SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

CORT-S

Hydrocortisone Sodium Succinate for Injection BP

Strength:

100 mg/vial

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Sr. No.	Particulars	Grade	Qty./vial	Function
1.	Hydrocortisone Sodium Succinate (Buffered sterile) equivalent to Hydrocortisone	BP	100 mg	Active

3. PHARMACEUTICAL FORM:

Powder for Injection

A white crystalline hygroscopic powder.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Status asthmaticus and acute allergic reactions including anaphylactic reaction to drugs. Hydrocortisone Sodium Succinate supplements the action of adrenaline. Severe shock arising from surgical or accidental trauma or overwhelming infection. Acute adrenal insufficiency caused by abnormal stress in Addison's disease, hypopituitarism, following adrenalectomy and when adrenocortical function has been suppressed by prolonged corticosteroid therapy.

Soft tissue conditions such as tennis elbow, tenosynovitis and bursitis.

Note:

Hydrocortisone Sodium Succinate does not replace other forms of therapy for the treatment of shock and status asthmaticus.

4.2 Posology and method of administration:

Route of administration: For I.M. / I.V. use

For intravenous injection 100mg, 250mg Hydrocortisone Sodium Succinate for Injection should be dissolved in 2ml of Sterilised Water for Injections B.P. immediately before administration. Hydrocortisone Sodium Succinate for Injection may also be given as an Intravenous Infusion.

A clinical effect is seen in two to four hours and it persists for upto eight hours after intravenous injection.

Hydrocortisone Sodium Succinate for Injection can be given Intramuscular Injection, but the response is likely to be less rapid, especially in shock.

Systemic therapy in adults: 100 to 500mg administered by slow Intravenous Injection taking half to one minute. This dose can be repeated three or four times in 24 hours depending upon the conditions being and the patient's response.

Systemic therapy in children: Infants upto 1year may be given 25mg Hydrocortisone Intravenously; children 1 to 5 years 50mg; 6 to 12 years, 100mg.

This dose can be repeated three or four times in 24 hours depending upon the conditions on the patient's response.

Other Uses: Local treatment of soft tissue lesions - 100mg to 200mg. This daily dose can be repeated on two or three occasions depending on the patient's response.

4.3 Contraindications:

Systemic infection, unless specific anti-infective therapy is employed.
Live virus immunisation. Hypersensitivity to any component of the injection.
Hydrocortisone Sodium Succinate for Injection should not be injected directly into tendons.

4.4 Special warnings and precautions for use:

Administration of corticosteroids may impair the ability to resist and counteract infection; in addition, clinical signs and symptoms of infection are suppressed.
Chickenpox is of particular concern since this normally minor illness may be fatal in immunosuppressed patients. Patients (or parents of children) without a definite history of chickenpox or herpes zoster and, if exposed, they should seek urgent medical attention.
Passive immunisation with varicella/zoster immunoglobulin (VZIG) is needed by exposed non-immune patients who are receiving systemic corticosteroids or who have used them within the previous three months. This should be given within ten days of exposure to chickenpox. If a diagnosis of chickenpox is confirmed, the illness warrants specialists care and urgent treatment.
Cortcosteroids should not be stopped and the dose may need to be increased.

4.5 Interaction with other medicinal products and other forms of interaction:

Steroids may reduce the effects of anticholinesterases in myasthenia gravis, cholecystographic X-ray media and salicylates.
The effect of steroids may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin.
Oestrogens may potentiate the effects of glucocorticoids and dosage adjustments may be required if oestrogens are added to or withdrawn from a stable dosage regimen.

4.6 Fertility, pregnancy and lactation:

The use of corticosteroids during human pregnancy and lactation requires that the benefits be weighed against the possible risks associated with the product or with any alternative therapy.
There is insufficient evidence of safety in human pregnancy.
With reference to literature administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to human beings has not been established, however, patients should avoid extensive use in pregnancy.
Hypoadrenalism may occur in the neonate.
Corticosteroids are excreted in small amounts in breast milk and infants of mothers taking pharmacological doses of steroids should be monitored carefully for signs of adrenal suppression.

4.7 Effects on ability to drive and use machines:

The effect of corticosteroids on the ability to drive or use machinery has not been systematically evaluated. Undesirable effects, such as syncope, vertigo, and convulsions are possible after treatment with corticosteroids. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects:

In the short term, high dosage of hydrocortisone involves little risk of adverse reactions, except that peptic ulceration may occur or be aggravated and there may be small but significant increase in the risk of infection.

With continued use, signs of hypercorticism may become apparent. Unwanted mineralocorticoid and gluco-corticoid effects especially with prolonged or excessive dosing. Rare reports of anaphylaxis.

4.9 Overdose:

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation the product should be discontinued slowly.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Glucocorticoids ATC code: H02AB09
Hydrocortisone sodium succinate has the same metabolic and anti-inflammatory actions as hydrocortisone. It is a glucocorticosteroid. Used in pharmacological doses, its actions supress the clinical manifestations of disease in a wide range of disorders.

5.2 Pharmacokinetic properties:

1 mg/kg i.m. dose of Hydrocortisone peaked in 30-60 minutes, with a plasma Cmax of 80 mg/100 ml.
In analysing hydrocortisone metabolism, a 25 mg IV dose resulted in higher plasma concentrations in females than in males.

5.3 Pre-clinical Safety Data:

Hydrocortisone was not mutagenic in bacterial assays but induced chromosome aberrations in human lymphocytes in vitro and in mice in vivo. Hydrocortisone did not increase tumor incidences in male and female rats during a limited 2- year carcinogenicity study.
Corticosteroids have been shown to reduce fertility when administered to rats.
Adverse effects on fertility in rats with corticosterone were observed in males only and were reversible. Decreased weights and microscopic changes in prostate and seminal vesicles were observed. The numbers of implantations and live fetuses were reduced and these effects were not present following mating at the end of the recovery period.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients:

None

6.2 Incompatibilities:

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf – life:

24 Months

6.4 Special precautions for storage:

Store below 30°C., protected from light.

6.5 Nature and contents of container:

7.5 ml flint vial USP – III stoppered, 20 mm GBRS, 20 mm T/O Biogreen “NEON” Embossed lacq. Aluminum seal packed in a carton along with package insert. Diluent – sterilized water for injection BP 5 ml ampoule.

6.6 Special Precautions for Handling and Disposal:

Instructions for reconstitution:
Hydrocortisone should be reconstituted by adding not more than 2ml of sterile Water for injections to the contents of one vial. A homogeneous solution will be obtained by shaking gently. The solution of the reconstituted product should be inspected visually for particulate matter and discoloration prior to administration. The formulation does not contain a preservative and is for single use only. Once opened, the content of a vial should normally be used immediately.
For instructions on administration, see section 4.2.
For IV infusion, the following solutions can be used: dextrose 5% in water, isotonic saline solution or 5% dextrose in isotonic saline solution if patient is not on sodium restriction.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER:

M/s. NEON LABORATORIES LIMITED
140, Damji Shamji Industrial Complex,
28, Mahal Indl. Estate, Mahakali Caves Road,
Andheri (East), Mumbai - 400 093

8. MARKETING AUTHORIZATION NUMBER:

08345/08203/VAR/2022

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORISATION:

Date of first authorization: 03-01-2023

10. DATE OF REVISION OF THE TEXT: JULY 2023

11. REFERENCE

- Hydrocortisone 100 mg Powder for Solution for Injection/Infusion - Summary of Product Characteristics (SmPC) - print friendly - (emc) (medicines.org.uk)

- Hydrocortisone 100 mg Powder for Solution for Injection/Infusion - https://dailymed.nlm.nih.gov/dailymed/