1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

1.1 Name of the medicinal Product

Hydrocortisone Sodium Succinate for Injection BP 100 mg

1.2 Strength

Each vial contains:

Hydrocortisone Sodium Succinate USP (Sterile)	
E.q. to Hydrocortisone	100 mg
Anhydrous Disodium Phosphate BP (As Buffering Agent)	Q.S.
Sodium Acid Phosphate BP (As Buffering Agent)	Q.S.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Hydrocortisone Sodium Succinate USP (Sterile)

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Label Claim (mg/vial)	Rational
1	Hydrocortisone Sodium Succinate (Sterile) with Buffer eq. to Hydrocortisone	USP	140.00 eq. to 100.0	Corticosteroid

3. Pharmaceutical Form

Dry Powder for Injection

White coloured hygroscopic sterile powder filled in 7.5 ml glass vial having flip off seal.

4. Clinical Particulars

4.1 Therapeutic Indications

Congenital hyperplasia, bursitis, epicondylitis, ankylosing spondylitis, osteoarthritis.

Systemic lupus erythematosus, pemphigus, Stevens-Johnson syndrome, exfoliative dermatitis, severe psoriasis, mycosis, fungoides .

Bronchial asthma, dermatitis, serum sickness, hypersensitivity reactions, iritis, keratitis.

Ulcerative colitis, idiopathic thrombocytopenic purpura, erythroblastopenia.

4.2 Posology and Method of Administration

The dose is 100 to 500 mg Hydrocortisone succinate given 3 to 4 times in 24 hours, dosage depending on the severity of the condition and the response.

Children up to 1 year may be given 25 mg, 1 to 5 years 50 mg and 6 to 12 years 100 mg.

DIRECTION FOR RECONSTITUTION:

For intravenous or intramuscular injection, prepare solution by adding 2 ml of Water for Injection to the contents of vial. For intravenous infusion, first prepare solution by adding 2 ml of Water for Injection to the vial; this solution may then be added to 50/100/1000 ml of the following: 5% dextrose and Sodium Chloride 0.9%. Use immediately after reconstitution. Use solution only if it is clear.

Unused solution should be discarded.

4.3 Contraindications

Hypersensitivity to corticosteroids, tuberculosis, ocular herpes simplex, primary glaucoma, acute psychosis and psychoneurosis, systemic infection, peptic ulcer, osteoporosis.

4.4 Special Warnings and Special Precautions for Use

Hydrocortisone sodium succinate injection should not be administered intrathecally or subconjunctivally. Toxic effects may result from withdrawal or from continued use of large doses.

Hydrocortisone sodium succinate should be given with extreme caution in the presence of congestive heart failure, hypertension, in patients with diabetes mellitus, chronic renal failure, uraemia and in elderly patients.

The use of this drug in pregnancy, nursing mothers or women of childbearing potential requires that the benefits of the drug be carefully weighed against the potential risk to the mother and embryo or foetus.

Live vaccines should not be given to patients receiving high doses of Hydrocortisone sodium succinate. Patients receiving long courses of Hydrocortisone sodium succinate should be regularly checked for hypertension, glycosuria, hypokalaemia, gastric discomfort and mental changes.

Sodium intake may have to be reduced and potassium supplements administered. Children are at special risk from raised intracranial pressure.

Infection should be treated as an emergency. Large doses should be given by infusion to prevent cardiovascular collapse.

4.5 Interaction with other medicinal products and other forms of interaction

Drug may interact with Cyclosporin, Rifampicin, Rifabutin, Carbamazepine, Phenobarbitone, Phenytoin, Primidone, Aminoglutethimide, Cimetidine, Erythromycin, Ketoconazole, ltraconazole, Diltiazem, Mibefradil, Aspirin, Pancuronium, Anticoagulants, Hypoglycemic agents (including Insulin), Diuretics and Antihypertensives.

4.6 Fertility, Pregnancy and Lactation

The use of this drug in pregnancy, nursing mothers or women of childbearing potential requires that the benefits of the drug be carefully weighed against the potential risk to the mother and embryo or foetus.

4.7 Effects on ability To Drive and use Machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects

Electrolyte disturbances, characterized by hypertension, oedema due to sodium/fluid retension. hypokalemic alkalosis, increased susceptibility to infection and delayed wound healing. Cardiac failure, peptic ulceration with haemorrhage and perforation, glycosuria, osteoporosis and spontaneous fractures , increased appetite, posterior subcapsular cataract, atrophy of the adrenal cortex and acute adrenal insufficiency during prolonged treatment, inhibition or arrest of growth in children, cushing syndrome, amenorrhoea, behavioural disturbances, including mental and neurological disturbances.

Intracranial hypertension, thrombo-embolic complications, lymphocytopaenia, myopathy, hyperglycaemia with accentuation or precipitations of the diabetic state, hyperhydrosis and aseptic necrosis of bone may occur.

4.9 Overdose

There has been no experience with overdosage of Hydrocortisone sodium succinate injection.

Treatment should include general supportive measures.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Glucocorticoid

Hydrocortisone sodium succinate has the same metabolic and anti-inflammatory action as hydrocortisone. It acts by controlling the rate of protein synthesis. It forms a steroid-receptor complex with receptor proteins, moves into the nucleus where it binds the chromatin and thus directs the genetic apparatus to transcribe RNA. It al so delays the mineralocorticoid activity.

5.2 Pharmacokinetic Properties

Following the intravenous injection of hydrocortisone sodium succinate, demonstrable effects are evident within one hour and persist for a variable period. Excretion of the administered dose is nearly complete within 12 hours. Thus, if constantly high blood levels are required, injections should be made every 4 to 6 hours. This preparation is also rapidly absorbed when administered intramuscularly and is excreted in a pattern similar to that observed after intravenous injection.

5.3 Preclinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Not Applicable

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light.

6.5 Nature and Contents of Container

White coloured hygroscopic sterile powder filled in 7.5 ml white USP Type-III glass vial having 20 mm grey butyl rubber stopper with 20 mm yellow flip-off seal. Such 50 vials are packed in printed inner with packing insert.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

GENERICS AND SPECIALITIES LTD.
31, AWONIYI ELEMO STREET,
OFF LATEEF SALAMI STREET.
AJAO ESTATE, LAGOS,
NIGERIA.
E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-02764-665000
Fax: +91-02764-281809
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable