

**HYDRAVOL IV- hydroxyethyl starch, sodium chloride injection, solution**  
**Vedco, Inc.**

*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.*

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**HYDRAVOL IV™**

**6% HYDROXYETHYL STARCH 130/0.4 IN 0.9% SODIUM CHLORIDE INJECTION**

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

**STERILE NONPYROGENIC SOLUTION**

For Animal Use Only

**DESCRIPTION**

HYDRAVOL IV™ (6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection) is a sterile, non-pyrogenic solution indicated for the treatment and prophylaxis of hypovolemia. It is not a substitute for red blood cells or coagulation factors in plasma. May be administered via intravenous infusion using aseptic technique. It contains no antimicrobial agents.

Composition, Osmolarity, pH, Ionic Concentration HYDRAVOL IV™ 250 mL and 500 mL:

TABLE 1. PRODUCT INFORMATION/ COMPOSITION/OSMOLARITY/pH/IONIC CONCENTRATION					IONIC Concentration	
PRODUCT	Composition (g/L) HYDROXYETHYL STARCH 130/0.4	Composition (g/L) SODIUM CHLORIDE NaCl	Osmolarity (mOsmol/L) (calc)	pH	SODIUM	CHLORIDE
HYDRAVOL IV™ 250 mL	60	9.0	308	4.0-5.5	154	154
HYDRAVOL IV™ 500 mL	60	9.0	308	4.0-5.5	154	154

The container is free of PVC and phthalates

**CLINICAL PHARMACOLOGY**

HYDRAVOL IV™ 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  $\alpha$ -amylase in the body.

**INDICATIONS**

HYDRAVOL IV™ acts as plasma volume substitute for the treatment and prophylaxis of hypovolemia. It is not a substitute for red blood cells or coagulation factors in plasma.

## **CONTRAINDICATIONS**

The use of HYDRAVOL IV™ is contraindicated in the following conditions:

- 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.
- 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 HYDRAVOL IV™ 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/hypersensitivity reactions.
- Prolonged administrations of high dosages of Hydroxyethyl starch may cause pruritus (itching), hemodilution (resulting in dilution of blood components, e.g., coagulation factors and other plasma proteins, and in a decrease 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**

- Do not administer unless solution is clear and seal is intact.
- This is a single dose unit. It contains no preservatives.
- Use entire contents when first opened.
- Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy, or whenever the patient's condition warrants such evaluation.

## **DRUG INTERACTIONS**

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

## **DOSAGE AND ADMINISTRATIONS**

- To be used as directed by a licensed veterinarian. HYDRAVOL IV™ is administered by intravenous infusion only. The daily dose and rate of infusion depend on the patient's blood loss, on the maintenance or restoration of hemodynamics and on the hemodilution (dilution effect).
- 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.
- HYDRAVOL IV™ can be administered repetitively over several days. The initial 10 to 20 mL should be infused slowly, keeping the patient under close observation due to possible anaphylactoid reactions. See Warnings and Precautions.

## **ADULT DOSE**

- As a general recommendation, the class of synthetic colloids are prescribed at doses up to 20 mL per kg of body weight per day in small animal patient<sup>1</sup>. In a 30 kg patient, this is a dose of 600 mL of HYDRAVOL IV™ (equivalent to 1.2 g hydroxyethyl starch and 3.1 mEq sodium per kg of body weight).

## **OVERDOSAGE**

As with all plasma volume substitutes, overdosage 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 and Precautions.

## **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 inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

### **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.

## **STORAGE**

Store at 15°C to 25°C (59°F to 77°F). Do not freeze.

## **HOW SUPPLIED**

HYDRAVOL IV™ (6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection) for intravenous infusion is supplied in the following primary container:  
Polyolefin bag with overwrap: 250 mL and 500 mL

NDC CODE	ITEM NUMBER	SIZE(mL)	PRODUCT NAME
50989-888-15	VINV-HYDR-250M	250 mL	HYDRAVOL IV™ ( 6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection)
50989-888-16	VINV-HYDR-500M	500 mL	HYDRAVOL IV™ ( 6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection)

Manufactured For:  
Vedco, Inc.  
5503 Corporate Dr.  
St Joseph, MO 64507 USA

For a Copy of the Safety Data Sheet (SDS) or to report adverse reactions call Vedco, Inc. customer service 1 (888) 708-3326

### References

1. Silverstein D, Hopper K. Small Animal Critical Care Medicine. (2009)

### Principal Display Panel

NDC 50989-888-15

HydraVol IV™

6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection

FOR INTRAVENOUS INFUSION ONLY

250mL

NDC 50989-888-15



250 mL

# HydraVol IV™

6% Hydroxyethyl Starch 130/0.4  
in 0.9% Sodium Chloride Injection  
FOR INTRAVENOUS INFUSION ONLY

50

Each 100 mL contains:

Hydroxyethyl Starch 130/0.4 ..... 6 g  
Sodium Chloride, USP ..... 900 mg

In Water for Injection, USP

Electrolytes (mEq/L) Sodium 154, Chloride 154

Calculated osmolarity 308 mOsmol/L pH 4.0 to 5.5

May contain Sodium Hydroxide or Hydrochloric Acid for pH adjustment.

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

100

Check for leakage by squeezing container firmly.

If any leakage, discard solution as sterility may be impaired.

Sterile. Nonpyrogenic. Single dose container.

Use immediately after opening. Discard unused portion.

Use only if solution is clear and container is undamaged.

150

Usual dosage: See package insert.

**Store at 15° to 25°C (59° to 77°F). Do not freeze**

**PVC-Free Non-DEHP Latex-Free**

200

**【Lot No. 000 000】**

**【Mft date. 08/2018】**

**【Exp date. 08/2020】**

FOR ANIMAL USE ONLY.  
CAUTION: Federal law (USA) restricts this drug to use by or on the order of a licensed veterinarian.



Manufactured for:  
**VEDCO**  
5503 Corporate Dr.  
St. Joseph, MO 64507

Customer  
Service No.  
1-888-708-3326

NDC 50989-888-16

HydraVol IV™

6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection

FOR INTRAVENOUS INFUSION ONLY

500mL

NDC 50989-888-16

500 mL



# HydraVol IV™

**6% Hydroxyethyl Starch 130/0.4  
in 0.9% Sodium Chloride Injection  
FOR INTRAVENOUS INFUSION ONLY**

Each 100 mL contains:

Hydroxyethyl Starch 130/0.4	.....	6 g
Sodium Chloride, USP	.....	900 mg
In Water for Injection, USP		

100

Electrolytes (mEq/L) Sodium 154, Chloride 154  
Calculated osmolarity 308 mOsmol/L      pH 4.0 to 5.5  
May contain Sodium Hydroxide or Hydrochloric Acid for pH adjustment.

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

200

Check for leakage by squeezing container firmly.  
If any leakage, discard solution as sterility may be impaired.  
Sterile. Nonpyrogenic. Single dose container.  
Use immediately after opening. Discard unused portion.  
Use only if solution is clear and container is undamaged.  
Usual dosage: See package insert.

300

**Store at 15° to 25°C (59° to 77°F). Do not freeze**  
**PVC-Free                      Non-DEHP                      Latex-Free**

【Lot No. 000 000】

【Mft date. 08/2018】

【Exp date. 08/2020】

400

**FOR ANIMAL USE ONLY.**

**CAUTION: Federal law (USA) restricts this drug to use by or on the order of a licensed veterinarian.**



Manufactured for:



5503 Corporate Dr.  
St. Joseph, MO 64507

Customer  
Service No.  
1-888-708-3326



## HYDRAVOL IV

hydroxyethyl starch, sodium chloride injection, solution

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:50989-888
<b>Route of Administration</b>	INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROXYETHYL STARCH 130/0.4</b> (UNII: 1GVO236S58) (HYDROXYETHYL STARCH 130/0.4 - UNII:1GVO236S58)	HYDROXYETHYL STARCH 130/0.4	6 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	900 mg in 100 mL
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50989-888-15	250 mL in 1 CONTAINER		
2	NDC:50989-888-16	500 mL in 1 CONTAINER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/24/2018	

**Labeler** - Vedco, Inc. (021634266)

**Registrant** - Vedco, Inc. (021634266)