

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Hydrocortisone 4 mg and 20 mg tablets – 17 February 2023

Details of affected product(s)	Hysone [®] hydrocortisone 4 mg tablet bottle – ARTG 27923 Hysone [®] hydrocortisone 20 mg tablet bottle – ARTG 27926 Viartis [®] hydrocortisone 4 mg tablet bottle – ARTG 290097 Viartis [®] hydrocortisone 20 mg tablet bottle – ARTG 290098
Reason for communication	Disruption to supply due to manufacturing issues.
Date issue made apparent	February 2022
Estimated resolution date	All brands and strengths expected to return by 31 March 2023

Main indications and use

Hydrocortisone (oral) is a corticosteroid commonly used as replacement for cortisol in adrenal insufficiency.

Situation

There is a current disruption to the supply of hydrocortisone (Hysone[®] and Viartis[®]) 4 mg and 20 mg tablets due to manufacturing issues. The product sponsor has advised that the estimated date of return of supply from all brands and strengths is 31 March 2023, although further delays may occur.

Alternative agents

Hydrocortisone is used as glucocorticoid replacement for adrenal insufficiency in which continuation of therapy is essential to ensure patients' cortisol levels are maintained and adrenal crisis is avoided.

There are no alternative brands of hydrocortisone listed on the Australian Register of Therapeutic Goods (ARTG), however there are alternative products registered internationally for the 20 mg product that are available under the Therapeutics Goods Administration Special Access Scheme (SAS) via Orspec Pharma and Reach Pharmaceuticals. These products are registered in Canada and the UK for the same indications as the Australian registered products (further details in table below). There are **no alternative brands available for the 4 mg product** as this product is unique to Australia.

Alternative SAS products (correct at the time of publication. Further SAS alternatives may become available – contact suppliers for additional information).

Supplier	Product details
Orspec Pharma	Hydrocortisone (Auro) 20 mg tablet – Bottle of 100 tablets
Orspec Pharma	Hydrocortisone (Auro) 10 mg tablet – Bottle of 100 tablets
Reach Pharmaceuticals	Hydrocortisone (Accord) 20 mg tablet – Box of 30 tablets

Other alternatives

Cortisone is a pro-drug of hydrocortisone and can be considered as an alternative in consultation with the patient's endocrinologist or relevant treating specialist. It is available as 5 mg and 25 mg tablets and is stocked at the regular suppliers. Note:

- 4 mg of hydrocortisone is equivalent to 5 mg of cortisone
- 20 mg of hydrocortisone is equivalent to 25 mg of cortisone.

Precautions, safety issues and other considerations associated with alternatives

- The ratio of glucocorticoid to mineralocorticoid action of cortisone is 1:1, which is the same as hydrocortisone. This is a critical factor to treat adrenal insufficiency. For more information, refer to a reference from the Allergy, Asthma and Clinical Immunology journal found [here](#).

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- The following features of the hydrocortisone products available under SAS should be considered:

	<i>Hydrocortisone 10 mg – Auro</i>	<i>Hydrocortisone 20 mg – Auro</i>	<i>Hydrocortisone 20 mg – Accord</i>
Split doses (See Don't Rush to Crush via CIAP for information on ARTG products)	Scored, can be halved	Not scored, cannot be halved	Scored, can be halved
Storage (Note – ARTG products are to be stored below 30°C)	15 to 30°C	15 to 30°C	Below 25°C
Pack size (Note – ARTG products contain 50 tablets of 4 mg and 60 tablets of 20 mg per bottle)	100 tablet bottle	100 tablet bottle	30 tablet box

Impacts of this communication on clinical practice

Actions to address the disruption to the supply of hydrocortisone should be planned and implemented at a local level by the Drug and Therapeutics committees in consultation with relevant clinicians. Alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy issues

[PD2022_032 Medication Handling](#)

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
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