

RISVAN® (RISPERIDONE)

MODIFIED RELEASE POWDER FOR INJECTION AND DILUENT

Instructions for Use for Healthcare Professionals

Please read complete instructions before using RISVAN.

RISVAN 75 mg

Single use device

1. CHECK CONTENTS

Working on a clean surface, open the sachets and discard the desiccant pack.

The kit box of RISVAN contains:

One aluminium foil pouch with a **RISVAN Powder** pre-filled syringe with a WHITE plunger rod and WHITE finger flange.

The syringe is marked with .

One aluminium foil pouch with **DILUENT** for RISVAN pre-filled syringe with a TRANSPARENT plunger rod and a RED

finger flange. The syringe is marked with .

Two administration needles (21G, 1 inch for deltoid [green cap] and a 20G, 2 inch for gluteus [yellow cap]).

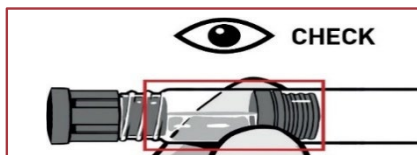
Discard the kit if any component is damaged.

In the event of any foreign particulate matter and/or variation of physical aspect is observed, do not administer RISVAN.

1.1 Inspect DILUENT syringe

ENSURE that **DILUENT** syringe content flows normally as a liquid.

If it is frozen or partially frozen, warm it until it is completely thawed by rolling the syringe between both hands.



1.2 Dislodge RISVAN powder syringe

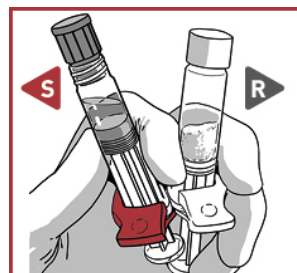
TAP the **RISVAN Powder** syringe to dislodge potential packed powder near the cap.



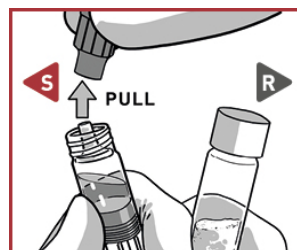
2 CONNECT THE SYRINGES

2.1 Uncap syringes in upright position

Hold both syringes in upright position to prevent loss of product.



PULL the cap off the **DILUENT** syringe .



TWIST and PULL the **RISVAN Powder** syringe

cap off.



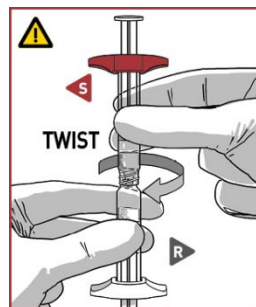
2.2 Connect the syringes

Pick the **DILUENT** syringe that has the coloured finger flange and place it on TOP of the **RISVAN Powder**

syringe , or slightly lean it when connecting.

TWIST the syringes together until you feel a slight resistance.

Make sure that the **RISVAN Powder** syringe is in the upright position to prevent loss of product.



3. MIX THE CONTENTS

STOP AND READ THIS SECTION BEFORE STARTING OR THE MEDICINE MAY NOT CORRECTLY RECONSTITUTE.

PUSH VIGOROUSLY the **DILUENT** content towards the

RISVAN Powder syringe 

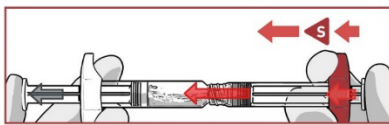
DO NOT WAIT for powder wetting and **QUICKLY START MIXING** contents by pushing the plungers **FAST** and alternately for **100 pushes (2 pushes within 1 second, approximately 1 minute)**.

ENSURE medicine is passing between both syringes for a **proper mix: medicine is viscous** and you will need to apply force when pressing on the plunger rods.

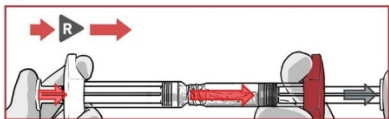
Mix for at least 100 pushes by doing alternately

1 followed by **2**.

1 **PUSH**  (color flange)



2 **PUSH** 



100 pushes  approx. 1 min
(2 pushes /second)

Make sure medicine is passing between both syringes.


When medicine is correctly mixed, the appearance will be a uniform suspension off white to yellowish colour and thick consistency.




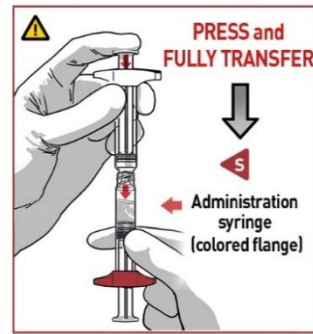
Once reconstituted, proceed immediately to prepare the injection syringe for administration to avoid loss of homogeneity.

4. PREPARE INJECTION SYRINGE

4.1 Transfer medicine

Place downward pressure on the **RISVAN Powder**  plunger rod and transfer all the content into the **DILUENT**

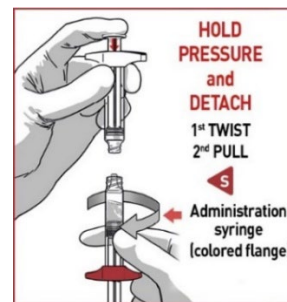
syringe  that has attached the coloured finger flange. **Make sure all the content is transferred.**



4.2 Detach syringes

Once the medicine is fully transferred, separate the two syringes by untwisting.

RISVAN should be administered immediately to avoid loss of homogeneity.



4.3 Attach the sterile needle with safety shield

Choose the proper needle:

Deltoid: 21G, 1 inch for deltoid (green cap).

Gluteus: 20G, 2 inches for gluteus (yellow cap).

Attach it using a clockwise twisting motion. Do not over-tighten.

4.4 Remove exceeding air

Remove needle cover and push out the excess of air (only big bubbles) from the syringe barrel.

DO NOT expel any drops of medicine.

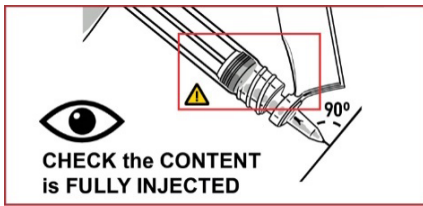
If medicine is seen at the needle tip, pull back slightly on the plunger to prevent medicine spillage.



5. ADMINISTER AND DISPOSE

5.1 Inject medicine

Insert the needle fully into the muscle. **DO NOT INJECT BY ANY OTHER ROUTE.**



THICK MEDICINE. MAKE SURE TO FULLY INJECT IT.

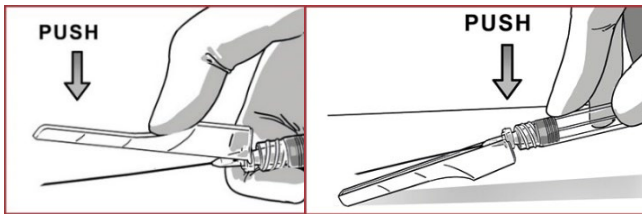
The injection time is longer than usual due to the viscosity of the medicine.

Wait a few seconds before removing the needle.

Avoid inadvertent injection into a blood vessel.

5.2 Dispose medicine

Cover the needle pressing on the needle guard using a finger or a flat surface and dispose immediately in a secure sharps disposal container.



RISVAN 100 mg


Single use device


1. CHECK CONTENTS

Working on a clean surface, open the sachets and discard the desiccant pack.

The kit box of RISVAN contains:

One aluminium foil pouch with a **RISVAN Powder** pre-filled syringe with a **WHITE** plunger rod and **WHITE** finger flange.

The syringe is marked with .


One aluminium foil pouch with **DILUENT for RISVAN POWDER** pre-filled syringe with a **TRANSPARENT** plunger rod and a **BLUE** finger flange. The syringe is marked with .

Two administration needles (21G, 1 inch for deltoid [green cap] and a 20G, 2 inch for gluteus [yellow cap]).

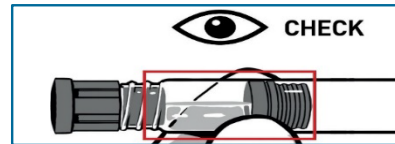
Discard the kit if any component is damaged.

In the event of any foreign particulate matter and/or variation of physical aspect is observed, do not administer RISVAN.


1.1 Inspect DILUENT syringe

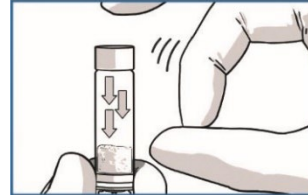
ENSURE that **DILUENT** syringe  content flows normally as a liquid.

If it is frozen or partially frozen, warm it until it is completely thawed by rolling the syringe between both hands.



1.2 Dislodge powder syringe

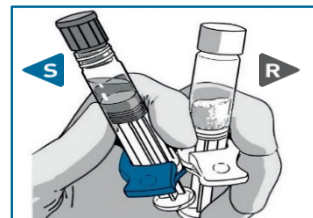
TAP the **RISVAN Powder** syringe  to dislodge potential packed powder near the cap.




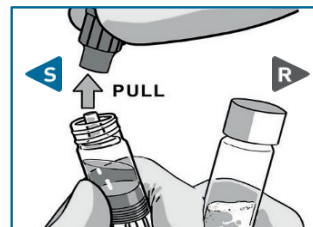
2 CONNECT THE SYRINGES


2.1 Uncap syringes in upright position

Hold both syringes in **upright position** to prevent loss of product.





PULL the cap off the **DILUENT** syringe .



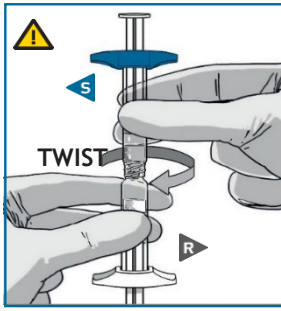
TWIST and PULL the **RISVAN Powder** syringe  cap off.



2.2 Connect the syringes

Pick the **DILUENT** syringe  that has the coloured finger flange and place it on **TOP** of the **RISVAN powder** syringe , or slightly lean it when connecting. TWIST the syringes together until you feel a slight resistance.

Make sure that **RISVAN Powder** syringe **R** is in the upright position to prevent loss of product.



3. MIX THE CONTENTS

STOP AND READ THIS SECTION BEFORE STARTING OR THE MEDICINE MAY NOT CORRECTLY RECONSTITUTE.

PUSH VIGOROUSLY the **DILUENT** content towards the **RISVAN Powder** syringe **R**.

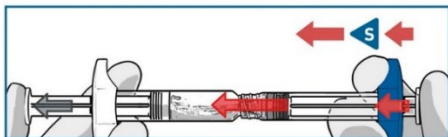
DO NOT WAIT for powder wetting and **QUICKLY START MIXING** contents by pushing the plungers **FAST** and alternately for **100 pushes (2 pushes within 1 second, approximately 1 minute)**.

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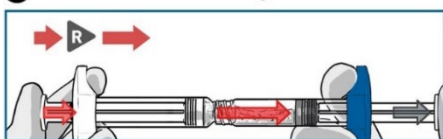
Mix for at least 100 pushes by doing alternately

1 followed by 2.

1 **PUSH** **S** (color flange)



2 **PUSH** **R**



100 pushes
(2 pushes /second)  approx. 1 min

Make sure medicine is passing between both syringes.

When medicine is correctly mixed, the appearance will be a uniform suspension off white to yellowish colour and thick consistency.

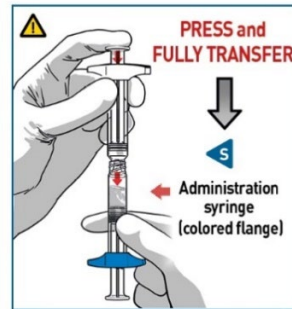


Once reconstituted, proceed immediately to prepare the injection syringe for administration to avoid loss of homogeneity.

4. PREPARE INJECTION SYRINGE

4.1 Transfer medicine

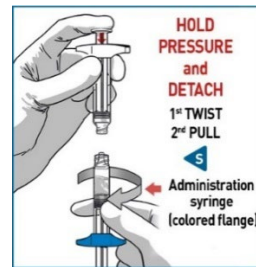
Place downward pressure on the **RISVAN Powder** **R** plunger rod and transfer all the content into the **DILUENT** syringe **S** that has attached the coloured finger flange. **Make sure all the content is transferred.**



4.2 Detach syringes

Once the medicine is fully transferred, separate the two syringes by untwisting.

RISVAN should be administered immediately to avoid loss of homogeneity.



4.3 Attach the sterile needle with safety shield

Choose the proper needle:

Deltoid: 21G, 1 inch for deltoid (green cap).

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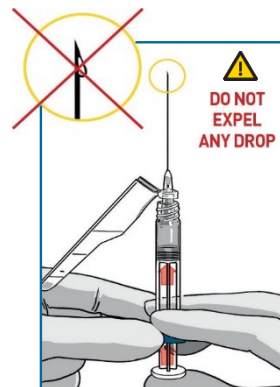
Attach it using a clockwise twisting motion. **Do not over-tighten.**

4.4 Remove exceeding air

Remove needle cover and push out the excess of air (only big bubbles) from the syringe barrel.

DO NOT expel any drops of medicine.

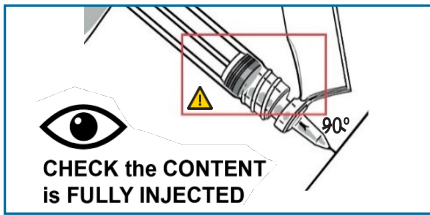
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