

## DivibaX® - 63170031

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### Product Description

Connection device for mixing powders and fluids between vials and IV-container.

DivibaX® is not intended to be connected to any active medical device.



Only for single use (disposable).

### Usage of the Device

Correct usage of the DivibaX® device is illustrated in the instructions for use, see Medical Device Manual for DivibaX®.

DivibaX® is intended for connection with an IV Container and a vial with a 20mm standard neck according to ISO 8362.

The user bears full responsibility for possible incompatibility between the DivibaX® device and liquids, powders and mixtures hereof used together with the device.

### Precautions

The blue Safety ring needs to be pushed towards the IV container in order to ensure a stable connection between the IV Container and the DivibaX® device.

### Storage and Handling



To be stored in the original carton, protected against light and moisture.



Do not use if product sterilisation barrier is compromised.

The cartons must not be subjected to bumps. Handle with care.

### Sterilization



DivibaX® is supplied sterile. Sterilization has been performed by irradiation.

### Marking

All cartons are marked with a label on the outside. This label is shown in figure A.

#### 63170031 (21 pcs. version)

A label is placed on the inner plastic bag. This label is shown in figure B. The bar code label shown in figure A is also placed on the inner plastic bag.

### Expiry Date

The DivibaX® device must be used no later than stated on the label.

### Disposal

The DivibaX® device, IV Container and vial should not be disconnected during disposal.

Incineration is recommended.

### CE Mark



DivibaX® is CE marked according to the Medical Device Directive (MDD).

### Manufacturer



MedicoPack A/S  
Industrivej 6  
DK - 5550 Langeskov  
DENMARK  
Tel.: +45 63 38 10 00  
Fax: +45 63 38 10 01




For further information please contact the manufacturer.

## DivibaX® - 63170031

**FIGURE A**







**63170031 Label on carton**

Product	DivibaX®	REF 63170031	Article number
Lot number	LOT 80063	168 Pcs.	Number of DivibaX® in each carton
Date of manufacture	Date: 2018.10.25	Time: 13:50	Time of manufacture
Packer Initials	Initials: APO/ASI		Keep dry
Manufacturer	 MEDICOPACK A/S INDUSTRIVEJ 6 DK-5550 LANGESKOV, DENMARK		

Product	DivibaX®	REF 63170031	Article number
Expiry date	USE BY 2021-10	STERILE R	Sterile by irradiation
Bar code Article No + Expiry date	 <21>63170031<17>211031		
Manufacturer	 MEDICOPACK A/S INDUSTRIVEJ 6 DK-5550 LANGESKOV, DENMARK		 Consult instructions before use

**FIGURE B**

**63170031 Inside label**

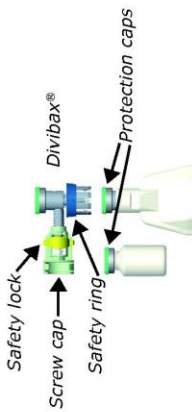
Product	DivibaX®	REF 63170031	Article number
Lot number	LOT 80063	84 Pcs.	Number of DivibaX® in each carton
Date of manufacture	Date: 2018.10.25	Time: 08:26	Time of manufacturer
Packer Initials	Initials: DW	 2018-10	Month of manufacture
CE mark	 0543	 	Do not reuse Keep dry
Manufacturer	 MEDICOPACK A/S INDUSTRIVEJ 6 DK-5550 LANGESKOV, DENMARK		 Consult instructions before use

Product	DivibaX®	REF 63170031	Article number
Expiry date	USE BY 2021-10	STERILE R	Sterile by irradiation
Bar code Article No + Expiry date	 <21>63170031<17>211031		
Manufacturer	 MEDICOPACK A/S INDUSTRIVEJ 6 DK-5550 LANGESKOV, DENMARK		 Consult instructions before use

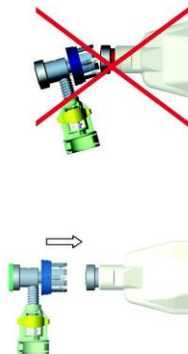
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### Use of the Transfer Device DivibaX®

1. Remove the protection cap from the IV-container and the vial. Disinfect the rubber stoppers of the vial and the IV-container in alcohol. Unpack the DivibaX®



2. The blue safety ring must be pulled up as shown on the drawing. The DivibaX® **must** be fitted on the IV-container vertically and **not** at an angle or askew.



3. Push the blue safety ring downwards to lock it.



4. Push the vial into the green screw cap.



5. Turn the green screw cap clockwise ½ a round (2 clicks) to secure the vial.



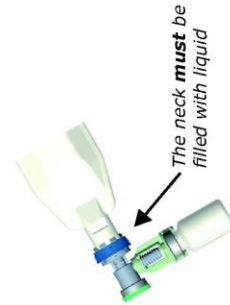
6. Remove the yellow safety lock with the thumb by pushing here.



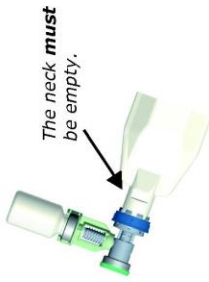
7. Hold on to the green screw cap and turn it **clockwise** to the bottom of the thread.



8. Hold the IV-container at an angle – the vial pointing **downwards** as shown. Pump the liquid into the vial by squeezing the IV-container. Shake until the dry matter is dissolved.



9. Hold the IV-container at an angle – the vial pointing **upwards** as shown. Pump the liquid back into the IV-container. Rinse by pumping the liquid back and forth from the vial to the IV-container. **Repeat item 8 and 9.**



10. Remove the protection cap from the DivibaX®. Disinfect the rubber stopper.



11. Insert the giving set by turning and pushing the spike through the rubber stopper. Make sure the spike is inserted properly.



12. The giving set closes for run-back of liquid to the vial. There may be some liquid left in the DivibaX® (Max. 0.3 ml). The vials stays on during the infusion as documentation (patient safety).

