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THE SAUDI ASSOCIATION FOR PULMONARY HYPERTENSION

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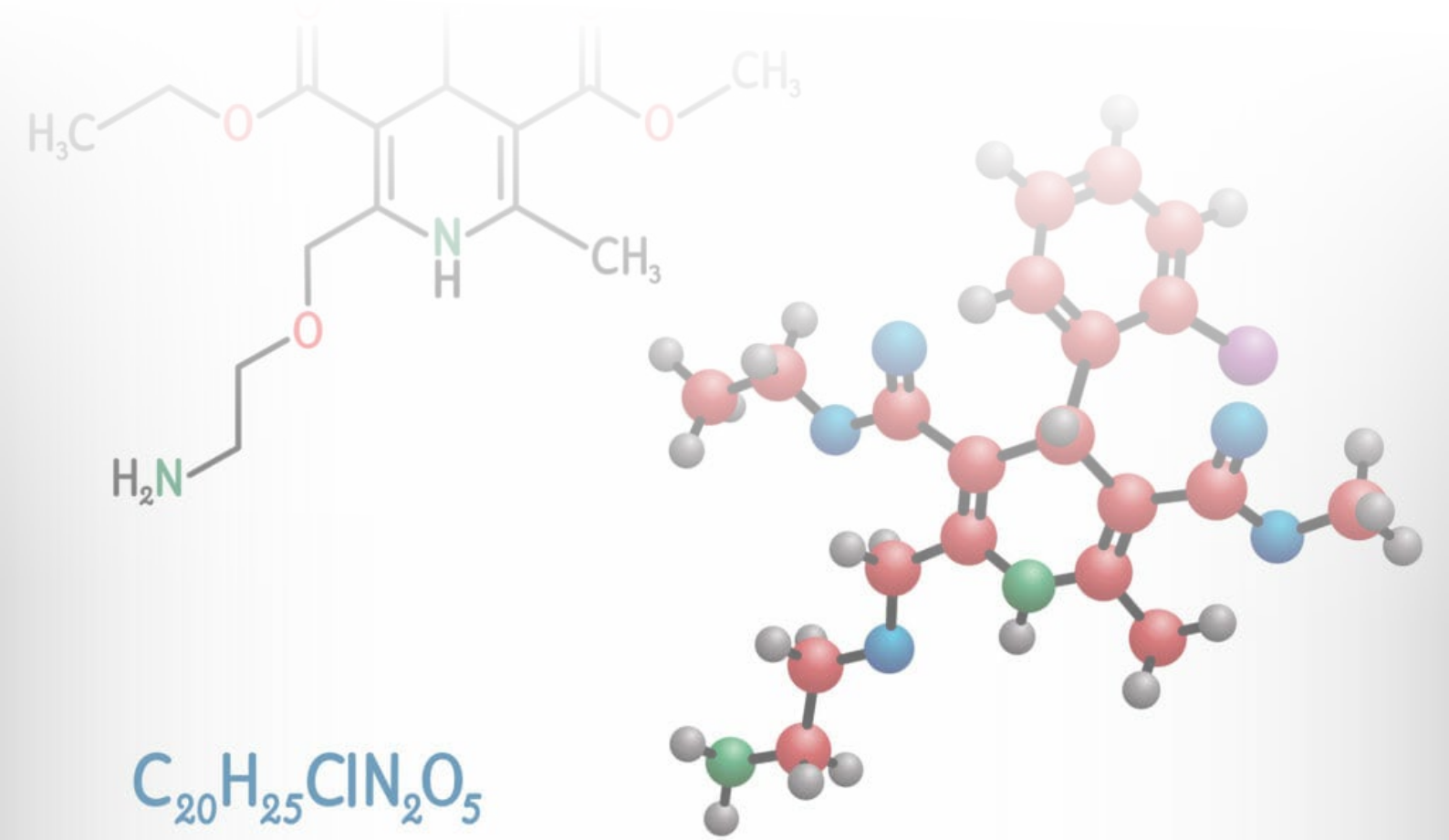
WORKSHOP

TREPROSTINIL ADMINISTRATION

(INTRAVENOUS ROUTE)



FACTS ABOUT TREPROSTINIL NA

Mechanism of Action	It is a prostacyclin, a potent pulmonary vasodilator and has antiproliferative effect
Half life	Relatively short ~4 hours[1] The longest among all parenteral prostacyclin approved for PAH
Routes of Administration	Continuous SubQ (undiluted) & stable for 14 days[1] continuous IV (diluted with NS) infusion stable for 24 hours[1]
Available Strengths	Two strengths: 5mg/mL and 10 mg/mL
Shelf life	Shelf life of the medicinal product as packaged for sale: 3 years Shelf-life of vial after first opening: 30 days at 30 °C

THERAPEUTIC INDICATIONS

Treatment of idiopathic or heritable pulmonary arterial hypertension (PAH) to improve exercise tolerance and symptoms of the disease in patients classified as New York Heart Association (NYHA) functional class III.

POSOLOGY AND METHOD OF ADMINISTRATION

Trisuva is administered by continuous subcutaneous or intravenous infusion. Due to the risks associated with chronic indwelling central venous catheters, including serious blood stream infections, subcutaneous infusion (undiluted) is the preferred mode of administration and continuous intravenous infusion should be reserved for patients stabilized with treprostinil subcutaneous infusion and who become intolerant of the subcutaneous route, and in whom these risks are considered acceptable

Since treprostinil Na is thermostable at room temperature which means no need to use ice bags or refrigeration

The treatment should be initiated and monitored only by clinicians experienced in the treatment of Pulmonary hypertension.

ADMINISTRATION BY CONTINUOUS INTRAVENOUS INFUSION

Trisuva is administered by continuous intravenous infusion, via a central venous catheter, using an ambulatory infusion pump. It may also be administered temporarily via a peripheral venous cannula, preferably placed in a large vein. Use of a peripheral infusion for more than a few hours may be associated with an increased risk of thrombophlebitis (see section 4.8).

In order to avoid potential interruptions in drug delivery, the patient must have access to a backup infusion pump and infusion sets in the event that the administration equipment malfunctions.

In general, the ambulatory infusion pump used to administer diluted Treprostinil Na intravenously should:

1. be small and lightweight,
2. be capable of adjusting infusion rates in increments of approximately 0.05 ml/h. Typical flow rates would be between 0.4 ml and 2 ml per hour;
3. have occlusion / no delivery, low battery, programming error and motor malfunction alarms,
4. have delivery accuracy of ±6% or better of the hourly dose
5. be positive pressure driven. The reservoir should be made of polyvinyl chloride, polypropylene or glass.

Trisuva should be diluted with either sterile Water for Injection or 0.9% (w/v) Sodium Chloride for Injection and is administered intravenously by continuous infusion, via a surgically placed indwelling central venous catheter or temporarily via a peripheral venous cannula, using an infusion pump designed for intravenous drug delivery.

When using an appropriate infusion pump and reservoir, a predetermined intravenous infusion rate should first be selected to allow for a desired infusion period. The maximum duration of use of diluted Trisuva should be no more than 24 hours

MINIMIZING THE RISK OF CATHETER RELATED BLOOD STREAM INFECTIONS

Particular attention must be given to the following to help minimize the risk of catheter related blood stream infections in patients that are receiving treprostinil via intravenous infusion (see section 4.4). This advice is in accordance with the current best practice guidelines for the prevention of catheter-related blood stream infections, and includes:

General Principles

- Use of a cuffed and tunneled central venous catheter (CVC) with a minimum number of ports.
- Insertion of the CVC using sterile barrier techniques.
- Use of proper hand hygiene and aseptic techniques when the catheter is inserted, replaced, accessed, repaired or when the catheter insertion site is examined and/or dressed.
- A sterile gauze (replaced every two days) or sterile, transparent, semi-permeable dressing (replaced at least every seven days) should be used to cover the catheter insertion site.
- The dressing should be replaced whenever it becomes damp, loosened, or soiled or after examination of the site
- Topical antibiotic ointments or creams should not be applied, as they may promote fungal infections and antimicrobial-resistant bacteria.

Duration of use of diluted Trisuva solution

- The maximum duration of use of the diluted product should be no more than 24 hours

Use of in-line 0.2-micron filter

- A 0.2-micron filter must be placed between the infusion tubing and the catheter hub and replaced every 24 hours at the time of changing the infusion reservoir

Two further recommendations, that are potentially important for the prevention of water-borne Gram-negative blood stream infections, relate to management of the catheter hub. These include:

Use of a split septum closed hub system

- The use of a closed-hub system (preferably a split septum rather than a mechanical valve device), ensures that the lumen of the catheter is sealed each time the infusion system is disconnected. This prevents the risk of exposure to microbial contamination
-The split-septum closed-hub device should be replaced every 7 days.

Infusion system Luer lock inter-connections

The risk of contamination with water-borne Gram-negative organisms is likely to be increased if a Luer lock inter-connection is wet at the time of exchanging either the infusion line or the closed hub Therefore:

- Swimming and submersion of the infusion system at the site of connection with the catheter hub should be discouraged
- At the time of replacing the closed hub device there should not be any water visible in the Luer-Lock connection threads
- The infusion line should only be disconnected from the closed hub device once every 24 hours at the time of replacement.

SUMMARY OF ESSENTIAL PATIENT TRAINING:

- Hand hygiene
- Area preparation
- Maintenance and observation of catheter insertion site and its dressing
- The importance and use of in-line filters & closed-hub systems
- The importance of maintaining dry connection hubs and the use of waterproof dressings or wraps when bathing or showering1
- The importance of avoiding swimming or other direct risks of water contact with the infusion connections or dressing
- Awareness of the signs of suspected CR-BSIs and system-related drug adverse events, and timely reporting of these to their Healthcare Professional