



Date: 16-02-2024

Important information for healthcare professionals

Removal of all paediatric indications
Hypovase 0.5 mg tablets,
(prazosin hydrochloride)
PA 0822/195/001

Dear Healthcare professional,

Pfizer Healthcare Ireland would like to inform you of the following:

Following the outcome of Article 45 work-sharing procedure DE/W/081/pdWS/001 for Hypovase 0.5 mg tablets, which concluded that there was insufficient data to support posology in paediatric patients (under 18 years) for any of the licensed indications, it was recommended to delete all indications of paediatric use of prazosin in the Summary of Product Characteristics and Patient Information Leaflet.

To implement the outcome of this procedure, the SmPC has been updated as follows (new text in bold, deleted text in strikethrough):

4.2 Posology and method of administration

...

Paediatric population

The safety and efficacy of Hypovase in the treatment of patients under the age of 18 years has not been established. The use of Hypovase is not recommended in patients under the age of 18 years.

~~*Hypovase is not recommended for the treatment of children under the age of 12 years since safe conditions for its use have not been established.*~~

...

The PIL has been updated in line with these changes.

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to all relevant parties.

This communication has been agreed with the Health Products Regulatory Authority (HPRA).

Breakthroughs that change patients' lives

Reporting of suspected adverse reactions

You can assist us with monitoring the safety of Hypovase by reporting suspected adverse reactions. Suspected adverse drug reactions (ADRs) should be reported to:

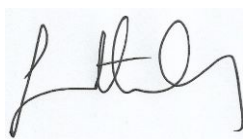
HPRA Pharmacovigilance,

Website: www.hpra.ie

Adverse events should also be reported to Pfizer Medical Information on 1800 633 363.

For any information about this medicine please contact Medical Information at Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland. Telephone 1800 633 363

Yours sincerely,



Garreth Dooley MA, MPharm, MSc, MPSI,
Medical Affairs Scientist,
Pfizer Healthcare Ireland

Annexes:

Hypovase 0.5 mg tablets SmPC