





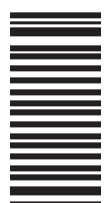
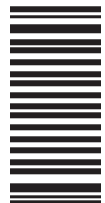


advicenne	BLEU BANQUISE 	
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PRODUCT NAME	SIBNAYAL*	
NEW ITEM CODE	GB 014E04-04.25	
OLD ITEM CODE	-	
TYPE	Leaflet	
STRENGTH(S)	8 mEq / 24 mEq	
PHARMA. FORM	capsules	
ZONE	-	
COUNTRY	GB	
LANGUAGE	ENGLISH	
MANUFACTURER	-	
FORMAT	480x780 mm	
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VERSION	1	



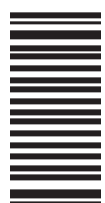
sibnayaL® 8 mEq

sibnayaL® 24 mEq



sibnayaL® 8 mEq

sibnayaL® 24 mEq



Package leaflet: Information for the user

sibnayaL® 8 mEq prolonged-release granules

sibnayaL® 24 mEq prolonged-release granules potassium citrate/potassium hydrogen carbonate

Read all of this leaflet carefully before you start taking 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SibnayaL is and what it is used for
2. What you need to know before you take SibnayaL
3. How to take SibnayaL
4. Possible side effects
5. How to store SibnayaL
6. Contents of the pack and other information

1. What SibnayaL is and what it is used for

SibnayaL contains two active substances, potassium citrate and potassium hydrogen carbonate (also known as potassium bicarbonate).

SibnayaL is an alkalisng medicine that is used to control blood acidity caused by a kidney disease called distal renal tubular acidosis (dRTA).

SibnayaL will help reduce the effect of dRTA on your everyday life.

SibnayaL is used in adults, adolescents and children above 1 year.

2. What you need to know before you take SibnayaL

Do not take SibnayaL if:

- you are allergic to potassium citrate or potassium bicarbonate or any of the other ingredients of this medicine (listed in section 6),
- you have a severe kidney disease or kidney failure,
- you have a high level of potassium in your blood (hyperkalaemia).

Warnings and precautions

Talk to your doctor before taking SibnayaL if:

- you have a disease or you take a medicine that can increase your blood potassium (see below "Other medicines and SibnayaL").
- you frequently have gastro-intestinal symptoms such as bloating, diarrhoea, nausea, vomiting,
- you have chronic kidney disease.

SibnayaL prolonged-release granules are designed to release the active substances slowly after taking the granules. You may see remains of the granules in your stools. This is normal and does not reduce the effectiveness of the medicine.

If you vomit within two hours after intake, you should take another dose.

You will need regular appointments with your doctor. From time to time, your doctor may need to do blood, urine or heart tests, to adjust the dose of SibnayaL. Your doctor will regularly check your kidney function if you are elderly and/or have worsening kidney function.

Children

Do not give this medicine to children below 1 year of age because of the risk of choking.

Other medicines and SibnayaL

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Some medicines may affect how SibnayaL works or make side effects more likely. These include:

- any medicine that increases the level of potassium in your blood such as:
 - angiotensin-converting enzyme (ACE) inhibitors (used to treat high blood pressure, heart disease and kidney disease in patients suffering from type 1 diabetes),
 - potassium-sparing diuretics (used to treat high blood pressure, fluid build-up in tissue (oedema) and heart conditions),
 - potassium supplements (used to prevent or treat low potassium levels in the blood),
 - ciclosporin (used to prevent or treat transplant rejection),
 - heparin sodium (used to prevent or delay blood clotting),
 - nonsteroidal anti-inflammatory drugs (NSAIDs) (used to reduce fever, pain and inflammation),
- any medicine that may be affected by a disturbance in the level of potassium in your blood such as:
 - digitalis glycosides (such as digoxin, used to treat heart failure and certain heart rhythm disorders),
 - corticosteroids (used to treat inflammation),
- any other medicine that could cause heart rhythm disorders such as:
 - amiodarone and quinidine (used to control cardiac rhythm),
 - chlorpromazine (used to treat certain mental illnesses),
 - cisapride (used to treat heartburn),
 - sparfloxacin (used to treat certain bacterial infections).

Some medicines may be affected by increased urine pH in relation with SibnayaL treatment such as :

- salicylates (used to treat pain and inflammation – aspirin-like medicines),
- tetracyclines (used to treat certain bacterial infections),
- barbiturates (sleep inducing medicines).

SibnayaL with food, drink and alcohol

Do not mix SibnayaL with hot food or hot liquids. Do not drink alcohol while you are taking SibnayaL.

Pregnancy, breast-feeding and fertility

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.

Driving and using machines

SibnayaL is not likely to affect your ability to drive or use machines.

SibnayaL contains potassium

SibnayaL 8 mEq contains 308 mg of potassium per sachet. This is to be taken into consideration if you have a reduced kidney function or if you are on a controlled potassium diet. SibnayaL 24 mEq contains 924 mg of potassium per sachet. This is to be taken into consideration if you have a reduced kidney function or if you are on a controlled potassium diet.

3. How to take SibnayaL

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The amount of SibnayaL that people have to take depends on their age, weight and condition. Your doctor will tell you exactly the dose of SibnayaL to take. This will always be one or more whole sachets.

Your doctor may need to adjust your dose of SibnayaL.

The use of this medicine requires medical supervision.

Dosage

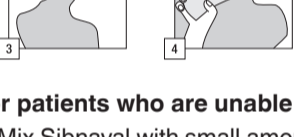
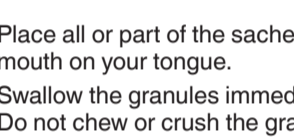
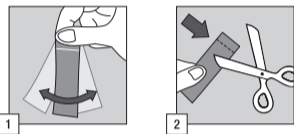
The dose is adjusted by the doctor according to the level of bicarbonate in your blood.

How to use

SibnayaL is for oral use (to be taken by mouth).

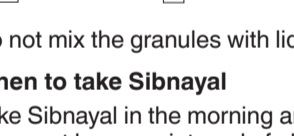
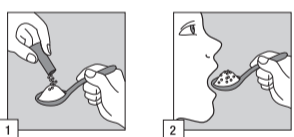
If you are not sure of how to use SibnayaL, contact your doctor or pharmacist.

1. Hold the sachet vertically with your fingers above the dotted line. Shake it from side to side to ensure the contents move to the bottom of the sachet.
2. Cut the sachet along the dotted line, using scissors if necessary.
3. Place all or part of the sachet contents directly into your mouth on your tongue.
4. Swallow the granules immediately with a large glass of water. Do not chew or crush the granules. **Repeat steps 1 to 4** as required until you have taken the full dose.



For patients who are unable to swallow granules

1. Mix SibnayaL with small amounts of soft and cold food (e.g. fruit puree or yoghurt) directly on the spoon. You must swallow the soft food mixture immediately. Do not store the mixture for use later.
2. Place the mixture directly into the mouth and swallow it without chewing. Make sure that SibnayaL does not remain in the mouth. **Repeat steps 1 and 2** as required until the full dose has been taken.



Do not mix the granules with liquid before taking them.

When to take SibnayaL

Take SibnayaL in the morning and in the evening, during a meal. You must leave an interval of about 12 hours in between each dose to cover the whole night-and-day period.



Dose adjustment

Dose increases/decreases should be gradual, taking place over a few weeks. Your doctor will adjust the dose according to your condition. The usual recommended dose is 4 to 6 whole sachets of 24 mEq each day.

Please consult your doctor in the event of any side effects, as he / she may have to adjust the dose of this medicine.

Switch from another alkalisng medicine

If you are switching from another alkalisng medicines to SibnayaL, your doctor should closely supervise the switchover.

If you take more SibnayaL than you should

Talk to your doctor or pharmacist if you have taken more SibnayaL than you should have.

You may feel nauseous, need to vomit and have diarrhoea. If you have taken a large amount of SibnayaL, you may feel weak or get unexplained tightness of the muscles, spasms (muscular contraction), abnormal tingling or burning sensations, pins and needles or numbness, mental confusion or an abnormal heart rate.

If you forget to take SibnayaL

Do not take a double dose to make up for a forgotten dose. Take it as soon as you remember. However, if your next dose is in less than six hours, skip the missed dose. Do not take more than two doses a day.

Talk to your doctor if you forget to take one or more doses.

If you stop taking SibnayaL

This medicine is for long-term use. It will only be effective as long as you are using it.

Do not stop unless your doctor tells you to, even if you feel better, as your disease may get worse. If you want to stop treatment, first talk to your doctor.

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

4. Possible side effects

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

Very common side effects (which may affect more than 1 in 10 people)

- abdominal pain (belly pain)

Common side effects (which may affect up to 1 in 10 people)

- upper abdominal pain (upper belly pain),
- gastrointestinal pain and disorders (stomach and intestinal pain and disorders),
- dyspepsia (poor digestion),
- vomiting,
- diarrhoea,
- feeling sick (nausea) when starting treatment.

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 via the national reporting system:

Yellow Card Scheme Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store SibnayaL

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 sachet and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

After opening a sachet, discard any unused content.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SibnayaL contains

The active substances are potassium citrate and potassium hydrogen carbonate (also known as potassium bicarbonate). Each sachet of SibnayaL 8 mEq contains 282 mg of potassium citrate and 527 mg of potassium hydrogen carbonate.

Each sachet of SibnayaL 24 mEq contains 847 mg of potassium citrate and 1.582 mg of potassium hydrogen carbonate.

The other ingredients are hypromellose (E464), microcrystalline cellulose (E460 (i)), glycerol dibehenate, magnesium stearate (E470b), silica colloidal anhydrous, magnesium oxide heavy (E530), ethylcellulose (E462), chlorophyllin (E140 (ii)), talc.

What SibnayaL looks like and contents of the pack

SibnayaL is a mixture of green and white prolonged-released granules supplied in sachets.

Cartons contain 60 sachets.

SibnayaL is available in multipacks comprising 2, 3, 4, 5 and 6 cartons, each containing 60 sachets.

Not all pack sizes may be marketed.


Marketing Authorisation Holder and Manufacturer

ADVICENNE
262 rue du Faubourg Saint Honoré
75008 Paris
France

This leaflet was last revised in 04/2025.

Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency (MHRA) web site: www.mhra.gov.uk

adivcenne	BLEU BANQUISE 
	Folder n° : 251142
PRODUCT NAME	SIBNAVAL®
NEW ITEM CODE	GB 014E04-04.25
OLD ITEM CODE	-
TYPE	Leaflet
STRENGTH(S)	8 mEq / 24 mEq
PHARMA. FORM	capsules
ZONE	-
COUNTRY	GB
LANGUAGE	ENGLISH
MANUFACTURER	-
FORMAT	480x780 mm
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TECHNICAL COLOURS	Technical data
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MIN. FONT SIZE	9 pts
SOFTWARE	Indesign CC
BAR CODES	128 00000000
DATE (day/month/year)	23/04/2025
VERSION	1

