FRESENIUS KABI
caring for life

Volulyte® and Voluven®

Withstanding the test of time

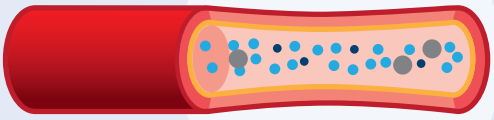
Volume effect of HES 130/0,4

Modern tetrastarch[1]

- Hydroxyethyl starch (HES 130/0,4) is an artificial colloid made from waxy maize starch
- HES molecules remain inside vessels with intact barrier function, thus exerting colloid osmotic pressure which retains fluid in the vasculature
- HES molecules are degraded and excreted renally

Hydroxyethyl starch (HES): mode of action

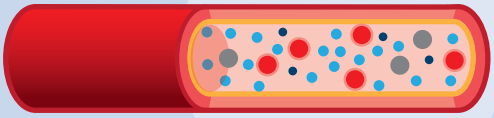
BLOOD LOSS



Blood vessel

Blood loss leads to vasoconstriction to compensate for the loss of volume

HYDROXYETHYL STARCH (HES)



Blood vessel

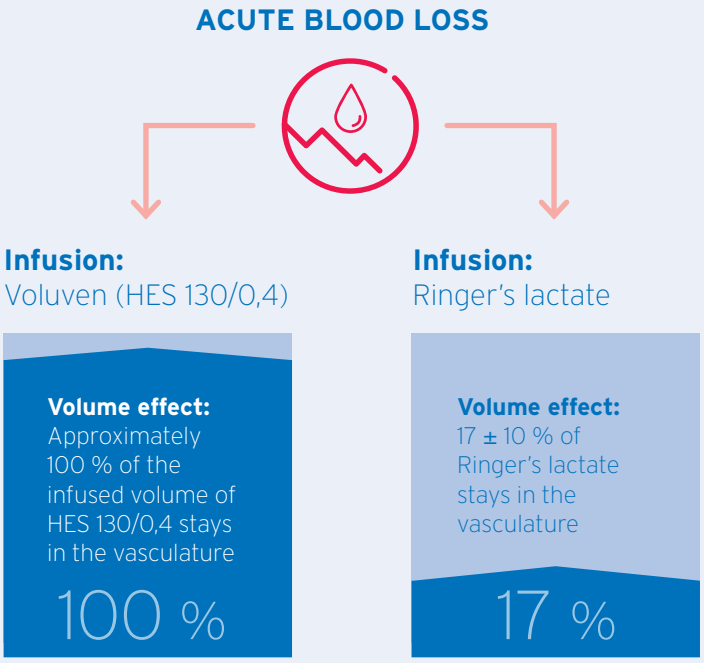
- HES replaces lost volume and maintains the colloid osmotic pressure
- Infused fluid is retained in the vessels and tissue oedema avoided

- Macromolecule (e.g. protein)
- HES molecule
- Water molecule
- Electrolytes

HES 130/0,4 stabilises blood pressure by retaining infused volume inside the vasculature[1]

Isovolaemic volume effect with Voluven (HES 130/0,4)

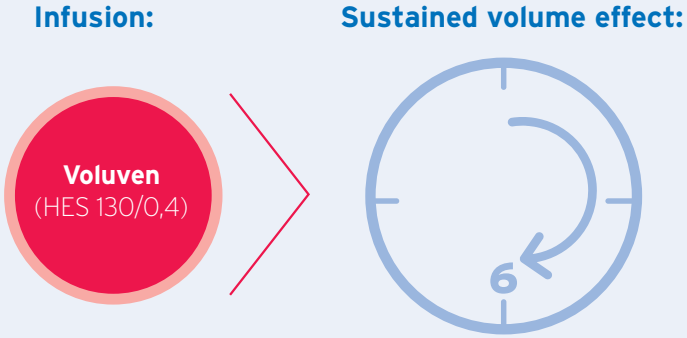
- In acute normovolaemic haemodilution, Voluven (HES 130/0,4) produced an isovolaemic volume effect[2]



Adapted from Jacob *et al.* 2003[2] and 2012[3]

6-hour volume effect with Voluven (HES 130/0,4)

- Voluven (HES 130/0,4) exerts a sustained volume effect for at least 6 hours[1,4]



Plasma expansion with Voluven (HES 130/0,4) for at least 6 hours[1,4]

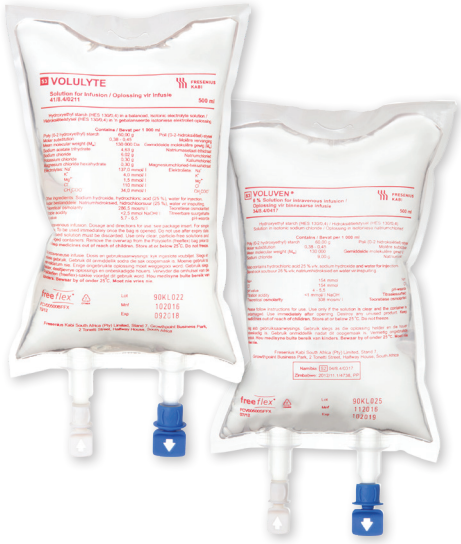
Data derived from an isovolaemic infusion model of 500 ml Voluven (HES 130/0,4)[1]

Adapted from Waitzinger 1999[4]

Voluven (HES 130/0,4) produces a plateau-like isovolaemic volume increase for 4-6 hours[1,4]

Use of **Volulyte** & **Voluven**

When needed and indicated[1]



The right patient

Volulyte/Voluven, in conjunction with crystalloids, is indicated for the treatment of adult and paediatric patients, excluding neonates, with acute hypovolaemia associated with trauma and/or surgery, to restore haemodynamic stability.[1]

The underlying cause of the hypovolaemia should be corrected and the patient should be continuously monitored.[1]

Do not use Volulyte/Voluven in:[1]

- Critically ill patients with or without sepsis/septicaemia,
- Patients with moderate to severe renal impairment (Cl_{cr} < 50 ml/min),
- Renal failure with oliguria or anuria,
- Patients receiving dialysis treatment,
- Severe burns,
- Patients with severe hepatic impairment (Child-Pugh class C),
- Patients with moderate to severe dehydration,
- Over-hydration, with or without pulmonary oedema,
- Patients with congestive cardiac failure,
- Patients with pre-existing coagulation or bleeding disorders,
- Patients with intracranial bleeding,
- Patients with severe hypernatraemia or severe hyperchloraemia
- Severe hyperkalaemia (applies to Volulyte only)
- Patients with known hypersensitivity to hydroxyethyl starch.

Use of **Volulyte** & **Voluven**

When needed and indicated[1]

The right dose

Adult dose[1]

The maximum dose of 30 ml/kg in 24 hours should not be exceeded. The dose in adolescents > 12 years of age is the same as the adult dose.[1] Duration of treament should not exceed 24 hours.

Paediatric dose[1]

Volulyte/Voluven should not be used in neonates (babies less than 1 month old). The dosage in children < 12 years of age should not exceed 15 ml/kg in 24 hours.

Use of **Volulyte** & **Voluven**

When needed and indicated[1]

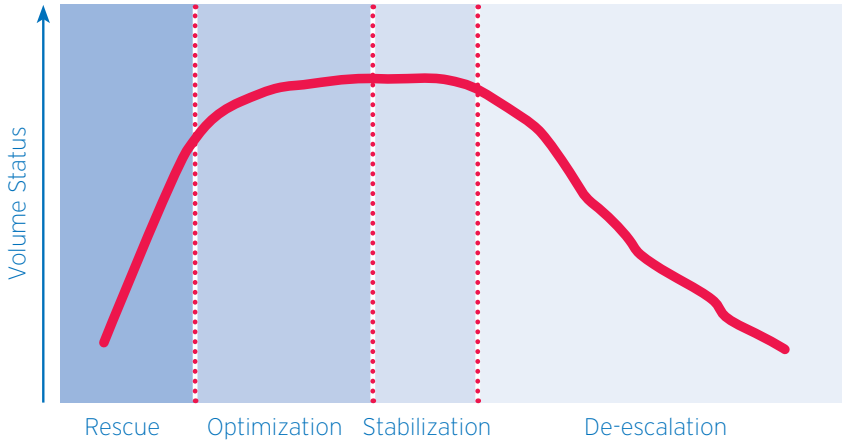
The right time

The following framework recognizes four distinct phases or stages of resuscitation:[5]

1) Rescue,
2) Optimization,
3) Stabilization, and
4) De-escalation.

These describe the four different clinical phases of fluid therapy, occurring over a time course in which patients experience a decreasing severity of illness.[5]

Fig 1: Patients' volume status at different stages of resuscitation.[5]



Most patients requiring fluid resuscitation will enter in the Rescue phase.[5]

Composition of **Volulyte** & **Voluven**

Waxy Maize 6 % HES 130/0,4

	Plasma	Volulyte 6 % [1]	Voluven 6 % [1]
Carrier solution	-	Balanced electrolyte	0,9 % Sodium Chloride
Therapeutic indication	-	Used in conjunction with crystalloids, for the treatment of adult and paediatric, excluding neonates, with acute hypovolaemia associated with trauma and/or surgery, to restore haemodynamic stability. The underlying cause of the hypovolaemia should be corrected and the patient should be continuously monitored.	
Active ingredient	-	Waxy maize HES 130/0,4/9:1	Waxy maize HES 130/0,4/9:1
Concentration (HES)	-	6 g/100 ml (6 %)	6 g/100 ml (6 %)
MW(KD)	-	130	130
pH	7,35	5,7 - 6,5	4 - 5,5
Osmolarity (mOsm/l)	290	286,5	308
Na (mmol/l)	142	137	154
K (mmol/l)	4,5	4	-
Cl (mmol/l)	103	110	154
Mg (mmol/l)	-	1,5	-
Lactate (mmol/l)	1,5-2,5	-	-
Ca (mmol/l)	2,5	-	-
Acetate (mmol/l)	-	34	-
Oncotic effect	-	Isooncotic plasma substitute	Isooncotic plasma substitute
Further Characteristics	-	Plateau-like isovolaemic volume increase for 4-6 hours. Electrolyte composition with lower sodium and chloride content and acetate as precursor of bicarbonate.	Plateau-like isovolaemic volume increase for 4-6 hours.

The date of registration of Voluven in South Africa was 2002. Volulyte registration followed thereafter in 2010.

References:
1. SA Professional information: Volulyte and Voluven
2. Jacob M, *et al*. Anaesthesist 2003;52:896-904
3. Jacob M, *et al*. Crit Care 2012;16:R86
4. Waitzinger J, *et al*. Clinical Drug Investigation 1999;17(2):119-125
5. Hoste EA, *et al*. BJA 2014;113(5):740-7.

S3 Voluven®. Reg. No. 34/8.4/0417. Each 100 ml contains: HES 130/0,4 6 g. Sodium chloride 0,9 g.
S3 Volulyte®. Reg. No. 41/8.4/0211. Each 100 ml contains: HES 130/0,4 6 g. Sodium acetate trihydrate 0,463 g. Sodium chloride 0,602 g. Potassium chloride 0,03 g. Magnesium chloride hexahydrate 0,03 g.

For full prescribing information refer to professional information approved by the South African Health Products Regulatory Authority

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Fresenius Kabi South Africa (Pty) Ltd,
Reg. No.: 1998/006230/07
Stand 7, Growthpoint Business Park
162 Tonetti Street, Halfway House
Extension 7, Midrand, Gauteng, 1685
PO Box 4156, Halfway House 1685
Tel: + 27 11 545 0000 Fax: + 27 11 545 0060
www.fresenius-kabi.co.za

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