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## Worldwide Biopharmaceutical Businesses

Date: 7 April 2020

### INFORMATION FOR HEALTHCARE PROFESSIONALS

To: Healthcare Professionals

**Re: Temporary supply of a different presentation in market and changes to the instructions Noradrenaline (Norepinephrine) 4mg/4ml Concentrate For Solution For Infusion (PL 04515/0240)**

- Due to a significant demand increase we are temporarily managing the supply of Noradrenaline (norepinephrine) 4mg/4ml from 7 April 2020 with alternative US product - Levophed Bitartrate Concentrate for Solution for Infusion.
- US vials of Levophed Bitartrate are considered an unlicensed product in the UK
- See table for differences in presentation, dilution, storage conditions, and warnings between products
- Levophed contains sodium metabisulfite (not more than 0.2mg/ml), a sulphite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people
- Please note the expiry of the LEVOPHED 4mg/4ml is July 1 2020.

To help mitigate the national shortfall in supply against demand Pfizer has obtained a non objection from the Medicines and Healthcare products Regulatory Agency (MHRA) to import Pfizer stock of Levophed Bitartrate Concentrate for Solution for Infusion from the US.

The UK Summary of Product Characteristics and Patient Information Leaflet for Noradrenaline (norepinephrine) 4mg/4ml can be found at:

<https://www.medicines.org.uk/emc/product/4115/smpc#companyDetails>

The US Summary of Product Characteristics and Patient Information Leaflet Levophed Bitartrate Concentrate for Solution for Infusion can be found at:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c4de72a8-2a75-4984-ce90-e4870226dc12>

### DIFFERENCES IN PRESENTATION:

For your awareness the key differences between Noradrenaline (Norepinephrine) 4mg/4ml Concentrate for Solution for Infusion (PL04515/0240) and Levophed Bitartrate Concentrate for Solution for Infusion product have been highlighted in the table below.

Table 1. Notable differences between the US and UK product

Distributed by	Hospira Inc USA	Hospira Ltd UK
Product Name	Levophed 4mg base/4ml	Noradrenaline (Norepinephrine) 4mg base/4ml
Primary Container	Vial - 4mL Type I amber tubing glass vial	Ampoule - 4 mL Type I flint glass colourless ampoule Brown colour break
No. of Packs	10 vials of 4mls; Each vial contains 4 ml of concentrate for solution for infusion	5 ampoules of 4ml; Each ampoule contains 4ml of concentrate for solution for infusion.
Dilution details	LEVOPHED should be diluted in 5 percent dextrose injection or 5 percent dextrose and sodium chloride injections. Administration in saline solution alone is not recommended.	Dilute before use with glucose 5% solution or sodium chloride 9 mg/ml (0.9%) with glucose 5 % solution.
Storage Conditions	Store at 20 to 25°C ; excursions permitted to 15 to 30°C . Protect from light.	Do not store above 25°C. Keep ampoules in the outer carton in order to protect from light
Warnings	Contains sodium metabisulfite (Not More Than 0.2mg/ml), a sulfite (sulphite) that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.	Does not contain preservatives

### Further Information

LEVOPHED 4mg/4ml SSOL 1X10 FTV which is the alternative to Noradrenaline 4mg/4ml can be ordered through the new PIP code **8019796** via Alliance Healthcare. **EAN Code is 1030093375043**

**Please note expiry of the LEVOPHED 4mg/4ml is July 1 2020.**

If you have any questions about this letter, please contact Pfizer Medical Information at the following address:

**Medical Information**, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS. United Kingdom. Telephone: **01304 616161** or visit <https://www.pfizermedicalinformation.co.uk/>

Kind regards,

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