תאריך : יוני 2023

הנדון:

<u>Flolan Infusion of Epoprostenol 1500 mcg / פלולן אפופרוסטנול 1500 מק"ג לעירוי</u>
<u>Flolan Infusion of Epoprostenol 500 mcg / פלולן אפופרוסטנול 500 מק"ג לעירוי</u>
<u>Epoprostenol (as sodium) 0.5 mg / vial</u>
<u>Epoprostenol (as sodium) 1.5 mg / vial</u>
<u>Powder for solution for infusion</u>
<u>I.V</u>

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשירים:
.Flolan Infusion of Epoprostenol 500&1500 mcg

ההתוויה הרשומה לתכשירים בישראל:

Flolan is indicated for the treatment of pulmonary arterial hypertension (PAH) (idiopathic or heritable PAH and PAH associated with connective tissue diseases) in patients with WHO Functional Class III-IV symptoms to improve exercise capacity.

לשימת ליבכם, עדכון העלון לרופא כולל שינויים נוספים. בהודעה זו מצויינים השינויים המהותיים בלבד.
למידע נוסף יש לעיין בעלון לרופא המעודכן.

<u>מקרא לעדכונים המסומנים:</u>
תוספת טקסט - כתב **כחול**
תוספת החמרה - כתב **כחול**

<u>עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:</u>

6.6 Special precautions for disposal and other handling

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Reconstitution, dilution and calculation of infusion rate:

Particular care should be taken in the preparation of the infusion and in calculating the rate of infusion. The procedure given below should be closely followed.

<u>Flolan Infusion of Epoprostenol 500 mcg</u>
There are two 0.5 mg packs available for use in the treatment of pulmonary arterial hypertension, as follows:

- One vial containing sterile, freeze-dried Flolan equivalent to 0.5 mg Flolan, supplied with one 50 mL vial of solvent and a filter unit.
- One vial containing sterile, freeze-dried Flolan equivalent to 0.5 mg Flolan, supplied with two 50 mL vials of solvent and a filter unit.

<u>Flolan Infusion of Epoprostenol 1500 mcg</u>
There is one 1.5 mg pack available for use in the treatment of pulmonary arterial hypertension, as follows:

- One vial containing sterile, freeze-dried Flolan equivalent to 1.5 mg Flolan, supplied with two 50 mL vials of solvent and a filter unit.

Initially a pack containing solvent for parenteral use must be used. During chronic Flolan therapy higher concentrated solutions may be required. The final concentration of the solution may be increased by the addition of further 0.5 mg or 1.5 mg vials of freeze-dried Flolan.

Only vials of the same amount of freeze-dried Flolan as that included in the initial starter pack may be used to increase the final concentration of solution.

Reconstitution:

1. Use only the sterile solvent solution provided for reconstitution.

2. Withdraw approximately 10 mL of the sterile solvent solution into a sterile syringe, inject it into the vial containing the freeze-dried epoprostenol and shake gently until the powder has dissolved.

3. Draw up the resulting epoprostenol solution into the syringe, re-inject it into the remaining volume of the sterile solvent solution and mix thoroughly.

This solution is now referred to as the concentrated solution.

- Where a pack containing 0.5 mg epoprostenol is reconstituted with 50 mL sterile solvent the resultant concentration is 10,000 nanograms/mL epoprostenol.

- Where a pack containing 1.5 mg epoprostenol is reconstituted with 50 mL sterile solvent the resultant concentration is 30,000 nanograms/mL.

Dilution:

Flolan may be used either as a concentrated solution or in a diluted form for the treatment of pulmonary arterial hypertension. Only concentrated solutions are suitable for further dilution with the sterile solvent prior to use.

Only the solvent provided may be used for the further dilution of reconstituted Flolan. Sodium chloride 0.9% w/v solution must not be used when Flolan is to be used for the treatment of pulmonary arterial hypertension as the required pH is not maintained. Flolan solutions are less stable at low pH. Flolan must not be administered with other parenteral solutions or medications when used for pulmonary arterial hypertension.

The final solution to be administered to the patient must be filtered using a 0.22 or 0.20 micron filter. Use of an in-line filter as part of the infusion set during administration is preferable. Alternatively, where in-line filtration is not possible, the final solution (either as concentrated or further diluted solution) must be filtered with the provided sterile 0.22 micron filter prior to storage in the medication cassette using firm but not excessive pressure; the typical time taken to for filtration of 50mL of solution is 70 seconds.

If an in-line filter has been used during administration, then the in-line filter should be discarded when the infusion set is exchanged.

If instead a syringe filter has been used during preparation, the syringe filter unit must be used only during preparation and then discarded.

Concentrations commonly used in the treatment pulmonary arterial hypertension are as follows:

<u>Flolan Infusion of Epoprostenol 500 mcg</u>

- 5,000 nanograms/mL - One vial containing 0.5 mg Flolan reconstituted and diluted to a total volume of 100 mL in solvent.

- 10,000 nanograms/mL - Two vials containing 0.5 mg Flolan reconstituted and diluted to a total volume of 100 mL in solvent.

<u>Flolan Infusion of Epoprostenol 1500 mcg</u>

- 15,000 nanograms/mL - 1.5 mg Flolan reconstituted and diluted to a total volume of 100mL in solvent.

- 30,000 nanograms/mL - Two vials containing 1.5 mg Flolan reconstituted and diluted to a total volume of 100 mL in solvent.

Calculation of infusion rate:

The infusion rate may be calculated from the following formula:

$$\text{Infusion rate (mL/min)} = \frac{\text{dosage (nanogram/kg/min) x bodyweight (kg)}}{\text{concentration of solution (nanogram/mL)}}$$

Infusion rate (mL/h) = Infusion rate (mL/min) x 60

For Examples of some concentrations commonly used in pulmonary arterial hypertension please refer to the full physician leaflet.

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העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug וניתן לקבלו מודפס על-ידי פניה לחברת גלקסוסמיתקליין
רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,

עינת טל
רוקחת ממונה