

PACKAGE LEAFLET: INFORMATION FOR THE USER

EquiHes 60 mg/ml solution for infusion Ecobag

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What EquiHes 60 mg/ml is and what it is used for
2. What you need to know before you use EquiHes 60 mg/ml
3. How to use EquiHes 60 mg/ml
4. Possible side effects
5. How to store EquiHes 60 mg/ml
6. Contents of the pack and other information

1. What EquiHes 60 mg/ml is and what it is used for

EquiHes 60 mg/ml is an infusion solution which is administered via a cannula into a vein.

EquiHes 60 mg/ml is a plasma volume substitute that is used to restore the blood volume when you have lost blood when other products called crystalloids are not considered sufficient alone.

2. What you need to know before you use EquiHes 60 mg/ml

Do not use EquiHes 60 mg/ml if you:

- are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6).
- suffer from serious generalised infection (sepsis)
- suffer from burn injury
- have kidney impairment or receive dialysis
- have severe liver disease
- suffer from bleeding in the brain (intracranial or *cerebral* bleeding)

- are critically ill (e.g. you need to stay in an intensive care unit)
- have too much fluid in your body and you have been told that you have a condition known as hyperhydration.
- have fluid in the lungs (pulmonary oedema)
- are dehydrated
- have been told that you have a severe increase potassium, sodium or chloride in your blood
- have severely impaired liver function
- have severe heart failure have severe problems with your blood clotting
- have received an organ transplant

Warnings and precautions

It is important to tell your doctor if you have:

- impairment of your liver function
- problems with your heart or circulation
- blood clotting (coagulation) disorders
- problems with your kidneys

Because of the *risk of allergic* (anaphylactic/anaphylactoid) *reactions*, you will be monitored closely to detect early signs of an allergic reaction when you receive this medicine.

Surgery and trauma:

Your doctor will consider carefully if this medicine is suitable for you.

Your doctor will adjust the dose of EquiHes 60 mg/ml carefully in order to prevent fluid overload. This will be done especially if you have problems with your lungs or with your heart or circulation.

The nursing staff will also take measures to observe your body's fluid balance, blood salt level, kidney function. If necessary you may receive additional salts.

In addition it will be ensured that you receive enough fluids.

EquiHes 60 mg/ml is contraindicated if you have kidney impairment or kidney injury requiring dialysis.

If impaired kidney function occurs during therapy:

If the doctor detects first signs of kidney impairment he/she will stop giving you this medicine. In addition your doctor may need to monitor your kidney function for up to 90 days.

If you are given EquiHes 60 mg/ml repeatedly your doctor will monitor the ability of your blood to clot, bleeding time and other functions. In case of an impairment of the ability of your blood to clot, your doctor will stop giving you this medicine.

If you are undergoing open heart surgery and you are on a heart/lung machine to assist in pumping your blood during the surgery, the administration of this solution is not recommended.

Elderly patients

Your doctor will closely monitor your condition during treatment and may adjust your dose, as elderly patients are more likely to suffer from problems with kidneys and heart.

Other medicines and EquiHes 60 mg/ml

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,

Your doctor will take special care about you if you receive/take

- a special type of antibiotics called aminoglycosides
- medicines that make you retain potassium or sodium
- medicines for the treatment of heart weakness (e.g. digitalis preparations, digoxin).

EquiHes 60 mg/ml may increase the undesirable effects of these medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Harmful effects on the unborn child can occur with Hydroxyethyl starch when you have an allergic reaction to the product.

You will receive this medicine only if the doctor has considered the potential benefits outweighing the possible risks to the unborn child, especially when you are in the first trimester.

Breast-feeding

It is not known whether Hydroxyethyl starch passes into the breast milk. Therefore your doctor will administer this solution to you only if he/she thinks it is necessary and a decision will be made whether to temporarily discontinue breast-feeding.

Driving and using machines

EquiHes 60 mg/ml does not influence your ability to drive and use machines.

3. How to use EquiHes 60 mg/ml

EquiHes 60 mg/ml is administered to you by a drip into the vein (intravenous infusion).

Dosage

Your doctor will decide on the correct dose for you to receive.

Your doctor will use the lowest possible effective dose and will not infuse EquiHes 60 mg/ml for more than 24 hours.

Adults

The maximum daily dose is 30 ml (1.8 g Hydroxyethyl starch) per kg body weight.

Use in children

There is only limited experience of the use of this medicine in children. Therefore it is not recommended to use this medicine in children.

Elderly patients and patients with a special condition

If you are an elderly patient or have problems with the lungs, heart or circulation the dosage will be adjusted to your individual situation.

If you receive more EquiHes 60 mg/ml than you should

If you have received too much EquiHes 60 mg/ml, you may suffer from fluid overload that may affect your heart and lung function.

If this happens, your doctor will stop the infusion of EquiHes 60 mg/ml immediately and give you any necessary treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects observed are directly related to the therapeutic effect of starch solutions and the doses administered, which means dilution of your blood and parts of your blood which are responsible for blood clotting. Furthermore serious allergic reactions have been observed.

The following side effects may be serious. If any of the following side effects occur, the medication must be stopped and a doctor should be consulted immediately.

Very common (may affect more than 1 in 10 people):

Decreased red blood cells and reduced blood protein concentration due to dilution.

Common, depending on the administered dose (may affect up to 1 in 10 people):

Dilution of your blood clotting factors (parts of your blood which are responsible for blood clotting). This may cause bleeding complications.

Rare (may affect up to 1 in 1000 people):

Allergic reactions may occur independent of dose. They can be serious and even progress to shock. If an allergic reaction, especially an anaphylactic/anaphylactoid reaction (including swelling of the face, tongue or throat, difficulties to swallow, hives and breathing difficulties) occurs, your doctor will stop the infusion of EquiHes 60 mg/ml immediately and treat you with basic medical measures.

It is not possible to predict by tests which patients may be expected to suffer from an allergic reaction nor to predict the course or the severity of such an allergic reaction.

Frequency not known (cannot be estimated from the available data)

Kidney injury

Liver injury

Other side effects

Very common (may affect more than 1 in 10 people):

Infusion of Hydroxyethyl starch results in increased levels of an enzyme called alpha-amylase in serum. This could be misinterpreted as evidence of a pancreatic disorder.

Uncommon (may affect up to 1 in 100 people):

Itching may occur after treatment, even some weeks after the treatment is stopped. The itching can persist for several months.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store EquiHes 60 mg/ml

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last date of that month.

For single use only. After use, throw away the container and any unused content.

Do not freeze.

Do not use this medicine if the solution is not clear, colourless or the container or its closure show visible signs of damage.

6. Contents of the pack and other information

What EquiHes 60 mg/ml contains

- The active substances in 1000 ml solution are:

| | |
|---------------------------|--------|
| Hydroxyethyl starch (HES) | 60.0 g |
| (Molar substitution: | 0.42) |

| | |
|--------------------------------|-------------|
| (Average molecular weight: | 130,000 Da) |
| Sodium chloride | 6.25 g |
| Potassium chloride | 0.30 g |
| Calcium chloride dihydrate | 0.37 g |
| Magnesium chloride hexahydrate | 0.20 g |
| Sodium acetate trihydrate | 3.27 g |
| L-Malic acid | 0.67 g |

- The other ingredients are:
 - Sodium hydroxide (for pH adjustment)
 - Water for injections

Electrolyte concentrations:

| | |
|-----------|------------|
| Sodium | 140 mmol/l |
| Potassium | 4.0 mmol/l |
| Calcium | 2.5 mmol/l |
| Magnesium | 1.0 mmol/l |
| Chloride | 118 mmol/l |
| Acetate | 24 mmol/l |
| L-Malate | 5.0 mmol/l |

| | |
|--------------------------------|--------------|
| pH: | 5.6–6.4 |
| Theoretical osmolarity: | 296 mOsmol/l |
| Acidity (titration to pH 7.4): | <2.0 mmol/l |

What EquiHes 60 mg/ml looks like and contents of the pack

Clear, colourless, aqueous solution.

EquiHes 60 mg/ml is available in the following packs and pack sizes.

- Plastic bag (Ecobag) with butyl rubber stopper and a polypropylene outer bag in packs of:
 - 20 x 250 ml
 - 20 x 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

B. Braun Melsungen AG

Carl-Braun-Strasse 1

34212 Melsungen

Germany

Postal address:

34209 Melsungen, Germany

Telephone: +49 5661 71 0

Telefax: +49 5661 71 4567

This medicinal product is authorised in the Member States of the EEA under the following names:

| | |
|-----------------|--|
| Austria | Tetraspan 6% Infusionslösung |
| Belgium | Tetraspan 6%, 60 mg/ml oplossing voor infusie |
| Czech Republic | Tetraspan 6% |
| Denmark | Tetraspan 60 mg/ml infusionsvæske |
| Estonia | Tetraspan 60 mg/ml infusioonilahus |
| Finland | Tetraspan 60 mg/ml infuusioneste, liuos |
| Germany | Tetraspan 6% Infusionslösung |
| Greece | Tetraspan διάλυμα για έγχυση 6% |
| Hungary | Tetraspan 60 mg/ml oldatos infúzió |
| Ireland | EquiHes 60 mg/ml Solution for Infusion |
| Iceland | Tetraspan 60 mg/ml innrennslislyf, lausn |
| Italy | Tetraspan 60 mg/ml soluzione per infusione |
| Latvia | Tetraspan 60 mg/ml šķīdum infūzijām |
| Lithuania | Tetraspan 60 mg/ml infuzinis tirpalas |
| Luxembourg | Tetraspan 6% Infusionslösung |
| Norway | Tetraspan 60 mg/ml infusjonsvæske, oppløsning |
| Poland | Tetraspan 60 mg/ml HES roztwór do infuzji |
| Portugal | Tetraspan 60 mg/ml solução para perfusão |
| Slovak Republic | Tetraspan 6% |
| Slovenia | Tetraspan 60 mg/ml raztopina za infundiranje |
| Spain | Isohes 6% Solución para perfusión |
| Sweden | Tetraspan 60 mg/ml infusionsvätska, lösning |
| The Netherlands | Tetraspan 6% g/v, oplossing voor infusie 60g/l |
| United Kingdom | Tetraspan 6% Solution for Infusion |

This leaflet was last revised in 28 February 2014

The following information is intended for healthcare professionals only:

Use of Hydroxyethyl starch (HES) should be restricted to the initial phase of volume resuscitation with a maximum time interval of 24 h.

The first 10-20 ml should be infused slowly and under careful monitoring of the patient so that any anaphylactic/anaphylactoid reaction can be detected as early as possible.

The lowest possible effective dose should be applied. Treatment should be guided by continuous haemodynamic monitoring so that the infusion is stopped as soon as appropriate haemodynamic goals have been achieved. The maximum recommended daily dose must not be exceeded.

Use as soon as the primary packaging is opened. Any unused contents should be discarded.

Administration should begin immediately after connecting the container to the administration set.

For single use only. Do not re-connect partially used containers. Use only if the solution is clear, colourless and the container is undamaged.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

EquiHes 60 mg/ml is iso-oncotic:

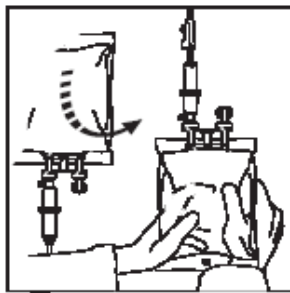
EquiHes 60 mg/ml is an iso-oncotic solution, i.e. the increase in the intravascular plasma volume is equivalent to the infused volume.

Instructions for use for infusion under pressure of EquiHes in:

Ecobag container:

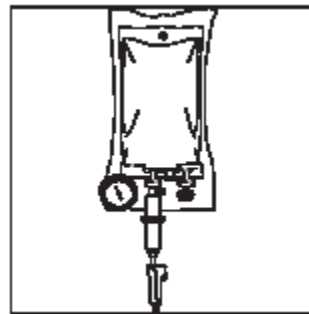
If it is wished to have a very rapid infusion under pressure, all air must be removed from the plastic packaging and the infusion set before the infusion is instituted to prevent the risk of an air embolism during the infusion. An infusion under pressure should be given with a pressure cuff.

Ecobag:



1

- Connect the infusion set.
- Place the container upright.
- Open the roller clamp, expel the air from the container and fill half the drip chamber with liquid.
- Turn the container upside down and prime the infusion tube free from air bubbles..
- Close the roller clamp.



2

- Place the Ecobag bag in a pressure cuff.
- Build up pressure.
- Open the roller clamp and start the infusion