

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SmofKabiven?

SmofKabiven contains the active ingredients alanine, arginine, glycine, histidine, isoleucine, leucine, lysine acetate, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride dihydrate, sodium glycerophosphate hydrate, magnesium sulfate heptahydrate, potassium chloride, sodium acetate trihydrate, zinc sulfate heptahydrate, glucose monohydrate, soya oil, medium chain triglycerides, olive oil and fish oil-rich in omega-3 acids.

SmofKabiven is used as parenteral nutrition for adult patients and paediatric patients aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated.

For more information, see Section [1. Why am I using SmofKabiven?](#) in the full CMI.

2. What should I know before I use SmofKabiven?

Do not use if you have ever had an allergic reaction to SmofKabiven or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SmofKabiven?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SmofKabiven and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SmofKabiven?

- Your doctor will decide on the dose for you individually depending on your body weight and function. SmofKabiven will be given to you by a health care professional.
- Follow the instructions provided and use SmofKabiven until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use SmofKabiven?](#) in the full CMI.

5. What should I know while using SmofKabiven?

Things you should do	<ul style="list-style-type: none">Follow the instructions provided and use SmofKabiven until your doctor tells you to stop.Remind any doctor, nurse, dentist or pharmacist you visit that you are using SmofKabiven.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine until your doctor tells you to stop.
Driving or using machines	<ul style="list-style-type: none">The effects of SmofKabiven on a person's ability to drive and use machines were not studied.
Drinking alcohol	<ul style="list-style-type: none">The effects of alcohol with SmofKabiven use were not studied. Your doctor will decide what you need to do.
Looking after your medicine	<ul style="list-style-type: none">SmofKabiven should be stored in its overpouch below 25°C and not be frozen. Do not use infusion bags that have been used, have expired or the container is damaged.

For more information, see Section [5. What should I know while using SmofKabiven?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects have been reported during post-market monitoring. If you get any adverse effects, talk to your doctor or nurse. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SmofKabiven®

Active ingredient(s): Amino acids 5.1%, lipids 3.8%, glucose 12.7% & electrolytes 0.7%

Consumer Medicine Information (CMI)

This leaflet provides important information about using SmofKabiven. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SmofKabiven.**

Where to find information in this leaflet:

- [1. Why am I using SmofKabiven?](#)
- [2. What should I know before I use SmofKabiven?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SmofKabiven?](#)
- [5. What should I know while using SmofKabiven?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SmofKabiven?

SmofKabiven contains the active ingredients alanine, arginine, glycine, histidine, isoleucine, leucine, lysine acetate, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride dihydrate, sodium glycerophosphate hydrate, magnesium sulfate heptahydrate, potassium chloride, sodium acetate trihydrate, zinc sulfate heptahydrate, glucose monohydrate, soya oil, medium chain triglycerides, olive oil and fish oil-rich in omega-3 acids.

SmofKabiven is a solution for parenteral nutrition comprising of amino acids (components used to build proteins), glucose (carbohydrates), lipids (fat) and salts (electrolytes). It is an emulsion for infusion given into your blood by a drip (intravenous infusion).

SmofKabiven is used as parenteral nutrition for adult patients and paediatric patients aged 2 years and above when oral or enteral nutrition is impossible, insufficient or contraindicated. A health care professional will give you SmofKabiven when other forms of feeding are not good enough or have not worked.

2. What should I know before I use SmofKabiven?

Warnings

Do not use SmofKabiven if:

- you are allergic to the active ingredients, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- if you are allergic to fish or egg

- if you are allergic to peanuts, soya or corn (maize) as SmofKabiven contains soya oil
- if you have too much fat in the blood (hyperlipidaemia)
- if you have serious liver disease
- if you have blood clotting problems (coagulation disorders)
- if your body has problems using amino acids
- if you have serious kidney disease without access to dialysis
- if you are in acute shock
- if you have too much sugar in your blood (hyperglycaemia) which is uncontrolled
- if you have high blood (serum) levels of the salts (electrolytes)
- if you have fluid in the lungs (acute pulmonary oedema)
- if you have too much body fluid (hyperhydrated)
- if you have heart failure that is not treated
- if you have a defect in your blood clotting system (haemophagocytotic syndrome)
- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, acute heart attack, stroke, blood clot, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis), coma and if you don't have enough body fluid (hypotonic dehydration).

Check with your doctor if you:

- kidney problems
- diabetes mellitus
- pancreatitis (inflammation of the pancreas)
- liver problems
- hypothyroidism (toxic goiter)
- sepsis (serious infection)
- take any medicines for any other condition

If during the infusion you get fever, rash, swelling, difficulty in breathing, chills, sweating, nausea or vomiting, tell the health care professional immediately because these symptoms might be caused by an allergic reaction or that you have been given too much of the medicine.

Your doctor may regularly need to check your blood for liver function tests and other values.

SmofKabiven is not suitable for use in neonates and infants below 2 years of age. There is at present no clinical trial conducted on the use of SmofKabiven in children age 2 years to 11 years.

Please tell your doctor if you have or recently have taken some medicines, even without prescription.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

SmofKabiven should only be given to pregnant or breastfeeding women if the doctor finds it necessary.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with SmofKabiven and affect how it works.

Some medicinal products, like insulin, may interfere with the body's lipase system. This kind of interaction seems, however, to be of limited clinical importance.

Heparin given in clinical doses causes a transient release of lipoprotein lipase into the circulation. This may result initially in increased plasma lipolysis followed by a transient decrease in triglyceride clearance.

Soya oil has a natural content of vitamin K₁. However, the concentration in SmofKabiven is so low that it is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SmofKabiven.

4. How do I use SmofKabiven?

How much to take / use

- Your doctor will decide on the dose for you individually depending on your body weight and function. SmofKabiven will be given to you by a health care professional.
- Follow the instructions provided and use SmofKabiven until your doctor tells you to stop.

When to take / use SmofKabiven

- SmofKabiven should be administered by continuous flow into a large main vein using a sterile tubing and a catheter needle. It should only be administered to you by qualified medical staff.

If you forget to use SmofKabiven

This rarely happens as SmofKabiven is usually administered under the care of a trained health care professional in a hospital or clinic setting.

If you use too much SmofKabiven

This rarely happens as SmofKabiven is usually administered under the care of a trained health care professional in a hospital or clinic setting.

If you think that you have been given too much SmofKabiven, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SmofKabiven?

Things you should do

Follow the instructions provided and use SmofKabiven until your doctor tells you to stop.

Call your doctor straight away if you:

- have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using SmofKabiven.

Things you should not do

- Do not stop using this medicine until your doctor tells you to stop.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SmofKabiven affects you.

The effects of SmofKabiven on a person's ability to drive and use machines were not studied.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol with SmofKabiven use were not studied. Your doctor will decide what you need to do.

Looking after your medicine

SmofKabiven should be stored in its overpouch below 25°C and not be frozen. Do not use infusion bags that have been used, have expired or the container is damaged.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

The below less serious side effects were reported during post-market monitoring.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> Nausea and Vomiting Flatulence Abdominal pain Swelling of hands, ankles or feet Fast heartbeat Difficulty in breathing Lack of appetite Low or high blood pressure Slight increase in body temperature Chills Dizziness Headaches Hypersensitivity reactions (skin rash) Sensations of hot and cold Pain in the neck, back, bones, chest Paleness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Tell your doctor if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SmofKabiven contains

Active ingredients (main ingredient)	Alanine, arginine, glycine, histidine, isoleucine, leucine, lysine acetate, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, calcium chloride dihydrate, sodium glycerophosphate hydrate,
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	magnesium sulfate heptahydrate, potassium chloride, sodium acetate trihydrate, zinc sulfate heptahydrate, glucose monohydrate, soya oil, medium chain triglycerides, olive oil and fish oil-rich in omega-3 acids
Other ingredients (inactive ingredients)	Glycerol, egg lecithin, dl- α -tocopherol, sodium hydroxide, sodium oleate, glacial acetic acid, hydrochloric acid and Water for Injections
Potential allergens	Egg lecithin, fish oil, phenylalanine and soya oil

Do not take this medicine if you are allergic to any of these ingredients.

SmofKabiven does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

SmofKabiven does not contain any preservative.

What SmofKabiven looks like

SmofKabiven comes in a 3-chamber plastic bag called Biofine bag in 4 pack sizes. Each chamber contains glucose, amino acids with electrolytes and a lipid emulsion separately. The glucose and amino acid solutions are clear, colourless or slightly yellow and free from particles. The lipid emulsion is white and homogeneous.

They can be identified by the following AUST R numbers:

AUST R 173890: 986 mL

AUST R 180543: 1477 mL

AUST R 180546: 1970 mL

AUST R 180547: 2463 mL

Who distributes SmofKabiven

Fresenius Kabi Australia Pty Limited

Level 2, 2 Woodland Way,

Mount Kuring-gai, NSW 2080,

Australia.

Telephone: 1300 361 004

This leaflet was prepared in November 2021.