzle assembly into the medicine reservoir.
7. Check that the black O-ring is correctly located in the groove of the nebuliser lower part.
8. Screw the nebuliser lower part into the medicine reservoir.

Attachment of hose between nebuliser and driving pressure source:

1. Screw in the hose connector nut on the nebuliser as far as possible
2. Attach the hose.
3. Unscrew the nut so that it locks the hose.
4. Connect the hose to the pressure source in a similar way.