



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD
 ABN: 20 605 457 430
www.propg.com.au

Dear Healthcare Professional,

Shortage of HYDROCORTISONE VIATRIS 20 hydrocortisone 20 mg tablet bottle

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of HYDROCORTISONE VIATRIS 20 hydrocortisone 20 mg tablet bottle in Australia.

The Australian registered medicine, HYDROCORTISONE VIATRIS 20 hydrocortisone 20 mg tablet bottle AUST R: 290098, sponsored by Alphapharm is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **HYDROCORTISONE tablets USP 20mg (Strides)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **31st May 2023** for the following indication(s):

Hydrocortisone is indicated for replacement therapy in Addison's disease or chronic adrenocortical insufficiency secondary to hypopituitarism

HYDROCORTISONE tablets USP 20mg (Strides) is registered and marketed in the USA by Strides, therefore all labelling is in English.

The S19A approved US product is identical in active ingredient and strength to the Australian registered product. A comparison table of differences between the products is given below:

	ARTG product HYDROCORTISONE VIATRIS 20 hydrocortisone 20 mg tablet bottle AUST R: 290098	S19A Product HYDROCORTISONE tablets USP 20mg (Strides)
Excipients	<ul style="list-style-type: none"> lactose monohydrate maize starch macrogol 8000 povidone magnesium stearate 	<ul style="list-style-type: none"> Lactose Monohydrate Cellulose, Microcrystalline Silicon Dioxide Magnesium Stearate
Additional warnings		This medicine contains lactose , this excipient is not declared on the product label.
Pack size	Bottles of 60 tablets	Bottles of 100 tablets
Storage	Store below 30°C	Store at 20° to 25°C

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing, available at: <https://www.ebs.tga.gov.au>.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with HYDROCORTISONE tablets USP 20mg (Strides) must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **HYDROCORTISONE tablets USP 20mg (Strides)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director Pro Pharmaceuticals Group