HYDROSTARCH- hydroxyethyl starch 130/0.4 substitution injection, solution
ASPEN VETERINARY

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

HYDROSTARCH

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

Description

HydroStarch™ is a sterile, non-pyrogenic solution as an aid for hypovolemia. May be administered via intravenous infusion using aseptic technique. It contains no antimicrobial agents. Discard any unused portion. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1

Composition (g/L)		Osmolarity (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)	
Hydroxyethyl Starch 130/0.4	Sodium Chloride NaCl			Sodium	Chloride
60	9.0	308	4.0-5.5	150	150

The container is free of PVC and phthalates. The container meets the requirements of USP and is registered with FDA.

Clinical Pharmacology

HydroStarch™ contains hydroxyethyl starch in a colloidal solution which expands plasma volume when administered intravenously. Hydroxyethyl starch is a derivative of thin boiling waxy corn starch, which mainly consists of a glucose polymer (amylopectin). Substitution of hydroxyethyl groups on the glucose units of the polymer reduces the normal degradation of amylopectin by α-amylase in the body.

Indications

HydroStarch™ act as a plasma volume substitute for the treatment and prophylaxis of hypovolemia in all species. It is not a substitute for red blood cells or coagulation factors in plasma.

Contraindications

HydroStarch™ is contraindicated in patients with a known hypersensitivity to hydroxyethyl starch, fluid overload (hyperhydration) and especially in cases of pulmonary edema and congestive heart failure, renal failure with oliguria or anuria not related to hypovolemia, patients receiving dialysis treatment, severe hypernatremia or severe hyperchloremia and intracranial bleeding.

Warnings

Anaphylactoid reactions (bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary edema) have been reported with solutions containing hydroxyethyl starch. If a hypersensitivity reaction occurs, administration of the drug should be discontinued immediately and the appropriate treatment and supportive measures should be undertaken until symptoms have resolved.

Fluid status and rate of infusion should be assessed regularly during treatment, especially in patients with cardiac insufficiency or severe kidney dysfunction.

In cases of severe dehydration, a crystalloid solution should be given first. Generally, sufficient fluid should be administered in order to avoid dehydration.

Caution should be observed before administering HydroStarch™ to patients with severe liver disease or severe bleeding disorders. With the administration of certain hydroxyethyl starch solutions, disturbances of blood coagulation can occur depending on the dosage.

If administered by pressure infusion, air should be withdrawn or expelled from the bag through the administration port prior to infusion.

Do not introduce additives into this container.

Adverse Reactions

Products containing hydroxyethyl starch may lead to anaphylactoid reactions (hypersensitivity, mild influenza-like symptoms, bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary edema).

Prolonged administration of high dosages of hydroxyethyl starch may cause pruritus (itching), an undesirable effect observed with all hydroxyethyl starches.

At high doses, the dilutional effects may result in decreased levels of coagulation factors and other plasma proteins, and a decreased in hematocrit.

If an adverse reaction does occur, discontinue the infusion and evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

Precautions

This is a single dose unit. It contains no preservatives. Use entire contents when first opened.

Do not administer unless solution is clear and seal is intact.

Solution must be warmed to body temperature prior to administration and administered at a slow rate. Use solution promptly following initial entry.

Reactions which may occur because of the solution or the technique of administration, include febrile response, infection at the site of injection, and extravasation.

Drug Interactions

No interactions with other drugs or nutritional products are known. The safety and compatibility of other additives have not been established.

Dosage and Administration

To be used as directed by a licensed veterinarian. The dosage of the HydroStarch™ is dependent upon the blood loss, hemodynamics and on the hemodilution effects of the patient. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

For use in one patient on one occasion only. Discard any unused portion. Care should be taken with

administration technique to avoid administration site reactions and infection.

HydroStarch™ can be administered repetitively over several days. The initial 10 to 20mL should be infused slowly, keeping the patient under close observation due to possible anaphylactoid reaction. See Warnings and Precautions.

Over-dosage

As with all plasma volume substitutes, over-dosage can lead to overloading of the circulatory system (e.g. pulmonary edema). In this case, the infusion should be stopped immediately and, if necessary, a diuretic should be administered. See Warnings, Precautions and Adverse Reactions.

Storage

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended that the product be stored at 59 to 77°F (15 to 25°C). Protect from freezing.

Directions for use of plastic container

To Open

Tear overwrap at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below:

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from inlet/outlet port at bottom of container.
3. Attach administration set.

WARNING: Do not introduce additives into this container.
CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.

Manufactured for:
Aspen Veterinary Resources® Ltd.
Liberty, MO 64068, USA
www.aspenveterinaryresources.com

Manufactured by:
Sypharma Pty Ltd
27 Healey Road, Dandenong
Victoria 3175 Australia

For customer service email:
info@aspenveterinaryresources.com

Rev. 04/16

HydroStarch 250mL

HydroStarch™
(6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

250mL (8.45 fl oz)

200
150
100
50
Approx.

Each 100mL contains:

Hydroxyethyl Starch 130/0.4	6g
Sodium Chloride	900mg

pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid

mEq/L Sodium 154, Chloride 154, pH: 4.0 to 5.5, Osmolarity: 308 mOsmol/L (calc)

INDICATIONS: As a plasma volume substitute for the treatment and prophylaxis for hypovolemia in all species.

DOSAGE AND ADMINISTRATION: As directed by a veterinarian. Dosage is dependent upon the blood loss, hemodynamics and on the hemodilution effects of the patient. Administer by intravenous infusion using strict aseptic technique. See Package Insert.

CAUTION: Solution must be warmed to body temperature prior to administration and administered at a slow rate. This is a single dose unit. It contains no preservatives. Use solution promptly following initial entry. Use entire contents when first opened. Squeeze and inspect inner bag which maintains product sterility. Discard if leaks are found or if the solution contains visible solid particles. Do not use unless solution is clear and seal is intact.

WARNING: If administered by pressure infusion, air should be withdrawn or expelled from the bag through the medication/administration port prior to infusion. Do not introduce additives into this container. If entire contents are not used, discard the unused portion.

STORAGE: Store at 59 to 77°F (15 to 25°C) in barrier over-pouch until ready for use. Protect from freezing.

CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN

Approx
50
100
150
200

Manufactured For: Aspen Veterinary Resources® LTD., Liberty, MO 64068, USA
www.aspenveterinaryresources.com

Manufactured By: Sypharma Pty Ltd, 27 Healey Road, Dandenong Victoria 3175 Australia.

For Customer Service Email: info@aspenveterinaryresources.com

NDC Number: 46066-513-04

A536SPH

Rev. 04/16

Barcode: 0 99355 01349 0

Lot:

Exp:

HydroStarch 500mL

HydroStarch™
(6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection)

STERILE NONPYROGENIC SOLUTION
For Animal Use Only

KEEP OUT OF REACH OF CHILDREN

500mL (16.91 fl oz)

Each 100mL contains:

Hydroxyethyl Starch 130/0.4	6g
Sodium Chloride	900mg

pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid

mEq/L Sodium 154, Chloride 154, pH: 4.0 to 5.5, Osmolarity: 308 mOsmol/L (calc)

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For Customer Service Email: info@aspenveterinaryresources.com

NDC Number: 46066-513-05

A537SPH

Rev. 04/16

Barcode: 0 99355 01353 7

Lot:

Exp:

400
300
200
100
Approx.

100
Approx.
200
300
400

HYDROSTARCH

hydroxyethyl starch 130/0.4 substitution injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:46066-513
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROXYETHYL STARCH 130/0.4 (UNII: 1GVO236S58) (HYDROXYETHYL STARCH 130/0.4 - UNII:1GVO236S58)	HYDROXYETHYL STARCH 130/0.4	6000 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	900 mg in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46066-513-04	250 mL in 1 CONTAINER		
2	NDC:46066-513-05	500 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/21/2016	

Labeler - ASPEN VETERINARY (627265361)

Registrant - SYPHARMA PTY LTD (753786292)

Establishment

Name	Address	ID/FEI	Business Operations
SYPHARMA PTY LTD		753786292	manufacture, pack, sterilize

Establishment

Name	Address	ID/FEI	Business Operations
Serumwerk Bernburg AG		330105057	api manufacture

Revised: 12/2017 ASPEN VETERINARY