SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

VAMIS GLUCOSE TABLET

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Glucose 3400mg.
For excipients see Section 6.1

3 PHARMACEUTICAL FORM

Chewable Tablet

A white rectangular shaped tablet with VAMI GLUCOSE and a breakline on both sides

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

VAMIS GLUCOSE TABLET is used to treat very low blood sugar (hypoglycemia), most often in people with diabetes mellitus. Glucose works by quickly increasing the amount of glucose in your blood. Glucose is also used to provide carbohydrate calories to a person who cannot eat because of illness, trauma, or other medical condition

4.2 Posology and method of administration

Glucose pharmaceutical formulations (oral tablets, injections) are indicated for caloric supply and carbohydrate supplementation in case of nutrient deprivation. It is also used in metabolic disorders such as hypoglycemia.

Take this product by mouth as directed. If you are taking a chewable form of this product, chew it thoroughly before swallowing, some liquid may need to be shaken before use. Check your blood sugar level 10 to 15 minutes after taking Vamis Glucose, if your blood sugar level is still low, take another tablet, the sugar level should be kept by eating snacks such as milk, cheese, ,meat sandwich etc. If your symptoms do not get better within 20minutes or they get worse, please consult your physician

4.3 Contraindications

Glucose is contra-indicated in patients presenting with:
• Uncompensated diabetes and diabetes insipidus,
• Hyperosmolar coma,
• Haemodilution and extracellular hyperhydration or hypervolaemia,
• Hyperglycaemia and hyperlactataemia,
• Severe renal insufficiency (with oliguria / anuria),
• Uncompensated cardiac failure,
• General oedema (including pulmonary and brain oedema) and ascitic cirrhosis,
• Other known glucose intolerances (such as metabolic stress situations).
• Hypersensitivity to the active substance. See sections 4.4 and 4.8 for corn allergies.
The contra-indications related to any medicinal product that is added to the glucose should be considered.

In case of prolonged administration or high glucose dose, care should be taken to avoid hypokalaemia by monitoring plasma potassium levels and administering a potassium supplement as appropriate.
Special clinical monitoring is required at the beginning of any intravenous infusion

4.4 Special warnings and precautions for use

Before taking glucose, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This product is safe to take during pregnancy when used as directed.

It is unknown if this product passes into breast milk. Consult your doctor before breast-feeding.

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4.5 Interaction with other medicinal products and other forms of interaction

comitant administration of catecholamines and steroids decreases the glucose up-take.
Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).
• Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics
• Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
• Vasopressin analogues, e.g.: Desmopressin, oxytocin, terlipressin
Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine.
No interaction studies have been performed.

4.6 Pregnancy and lactation

Pregnancy
Glucose solution can be used during pregnancy. However, caution should be exercised when glucose solution is used intrapartum.
Glucose solution should be administrated 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).
Fertility
There are no adequate data of the effect of Glucose on fertility. However, no effect on fertility is expected.
Lactation
There are no adequate data of using Glucose solution during lactation. However, no effect on lactation is expected. Glucose solution can be used during lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

This product usually has very few side effects. If you have any unusual effects from taking this product, tell your doctor or pharmacist promptly.

If your doctor has directed you to use this product, remember that your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this product do not have serious side effects.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

The administration of Glucose tablets can lead to the development of:
• Hyperglycaemia,
• Fluid-balance disturbances (hypervolaemia),
• Electrolyte disturbances (hypokalaemia, hypomagnesaemia, and hypophosphataemia).
The following Post-marketing adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then, where feasible, by Preferred Term in order of severity.

Table 3.
Tabulated list of adverse reactions

System Organ Class	*Adverse reaction (MedDRA term)*	*Frequency*
Immune system disorders	Anaphylactic reaction** Hypersensitivity **	Not known (*)
Metabolism and nutrition disorders	Electrolyte disturbances Hyperglycaemia Hemodilution Hypervolaemia Hospital Acquired Hyponatraemia***	
Skin and subcutaneous tissue disorders	Sweating Rash	
Nervous system disorders	Hyponatraemic encephalopathy	
General disorders and administration site conditions	Chills, Shivering Pyrexia, Febrile reaction, Fever Infection at site of injection Thrombophlebitis Infusion site reactions including, • Infusion site phlebitis • Infusion site erythema	
Investigations	Glycosuria	

(*) cannot be estimated from the available data
**Potential manifestation in patients with allergy to corn, see section 4.4 .
Other adverse reactions reported with glucose injection/infusions include:

• Adverse reactions reported when glucose is used with parenteral nutrition:
- Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased, Cholecystitis, Cholelithiasis
- Pulmonary vascular precipitates

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Prolonged use of large amount of Glucose Tablets may cause hyperosmolarity and hyponatraemia, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to hyperglycaemia).
In case of suspected overdose, treatment with Glucose tablet must be stopped immediately. Management of overdose is symptomatic and supportive, with appropriate monitoring.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group "Carbohydrates", ATC code: B05BA03**.**

Blood glucose is an obligatory energy source in humans involved in various cellular activities, and it also acts as a signalling molecule for diverse glucose-sensing molecules and proteins. Glucose undergoes oxidation into carbon dioxide, water and yields energy molecules in the process of glycolysis and subsequent citric cycle and oxidative phosphorylation. Glucose is readily converted into fat in the body which can be used as a source of energy as required. Under a similar conversion into storage of energy, glucose is stored in the liver and muscles as glycogen. Glucose stores are mobilized in a regulated manner, depending on the tissues' metabolic demands. Oral glucose tablets or injections serve to increase the supply of glucose and oral glucose administration is more effective in stimulating insulin secretion because it stimulates the incretin hormones from the gut, which promotes insulin secretion

5.2 Pharmacokinetic properties

Mechanism of action
Glucose supplies most of the energy to all tissues by generating energy molecules ATP and NADH during a series of metabolism reactions called glycolysis. Glycolysis can be

divided into 2 main phases where the preparatory phase is initiated by the phosphorylation of glucose by a hexokinase to form glucose 6-phosphate. The addition of the high-energy phosphate group activates glucose for subsequent breakdown in later steps of glycolysis and is the rate-limiting step. Products end up as substrates for following reactions, to ultimately convert C6 glucose molecule into two C3 sugar molecules. These products enter the energy-releasing phase where total of 4ATP and 2NADH molecules are generated per one glucose molecule. The total aerobic metabolism of glucose can produce up to 36 ATP molecules. This energy-producing reactions of glucose is limited to D-glucose as L-glucose cannot be phosphorlyated by hexokinase. Glucose can act as precursors to generate other biomolecules such as vitamin C. It plays a role as a signaling molecule to control glucose and energy homeostasis. Glucose can regulate gene transcription, enzyme activity, hormone secretion, and the activity of glucoregulatory neurons. The types, number and kinetics of glucose transporters expressed depends on the tissues and fine-tunes glucose uptake, metabolism, and signal generation in order to preserve cellular and whole body metabolic integrity

Absorption
Polysaccharides can be broken down into smaller units by pancreatic and intestinal glycosidases or intestinal flora. Sodium-dependent glucose transporter SGLT1 and GLUT2 (SLC2A2) play predominant roles in intestinal transport of glucose into the circulation. SGLT1 is located in the apical membrane of the intestinal wall while GLUT2 is located in the basolateral membrane, but it was proposed that GLUT2 can be recruited into the apical membrane after a high luminal glucose bolus allowing bulk absorption of glucose by facilitated diffusion [3]. Oral preparation of glucose reaches the peak concentration within 40 minutes and the intravenous infusions display 100% bioavailability.

Metabolism
Glucose can undergo aerobic oxidation in conjunction to the synthesis of energy molecules. Glycolysis is the initial stage of glucose metabolism where one glucose molecule is degraded into 2 molecules of pyruvate via substrate-level phosphorylation. These products are transported to the mitochondria where they are further oxidized into oxygen and carbon dioxide

5.3 Preclinical safety data

No data of relevance in addition to that already stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone, Magnesium Stearate, Orange Flavour, Ethanol, Aerosil

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and contents of container

25 X 1 X 6 ALU-PVC Blister in a Mono carton with leaflets

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

TUYIL PHARMACEUTICAL INDUSTRIES LIMITED

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