

SUMMARY

hydrocortisone (sodium succinate)

**HYDROCORTISONE
PHARMIS 100 mg****powder and solvent for solution for injection/infusion****Inclusion on list: First listing****Euro-generic****Original French opinion adopted by the Transparency Committee on
24 April 2024****The legally binding text is the original French opinion version****Summary of opinion**

Favourable opinion for reimbursement only in medical emergencies: hydrocortisone is indicated in the treatment of shock secondary to adrenal insufficiency or shock unresponsive to conventional therapy in the event of adrenal insufficiency.

Unfavourable opinion for reimbursement in the other clinical situations of the MA: Endocrine disorders (primary or secondary adrenal insufficiency), collagen diseases (systemic lupus erythematosus), dermatological diseases (severe erythema multiforme (Stevens-Johnson syndrome)) and allergic states (bronchial asthma, anaphylactic reactions).

No clinical added value compared to proprietary medicinal products based on hydrocortisone 100 mg powder and solvent for solution for injection/infusion.

This document and its bibliographic reference are available to download at www.has-sante.fr 

This opinion is published subject to intellectual property rights

Haute Autorité de Santé – Communication and Information Department

5 avenue du Stade de France – 93218 SAINT-DENIS LA PLAINE CEDEX – France. Tel.: +33 (0)1 55 93 70 00

© Haute Autorité de santé – April 2024

Transparency Committee's conclusions

Clinical Benefit

Medical emergencies: treatment of shock secondary to adrenal insufficiency or shock unresponsive to conventional therapy in the event of adrenal insufficiency

- ➔ Acute adrenal insufficiency is life-threatening for patients without treatment.
- ➔ HYDROCORTISONE PHARMIS 100 mg powder and solvent for solution for injection/infusion is a replacement therapy.
- ➔ The efficacy/adverse effects ratio of hydrocortisone is high.
- ➔ It is a first-line treatment for shock secondary to adrenal insufficiency or shock unresponsive to conventional therapy in the event of adrenal insufficiency.
- ➔ There are medicinal alternatives, which are the other injectable medicinal products based on hydrocortisone for injection.

➔ **Public health benefit**

HYDROCORTISONE PHARMIS 100 mg powder and solvent for solution for injection/infusion is unlikely to have an additional impact on public health compared to the corticosteroid medicinal products already listed.

The Committee considers that the clinical benefit of HYDROCORTISONE PHARMIS 100 mg (hydrocortisone sodium succinate) powder and solvent for solution for injection/infusion is substantial in the treatment of shock secondary to adrenal insufficiency or shock unresponsive to conventional therapy in the event of adrenal insufficiency.

Other MA indications

Indications concerned:

Treatment of other conditions in which a rapid and intense corticosteroid effect is required, such as:

- Endocrine disorders: primary or secondary adrenal insufficiency
 - Collagen diseases: systemic lupus erythematosus
 - Dermatological diseases: severe erythema multiforme (Stevens-Johnson syndrome)
 - Allergic states: bronchial asthma, anaphylactic reactions.
-
- ➔ Due to their anti-inflammatory, anti-allergy and immunosuppressive effects, corticosteroids are used in numerous conditions. The scope of the indications is broad and non-exclusive. Corticosteroids are indicated in the treatment of certain inflammatory, immune and allergic conditions.
 - ➔ HYDROCORTISONE PHARMIS 100 mg powder and solvent for solution for injection/infusion is a symptomatic or curative therapy.
 - ➔ The efficacy/adverse effects ratio in conditions in which a rapid and intense corticosteroid effect is required, such as endocrine disorders (primary or secondary adrenocortical insufficiency), systemic autoimmune diseases (systemic lupus erythematosus), dermatological diseases (severe erythema multiforme: Stevens-Johnson syndrome) and allergic states (bronchial

asthma, anaphylactic reactions) has not been adequately established given the absence of available robust data. According to expert opinion, the use of hydrocortisone for injection in these indications is not recommended. In these conditions, the use of a synthetic glucocorticoid should be favoured in order to maximise the anti-inflammatory effects and minimise the mineralocorticoid effects, responsible for adverse effects such as salt and fluid retention, weight gain, hypertension or hyperglycaemia.

- ➔ This proprietary medicinal product has no role in the care pathway in these indications.
- ➔ There are medicinal alternatives, represented by all the corticosteroids used in all of these indications.

➔ **Public health benefit**

HYDROCORTISONE PHARMIS 100 mg powder and solvent for solution for injection/infusion is unlikely to have an additional impact on public health.

In conditions in which a rapid and intense corticosteroid effect is required, such as: endocrine disorders (primary or secondary adrenocortical insufficiency), systemic autoimmune diseases (systemic lupus erythematosus), dermatological diseases (severe erythema multiforme: Stevens-Johnson syndrome) and allergic states (bronchial asthma, anaphylactic reactions), the Committee considers that the clinical benefit of HYDROCORTISONE PHARMIS 100 mg (hydrocortisone sodium succinate) powder and solvent for solution for injection/infusion is insufficient.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication “medical emergencies: treatment of shock secondary to adrenal insufficiency or shock unresponsive to conventional therapy in the event of adrenal insufficiency”, and at the MA dosages.

The Committee issues an unfavourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in conditions in which a rapid and intense corticosteroid effect is required, such as: endocrine disorders (primary or secondary adrenal insufficiency), systemic autoimmune diseases (systemic lupus erythematosus), dermatological diseases: severe erythema multiforme (Stevens-Johnson syndrome) and allergic states (bronchial asthma, anaphylactic reactions).

- ➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

This medicinal product is a euro-generic that provides no clinical added value (CAV V) compared to the medicinal products containing hydrocortisone for injection already listed in acute adrenal insufficiency.