SmPC (Summary of Product Characteristics)

1. Name of Finished Pharmaceutical Product:

AXADEX D50 (Glucose Intravenous Infusion BP 50% w/v)

2. Qualitative and Quantitative Composition:

a) Qualitative Composition

Product Name: AXADEX D50

Generic Name: Glucose Intravenous Infusion BP 50% w/v)

Label Claim:

Each 100 ml contains

Glucose Anhydrous BP……...50% w/v

Water for Injections BP……q.s.

b) Quantitative Composition

S. No.	Name of Ingredient	Reference	Qty. /100 ml	Function of Ingredient
1.	Glucose Anhydrous	BP	52.500 gm	Active Ingredient
2	Water for Injections	BP	q.s.	Vehicle

3. Pharmaceutical Form

Intravenous Infusion.

Glucose Intravenous Infusion BP 50% w/v is A colourless solution, may not be more than faintly yellow in colour.

4. Clinical Particulars

4.1 Therapeutic indications

Glucose 50% is hypertonic (in vitro tonicity, in a container) and provides a source of calories in a minimal volume of water. Glucose 50% is frequently used in both adults and children to restore blood glucose concentrations in the treatment of hypoglycaemia resulting from insulin excess or from other causes.

Glucose 50% may be used to provide temporary relief from the symptoms of cerebral oedema and from hypoglycaemic coma. Hyperosmotic Glucose with or without insulin may correct hyperkalaemia in renal failure.

4.2 Posology and method of administration

Fluid and acid base balance, serum glucose, serum sodium, and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonists due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids (in vivo tonicity). Glucose 50 % may become extremely hypotonic after administration due to glucose metabolism in the body.

Glucose 50% must be administered by the intravenous route; it must not be administered by subcutaneous or intramuscular route. Except in the emergency treatment of severe hypoglycaemia, Glucose 50% should be administered via a central vein after appropriate dilution. When used for the emergency treatment of hypoglycaemia.

Dosage of Glucose depends on the age, weight, clinical condition, the fluid, electrolyte and acid base balance of the patient. For the treatment of hypoglycaemia resulting from insulin excess or other causes in adults (including the elderly) and children, the usual dose is as follows:

20-50ml of Glucose 50% administered slowly intravenously. This represents 3mls per minute.

Repeated doses and supportive therapy may be required in some cases.

4.3 Contraindications

Glucose 50% is contraindicated in patients with:

- Hypersensitivity to the active substance or to any excipients listed in section 6.1 and known allergy to corn or corn products
- The glucose – galactose malabsorption syndrome

- Anuria or intraspinal or intracranial haemorrhage, or ischaemic stroke and in patients with delirium tremens if such patients are already dehydrated
- With hyperglycaemic coma.

4.4 Special warnings and precautions for use

Hypertonic solutions of Glucose should be administered via a large central vein to minimise damage at the site of injection (see section 4.2 Posology).

Glucose solutions should be used with caution in patients with overt or known sub-clinical diabetes mellitus, carbohydrate intolerance for any reason, severe under-nutrition, thiamine deficiency, hypophosphataemia, haemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.

Rapid administration of hypertonic glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome; patients should be observed for signs of mental confusion and loss of consciousness, especially those patients with chronic uraemia or carbohydrate intolerance.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored.

Glucose 50 % intravenous infusion is a hypertonic solution (in vitro, in a container). In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism (see section 4.2 and 5.2).

Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatraemia.

Hyponatraemia:

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns, and CNS disease), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with brain oedema are at particular risk of severe, irreversible and life-threatening brain injury.

Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by acute hyponatraemia.

Intravenous administration of Glucose 50% may result in other electrolyte disturbances such as: hypokalaemia, hypophosphataemia and hypomagnesaemia (see sections 4.2. and 4.8).

4.5 Interaction with other medicinal Products and other forms of interaction

Drugs increasing vasopressin effect, listed below, lead to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids.

- Drugs stimulating vasopressin release, e.g.: carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: NSAIDs , cyclophosphamide
- Vasopressin analogues, e.g.: desmopressin, oxytocin, vasopressin, terlipressin.

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.

4.6 Fertility, Pregnancy and Lactation

Intravenous glucose may result in foetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate. Infusions of glucose administered during Caesarean section and labour should not exceed 5-10g glucose/hour.

Glucose 50% should be administered with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to < 1/1,000); Very rare (<1/10,000), Not known (cannot be estimated from the available data)		
System Organ Class (SOC)	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutrition disorders	Hospital acquired hyponatraemia * Hyperglycaemia** Hypokalaemia Hypophosphataemia Hypomagnesaemia Fluid and electrolyte imbalance.	Not known
Nervous system disorders	Hyponatraemic encephalopathy*	Not known
General disorders and administration site conditions	Pain at the injection site Vein irritation Venous thrombosis Phlebitis	Not known

* Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

** Hyperglycaemia (possibly indicated by mental confusion or loss of consciousness) and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated hyperglycaemia can lead to dehydration, hyperosmolar coma and death.

The administration of glucose without adequate levels of thiamine may precipitate overt deficiency states e.g. Wernicke's encephalopathy. Sodium retention, oedema, pulmonary oedema and congestive heart failure may be induced in patients with severe under-nutrition.

4.9 Overdose

Overdose of Glucose 50% may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.

In the event of overdose of Glucose 50% it may be necessary to administer appropriate doses of insulin

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, Carbohydrates

ATC code: B05BA03

The metabolism of glucose is an energy source for the body.

5.2 Pharmacokinetic Properties

Glucose is rapidly metabolised into carbon dioxide and water

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics

6.0 Pharmaceutical particulars

6.1 List of Excipients

Water for Injections BP

6.2 Incompatibilities

Glucose solutions which do not contain electrolytes, should not be administered concomitantly with blood through the same infusion set, because of the possibilities of agglomeration.

6.3 Shelf life

24 months from the date of manufacturing

6.4 Special precautions for storage

Store below 30ºC. Protect from light. Do not refrigerate or freeze.

6.5 Nature and contents of container

100 ml LDPE bottle with Dust cap/Euro Head cap packed in a Unit Carton, along with the pack insert.

6.6 Special precautions/Instruction for disposal and other handling of use

Additives may be incompatible. Discard any unused portion. Must not be used in series connections.

Hold the bottle in vertical position & insert I.V. set.

To be used with a Pyrogen free I.V. administration set using aseptic technique.

Not to be used if container is found leaking or solution is hazy or contains visible solid particles.

Use as directed by the physician.

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

7. Marketing Authorization Holder

Axa Parenterals Limited
Plot No 936, 937 & 939
Vill. Kishanpur, Jamalpur, Roorkee-247667
Distt. Haridwar (Uttarakhand), INDIA.
Telephone: -- +91-1332-234041/42/43
Telefax: -- +91-1332-234040
E-Mail: -- dra@axapar.com

8. Marketing authorisation number(s)

Not Applicable

9. Date of first authorisation/renewal of the authorisation

Not Applicable

10. Date of revision of the text

Not Applicable