

SUMMARY OF PRODUCT CHARACTERISTICS

B. Braun Melsungen AG · 34209 Melsungen, Germany



Gelaspan solution for infusion

1. NAME OF THE MEDICINAL PRODUCT

Gelaspan solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml solution contain:

Succinylated gelatine (= modified fluid gelatine)	40.0 g
(Molecular weight, weight average: 26 500 Dalton)	
Sodium chloride	5.55 g
Sodium acetate trihydrate	3.27 g
Potassium chloride	0.30 g
Calcium chloride dihydrate	0.15 g
Magnesium chloride hexahydrate	0.20 g

Electrolyte concentrations

Sodium	151 mmol/l
Chloride	103 mmol/l
Potassium	4 mmol/l
Calcium	1 mmol/l
Magnesium	1 mmol/l
Acetate	24 mmol/l

Excipients:

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

Clear, colourless or slightly yellowish solution

Theoretical osmolality:	284 mosmol/l
pH:	7.4 ± 0.3

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gelaspan is a colloidal plasma volume substitute in an isotonic, fully balanced electrolyte solution for:

- Prophylaxis and treatment of imminent or manifest relative or absolute hypovolaemia and shock

4.2 Posology and method of administration

Posology

Dosage and infusion rate are adjusted according to the amount of blood loss and to individual needs for restoration and maintenance of a stable haemodynamic situation, respectively. The dose administered is initially 500 to 1000 ml on average; in case of severe blood loss higher doses have to be applied.

Adults

In adults, 500 ml is administered at an appropriate rate depending on the haemodynamic status of the patient. In the case of more than 20 per cent blood loss usually blood or blood components should be given in addition to Gelaspan.

Paediatric population

The safety and efficacy of Gelaspan in children have not yet been completely established. Therefore, no recommendation on a posology can be made. Gelaspan should only be administered to these patients if the expected benefits clearly outweigh potential risks. In those cases the patient's prevailing clinical condition should be taken into account and the therapy should be monitored especially carefully. (See also section 4.4.)

Maximum dose:

The maximum daily dose is determined by the degree of haemodilution. Care must be taken to avoid a decrease of the haematocrit below critical values, see section 4.4.

If necessary, blood or packed red cells must be transfused additionally.

Attention must also be paid to the dilution of plasma proteins (e.g. albumin and coagulation factors), which must be adequately substituted if necessary.

Infusion rate:

The infusion rate depends on the actual haemodynamic situation.

The first 20 – 30 ml of solution should be infused slowly in order to detect rare anaphylactoid reactions as early as possible. See also sections 4.4 and 4.8.

In shock situations, Gelaspan may be infused rapidly by pressure infusion, 500 ml within 5 – 10 min.

Method of administration

Intravenous use

When given rapidly Gelaspan should be warmed to not more than 37°C if possible. In case of pressure infusion, which might be necessary in vital emergencies, all air must be removed from the container and the infusion set before the solution is administered.

4.3 Contraindications

Gelaspan must not be used in the following situations:

- hypersensitivity to gelatine solutions or to any of the other ingredients of Gelaspan
- hypervolaemia
- hyperhydration
- hyperkalaemia

4.4 Special warnings and precautions for use

Gelaspan should be administered with caution to patients with a history of allergic diseases, e.g. asthma.

Gelatin preparations for volume replacement may rarely cause allergic (anaphylactic/anaphylactoid) reactions of varying degrees of severity. In order to detect the occurrence of an allergic reaction as early as possible, the first 20 – 30 ml should be infused slowly and the patient should be under careful observation especially at the beginning of the infusion. For symptoms of anaphylactoid reactions, see section 4.8. In case of an allergic reaction, the infusion must be stopped immediately and appropriate treatment given.

Gelaspan should be administered only with caution to patients

- at risk due to circulatory overload e.g. patients with congestive heart failure, right or left ventricular insufficiency, hypertension, pulmonary oedema or renal insufficiency with oligo- or anuria.
- with severely impaired renal function
- having oedema with water/salt retention
- with major blood coagulation disorders

Gelaspan must not be infused through the same infusion line together with blood or blood products (packed cells, plasma and plasma fractions).

Checks of serum electrolyte concentrations and water balance are necessary, in particular in patients with hypernatraemia, hyperkalaemia or impairment of renal function.

The haemodynamic, haematological and coagulation system should be monitored.

During compensation of severe blood losses by infusions of large amounts of Gelaspan, haematocrit and electrolytes must be monitored. The haematocrit should not decrease below 25 %. In elderly or critically ill patients it should not fall below 30%. Likewise in those situations the dilution effect on coagulation factors should be observed, especially in patients with existing disorders of haemostasis. Because the product does not substitute lost plasma protein, it is advisable to check the plasma protein concentrations, see also section 4.2, "Maximum dose".

Paediatric population

There is no sufficient experience with the use of Gelaspan in children. Therefore Gelaspan should only be administered to these patients if the expected benefits clearly outweigh potential risks. (See also section 4.2)

Influence on laboratory tests

Laboratory blood tests (blood group or irregular antigens) are possible after Gelaspan infusions. Nevertheless it is recommended to draw blood samples before the infusion of Gelaspan in order to avoid hampered interpretation of results.

Gelaspan may have an influence on the following clinical-chemical tests, leading to falsely high values:

- erythrocyte sedimentation rate,
- specific gravity of urine,
- unspecific protein assays, e.g. the biuret method.

4.5 Interactions with other medicinal products and other forms of interaction

Caution should be exercised in patients concurrently taking or receiving medicinal products that can cause potassium (e.g. potassium sparing diuretics, ACE inhibitors) or sodium retention.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

No data available

Contraception in males and females

No data available

Pregnancy

There are no or limited amount of data from the use of Gelaspan in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Due to possible anaphylactoid reactions with consecutive foetal and neonatal distress due to maternal hypotension, the use of Gelaspan should be avoided during pregnancy unless the clinical condition of the woman requires treatment with the medicinal product.

Breastfeeding

There is insufficient information on the excretion of Gelaspan in human or animal milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Gelaspan therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There are no data on the effect of Gelaspan on human or animal fertility.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The only potentially serious adverse reactions are anaphylactoid reactions described below. However, severe reactions are very rare.



PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Melsungen AG · 34209 Melsungen, Germany

Gelaspan solution for infusion

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Gelaspan is and what it is used for
2. Before you use Gelaspan
3. How to use Gelaspan
4. Possible side effects
5. How to store Gelaspan
6. Further information

1. WHAT GELASPAN IS AND WHAT IT IS USED FOR

Gelaspan is a so-called plasma volume substitute. This means that it replaces fluid lost from the circulation.

Gelaspan is used to replace blood and body fluid, which have been lost as a result of, for example, an operation, an accident or a burn.

2. BEFORE YOU USE GELASPAN

Do not use Gelaspan

- if you are allergic (hypersensitive) to gelatine or any of the other ingredients of Gelaspan
- if your blood volume is too high
- if you have too much water in your body
- if you have an abnormally high blood potassium level.

Special care will be taken with Gelaspan

if you suffer from:

- heart problems
- high blood pressure
- water on your lungs
- severe kidney problems

Giving large amounts of liquids through an intravenous drip may worsen your condition.

Your doctor will also exercise caution

- if your blood clotting is severely impaired
- if you retain water and salt, which may be associated with tissue swelling.

Children:

There is only little experience regarding the use of Gelaspan in children. So the doctor will only administer this medicine to your child when he/she thinks that it is absolutely necessary.

All plasma substitutes carry a slight risk of allergic reactions that are mostly mild or moderate but can in very few cases also become severe. Such reactions are assumed to be more frequent in patients with known allergic conditions such as asthma. For that reason you will be under close observation by a health professional, especially at the beginning of the infusion. While receiving Gelaspan, your blood composition will be monitored.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or using or have recently taken or used any other medicines, including medicines obtained without a prescription.

In particular your doctor should know if you are taking or receiving medicines that make you retain sodium or potassium (e.g. spironolactone, triamterene, amiloride; ACE-inhibitors like captopril or enalapril), such as certain water tablets or cortisones.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Your doctor will give you Gelaspan only if he thinks it is essential for you.

Driving and using machines

Gelaspan is normally given to immobile patients in a controlled setting (e.g.

emergency treatment, acute treatment in a hospital or a day therapy unit). This will exclude driving and using machines.

3. HOW TO USE GELASPAN

Gelaspan is given intravenously, i.e. by a drip.

Adults

How much you are given and for how long will depend on how much blood or fluid you have lost and on your condition.

Children:

There is only little experience of the use of Gelaspan in children. Your doctor will only administer this medicine to your child if he/she considers it essential for your child's recovery. In those cases the clinical condition of your child will be taken into account and his/her therapy will be monitored especially carefully. The doctor will carry out tests (on blood and blood pressure, for example) during treatment, and the dose of Gelaspan will be adjusted according to the patients needs.

In case of pressure infusion, all air must be removed from the container and the infusion set before the solution is administered.

If you received more Gelaspan than you should

An overdose of Gelaspan may cause too high blood volume (hypervolaemia), circulatory overload and imbalances of your blood composition.

You may notice the following symptoms:

- impairment of heart-and lung function
- headache, difficulties to breathe, congestion of blood in the jugular vein

If an overdose occurred your doctor will give you any necessary treatment. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

In this section, side effects are ranked according to their frequency using the following terms:

very common:	affecting more than 1 treated patient of 10
common:	affecting 1 to 10 treated patients of 100
uncommon:	affecting 1 to 10 treated patients of 1,000
rare:	affecting 1 to 10 treated patients of 10,000
very rare:	affecting less than 1 treated patient of 10,000
not known:	cannot be estimated from the available data

The following side effects may become serious and require immediate medical treatment:

Rare:

- allergic skin reactions such as hives or nettle rash
- other allergic (anaphylactoid) reactions, including e.g. difficulty breathing, wheeze, nausea, vomiting, dizziness, sweating, chest or throat tightness, stomach ache, swelling of neck and face

If an allergic reaction, especially an anaphylactoid reaction occurs your infusion will be stopped immediately and you will be given any necessary treatment.

Very rare:

- quickening of heartbeat
- severe allergic (anaphylactoid) reactions such as drop of blood pressure, confusion, involuntary excretion of urine, blue coloration of the skin and mucous membranes (so-called cyanosis) and extremely rare cases of loss of consciousness and collapse.



Approval for Printing

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Approved for Printing when corrected ☐

New draft required ☐

Date _____ Signature _____

Name in capital letters



	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Very rare (< 1/10,000)
Immune system disorders		Anaphylactoid reactions, all grades*	Severe anaphylactoid reactions*
Cardiac disorders			Tachycardia
Vascular disorders			Hypotension
Respiratory, thoracic and mediastinal disorders			Respiratory difficulties
Skin and subcutaneous tissue disorders		Allergic skin reactions*	
General disorders and administration site conditions	Mild transient increase of body temperature		Fever, chills

*

Mild anaphylactoid reactions include:

Generalised oedema, urticaria, periorbital oedema, or angioedema.

Moderate anaphylactoid reactions include:

Dyspnoea, stridor, wheeze, urticaria, nausea, vomiting, dizziness (presyncope), diaphoresis, chest or throat tightness, or abdominal pain.

Severe anaphylactoid reactions include:

Cyanosis or SaO₂ ≤ 92% at any stage, hypotension (systolic blood pressure < 90 mmHg in adults), confusion, collapse, loss of consciousness or incontinence.

In the event of an anaphylactoid reaction, the infusion must be discontinued immediately and the usual acute treatment given.

Paediatric patients:

No special features

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 following:

United Kingdom

– Yellow card scheme:

www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

Symptoms

Overdose of Gelaspan may cause hypervolaemia and circulatory overload with a significant fall in haematocrit and plasma proteins. This may be associated with consecutive impairment of heart and lung function (pulmonary oedema). Symptoms of circulatory overload are e.g. headache, dyspnoea, and jugular vein congestion.

Treatment

In case of circulatory overload the infusion must be stopped and a rapid-acting diuretic should be given. If an overdose occurs, the patient should be treated symptomatically and electrolytes should be monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group

Blood substitutes and plasma protein fractions

ATC code: B05A A06, gelatine agents.

Gelaspan is a 4 % w/v solution of succinylated gelatine (also known as modified fluid gelatine) with an average molecular weight of 26 500 Dalton (weight average) in a plasma-adapted, balanced isotonic electrolyte solution. The negative charges introduced into the molecule by succinylation cause an expansion of the molecule. The molecular volume is therefore higher than that of unsuccinylated gelatine of the same molecular weight.

The measured initial volume effect of Gelaspan is about 100% of the infused volume with a sufficient volume effect over 4 – 5 hours.

Gelaspan does not interfere with the determination of blood groups and it is neutral regarding clotting mechanisms.

Therapeutic effect

Gelaspan substitutes intra- and extravascular volume deficits caused by losses of blood, plasma and interstitial fluid. Thus the mean arterial pressure, the left-ventricular end-diastolic pressure, the cardiac stroke volume, the cardiac index, the oxygen supply, the microcirculation and the diuresis are increased without dehydrating the extravascular space.

Mechanisms of action

The colloid-osmotic pressure of the solution determines its initial volume effect. The duration of the effect depends on the clearance of the colloid mainly by renal excretion. Since the volume effect of Gelaspan is equivalent to the administered amount of solution, Gelaspan is a plasma substitute, not a plasma expander. The solution also restores the extravascular compartment, does not disturb the electrolyte bal-

ance of the extracellular space. Gelaspan is isotonic, it therefore does not cause fluid shifts into the intracellular space as caused by hypotonic solutions. Gelaspan contributes in the restoration of electrolyte balance and the correction of acidosis. Gelaspan is lactate free and can be used in patients with liver diseases. As a precursor of bicarbonate the solution contains acetate which is metabolisable in all organs and muscles.

5.2 Pharmacokinetic properties

Distribution

After infusion, Gelaspan is rapidly distributed in the intravascular compartment. There is no evidence that Gelaspan is stored in the reticulo-endothelial system or elsewhere in the organism.

Metabolism/elimination

Most of the infused Gelaspan is excreted via the kidneys. Only a minor amount is excreted in faeces and not more than about 1 % is metabolised. The smaller molecules are excreted directly by glomerular filtration while the larger molecules first are degraded proteolytically and then excreted via kidneys. The proteolytic metabolism is so adaptable that even under the condition of renal insufficiency no accumulation of Gelaspan is observed.

Pharmacokinetics in special clinical situations

The plasma half-life of Gelaspan may be prolonged in patients on haemodialysis (GFR < 0.5 ml/min). Gelaspan minimizes the risks of dilutional acidosis and rebound alkalosis as observed with lactate containing solutions infused to patients with liver diseases. Gelaspan contains acetate and is lactate free. It therefore can also be indicated in hypovolaemic patients with liver disease.

5.3 Preclinical safety data

Non-clinical data for the individual components of Gelaspan reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity. There is no or limited non-clinical data available for reproductive toxicity.

The maximum dose of the product is limited by its volume and dilution effects, not by any intrinsic toxicological properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide (for pH adjustment),

Hydrochloric acid, diluted (for pH-adjustment),

Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

• **Unopened**

Polyethylene containers "Ecoflac plus": 2 years

Plastic bags "Ecobag" (non-PVC): 2 years

• **After first opening the container**

The infusion should commence immediately after connecting the container to the giving set.

• **After admixture of an additive**

Not applicable (see section 6.2)

6.4 Special precautions for storage

Do not store above 25 °C. Do not freeze.

6.5 Nature and contents of container

Gelaspan is supplied in:

• Bottles of low-density polyethylene "Ecoflac plus", contents: 500 ml

available in packs of 10 × 500 ml

• Plastic bags "Ecobag" (non-PVC), sealed with halogenbutyl rubber stoppers contents: 500 ml

available in packs of 20 × 500 ml

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

No special requirements for disposal

The product is supplied in containers for single use only. Unused contents of an opened container must be discarded.

Only to be used if solution is clear and free of precipitate and the container undamaged.

Use immediately after connecting container to the giving set.

7. MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG

Carl-Braun-Straße 1

34212 Melsungen, Germany

Postal address

34209 Melsungen

8. MARKETING AUTHORISATION NUMBER(S)

PA 736/34/1 (Ireland)

PL 03551/0120 (United Kingdom)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation:

9th September 2011 (Ireland)

14th June 2011 (United Kingdom)

10. DATE OF REVISION OF THE TEXT

September 2014

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B. Braun Melsungen AG
34209 Melsungen, Germany

Such reactions are assumed to be more frequent in patients with known allergic conditions such as asthma.

Unfortunately, there is no test which can show in advance who is likely to experience such reactions, nor can their course be predicted.

Other side effects include:

Uncommon:

• mild short lasting increase of body temperature

Very rare:

• fever, chills

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

5. HOW TO STORE GELASPAN

Keep out of the reach and sight of children.

Do not use Gelaspan after the expiry date which is stated on the label and the outer carton. The expiry date refers to the last day of that month.

Do not store above 25 °C. Do not freeze.

Do not use Gelaspan if you notice:

- cloudiness or discolouration of the solution
- leaking of the container.

Previously opened or partly used Gelaspan should be thrown away. Partially used bottles or bags should not be reconnected.

6. FURTHER INFORMATION

What Gelaspan contains

Active substances:

1000 ml of the solution contain:

Succinylated (modified fluid) gelatine 40.0 g

Sodium chloride 5.55 g

Sodium acetate trihydrate 3.27 g

Potassium chloride 0.30 g

Calcium chloride dihydrate 0.15 g

Magnesium chloride hexahydrate 0.20 g

Electrolyte concentrations

Sodium 151 mmol/l

Chloride 103 mmol/l

Potassium 4 mmol/l

Calcium 1 mmol/l

Magnesium 1 mmol/l

Acetate 24 mmol/l

The other ingredients are:

Water for injections, hydrochloric acid, diluted (for pH-adjustment) and sodium hydroxide (for pH adjustment).

What Gelaspan looks like and contents of the pack

Gelaspan is a solution for infusion administered through an intravenous drip (a drip into a vein).

It is a clear colourless or slightly yellowish sterile solution.

Gelaspan is supplied in:

• Bottles of low-density polyethylene "Ecoflac plus", contents: 500 ml

available in packs of 10 × 500 ml

• Plastic bags "Ecobag" (non-PVC), sealed with rubber stoppers, contents: 500 ml

available in packs of 20 × 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Carl-Braun-Straße 1

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Fax: +49-5661-4567

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

Austria	Gelofusin Iso 40mg/ml Infusionslösung
Belgium	Isogelo oplossing voor infusie, solution pour perfusion, Infusionslösung
Bulgaria	Gelofusine Balance 4% solution for Infusion
Czech Republic	Gelaspan 4%
Germany	Gelafundin ISO 40mg/ml Infusionslösung
Denmark	Gelaspan
Estonia	Gelaspan infusioonilahus 4%
Greece	Gelaspan solution for Infusion 4%
Spain	Gelaspan 40mg/ml solución para perfusión
Finland	Gelaspan
France	Gelaspan, solution pour perfusion
Hungary	Gelaspan 4% oldatos infúzió
Ireland	Gelaspan Solution for Infusion
Italy	Gelaspan
Lithuania	Gelaspan 4% infuzinis tirpalas
Luxemburg	Gelafundin ISO 40mg/ml Infusionslösung
Latvia	Gelaspan 4% Solution for Infusion
Malta	Gelaspan 4% Solution for Infusion
Norway	Gelaspan
Netherlands	Gelaspan, oplossing voor infusie
Portugal	Gelaspan
Poland	Gelaspan
Romania	Gelaspan 40 mg/ml solutie perfuzabila
Sweden	Gelaspan
Slovenia	Gelaspan 40 mg/ml raztopina za infundiranje
Slovakia	Gelaspan 4%
United Kingdom	Gelaspan solution for infusion

This leaflet was last approved in January 2015

The following information is intended for health-care professionals only:

Precautions for use

Gelaspan must not be infused through the same infusion line together with blood or blood products (packed cells, plasma and plasma fractions).

During compensation of severe blood losses by infusions of large amounts of Gelaspan, haematocrit and electrolytes must be monitored. The haematocrit should not decrease below 25 %. In elderly or critically ill patients it should not fall below 30%.

Likewise in those situations the dilution effect on coagulation factors should be observed, especially in patients with existing disorders of haemostasis.

Because the product does not substitute lost plasma protein, it is advisable to check the plasma protein concentrations.

Influence on laboratory tests

Laboratory blood tests (blood group or irregular antigens) are possible after Gelaspan infusions. Nevertheless it is recommended to draw blood samples before the infusion of Gelaspan in order to avoid hampered interpretation of results.

Gelaspan may have an influence on the following clinical-chemical tests, leading to falsely high values:

- erythrocyte sedimentation rate,
- specific gravity of urine,
- unspecific protein assays, e.g. the Biuret method.

Incompatibilities

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