

Package leaflet: information for the user

Bergal SR 8 mg hard capsules with prolonged release
Bergal SR 16 mg hard capsules with prolonged release
Bergal SR 24 mg hard capsules with prolonged release
Galantamine

Read the entire 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.
- Do you have any questions? Then contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Bergal SR and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you take this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the pack and other information.

1. What is Bergal SR and what is this medicine used for?

Bergal SR contains the active substance 'galantamine', a medicine for dementia. It is used in adults for the treatment of symptoms of mild to moderately severe Alzheimer's disease, a type of dementia that alters brain function.

Alzheimer's disease causes increasing memory loss, confusion, and behavioral changes, making it increasingly difficult to perform daily activities. These effects are thought to be due to a deficiency of 'acetylcholine', a substance responsible for communication between brain cells. This medicine increases the amount of acetylcholine in the brain and thus treats the symptoms of the disease.

The capsules are made in an 'extended-release' form. This means they release the medicine more slowly.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine. You can find these substances in section 6 of this leaflet.
- You have a severe liver or kidney disorder.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine.

This medicine should only be used for Alzheimer's disease and is not recommended for other types of memory loss or confusion.

Serious side effects

This medicine can cause serious skin reactions, heart problems, and seizures (epileptic fits). You should be aware of these side effects if you use this medicine. See 'Watch out for serious side effects' in section 4.

Before taking this medicine, your doctor needs to know if you have or have had any of the following conditions:

- liver or kidney problems;
- a heart condition (such as chest discomfort often caused by physical activity, a heart attack, heart failure, slow or irregular heartbeat, prolonged QT interval);
- changes in the amount of 'electrolytes' (these are naturally occurring chemicals in the blood, such as potassium);
- a stomach ulcer;
- blockage of the stomach or intestines;
- a disorder of the nervous system (such as epilepsy or problems with controlling movements of the body or limbs (extrapyramidal disorder));
- a respiratory disease or infection affecting breathing (such as asthma, chronic obstructive pulmonary disease, or pneumonia);
- problems with urination.

Your doctor will decide if this medication is suitable for you or if the dose needs to be changed.

Also inform your doctor if you have recently undergone surgery on your stomach, intestines, or bladder. Your doctor may then decide that this medication is not suitable for you.

This medication can cause weight loss. Your doctor will regularly monitor your weight while you are using this medication.

Children and adolescents under 18 years

This medication is not recommended for children and adolescents under 18 years.

Are you taking any other medications?

Are you taking any other medications besides Bergal SR, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist.

Bergal SR should not be used in combination with medications with a similar action, including:

- donepezil or rivastigmine (for Alzheimer's disease)
- ambenonium, neostigmine, or pyridostigmine (for severe muscle weakness)
- pilocarpine (for dry mouth or dry eyes when taken orally).

Some medications can increase the risk of side effects in people using Bergal SR. This applies to:

- paroxetine or fluoxetine (antidepressants)
- quinidine (used for irregular heartbeat)
- ketoconazole (an antifungal agent)
- erythromycin (an antibiotic)

- ritonavir (a medicine against the human immunodeficiency virus or 'HIV')
- non-steroidal anti-inflammatory painkillers (such as ibuprofen) that can increase the risk of (stomach) ulcers
- medicines used for heart conditions or high blood pressure (such as digoxin, amiodarone, atropine, beta-blockers, or calcium channel blockers). If you are taking medication for an irregular heartbeat, your doctor may find an electrocardiogram (ECG) necessary.
- medicines that affect the QTc interval.

If you are taking some of the above medicines, your doctor may give a lower dose of this medicine.

Bergal SR can affect some anesthetics. If you need to undergo surgery with full anesthesia, inform the doctor well in advance that you are using this medicine. If you have any questions about the use of this medicine, ask your doctor or pharmacist for advice.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

You should not breastfeed if you are using Bergal SR.

Driving and using machines

This medicine can make you feel dizzy or drowsy, especially during the first weeks of treatment. If you feel drowsy or dizzy, you should not drive or handle dangerous tools or operate machines.

Bergal SR contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per extended-release capsule, which means it is essentially 'sodium-free'.

3. How do you take this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

If you are currently taking galantamine tablets or liquid and your doctor has told you to switch to galantamine extended-release hard capsules, carefully read the instructions under 'Switching from galantamine tablets or liquid to Bergal SR extended-release hard capsules' in this section.

How much of this medicine should you take?

You start with this medicine at a low dose. The usual dose is 8 mg, taken once a day. Your doctor may gradually increase your dose, every 4 weeks or later, until you reach a dose that is suitable for you. The maximum dose is 24 mg, taken once a day.

Your doctor will explain with which dose you should start and when the dose should be increased. If you are unsure what to do or feel that the effect of this medicine is too strong or too weak, discuss it with your doctor or pharmacist.

Your doctor will need to see you regularly to check if this medicine is working well for you and to discuss how you are feeling.

If you have liver or kidney problems, your doctor may give you a lower dose of this medicine or decide that this medicine is not suitable for you.

Switching from galantamine tablets or liquid to Bergal SR hard capsules If you are currently taking galantamine tablets or liquid, your doctor may decide to switch to Bergal SR extended-release hard capsules. If this applies to you:

- Take your last dose of galantamine tablets or liquid in the evening.
- The next morning, take your first dose of Bergal SR extended-release hard capsules.

DO NOT take more than one capsule per day. While using Bergal SR extended-release capsules once daily, you MUST NOT take galantamine tablets or liquid.

How to take?

Bergal SR capsules should be swallowed whole, they MUST NOT be chewed or crushed. If you find the capsules difficult to swallow, you can empty the contents of the capsule and swallow the entire contents without chewing or crushing.

Take your dose of Bergal SR once a day in the morning, with water or another liquid. Try to take this medicine with food.

Drink plenty of fluids while using Bergal SR to keep yourself hydrated (to avoid becoming dehydrated).

Have you used too much of this medicine?

If you have taken too much Bergal SR, consult a doctor immediately or go to the hospital. Take any remaining capsules and the packaging with you. The signs and symptoms of overdose may include:

- severe nausea and vomiting
- weak muscles, slow heartbeat, seizures (epileptic fits), and loss of consciousness

Have you forgotten to take this medicine?

If you have forgotten to take one dose, you should not take the missed dose anymore. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose. If you have missed more than one dose, consult your doctor.

If you stop taking this medicine

Never stop Bergal SR without consulting your doctor. It is important to continue taking this medicine to treat your condition.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone will experience them.

Watch out for serious side effects

Stop using Bergal SR and consult a doctor or the nearest emergency department immediately if you notice any of the following side effects:

Skin reactions including:

- severe skin rash with blisters and peeling skin, mainly around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome);
- red skin rash covered with small, pus-filled bumps, which can spread over the body and is sometimes accompanied by fever (acute generalized exanthematous pustulosis);
- skin rash that may cause blistering, with spots that look like 'target lesions'.

These skin reactions are rare in people using Bergal SR (may affect up to 1 in 1000 people).

Heart problems, including a change in your heart rate (such as slow or irregular heartbeat, extra heartbeats) or palpitations (heart palpitations, your heartbeat feels fast or irregular). Heart problems can cause an abnormal recording on an electrocardiogram (ECG) and they can often occur in people using this medicine (occur in less than 1 in 10 people).

Seizures (epileptic fits). These sometimes occur in people using this medicine (occur in less than 1 in 100).

You should stop using Bergal SR and seek help immediately if you notice any of the above side effects.

Other side effects

Very common (occur in more than 1 in 10 people):

- Nausea and vomiting. These side effects are more likely in the first weeks of treatment or if the dose is increased. They usually subside gradually as the body gets used to this medicine and will generally last only a few days. If you experience these effects, your doctor may advise you to drink more and prescribe an anti-nausea medication.

Common (occur in less than 1 in 10 people):

- Decreased appetite; weight loss
- Perceptions (seeing, hearing, smelling, feeling) of things that are not there (hallucinations)
- Depression (vital features of depression are: loss of interest, lack of appetite, weight loss, lack of feeling, feelings of guilt, daily fluctuations changes in mood)
- Feeling dizzy or fainting
- Muscle twitches or spasms
- Headache
- Feeling very tired, weak, or generally unwell (not well)
- Feeling very sleepy and having low energy
- High blood pressure
- Stomach pain or discomfort
- Diarrhea
- Indigestion
- Falls
- Wounds

Sometimes (occur in less than 1 in 100 people):

Allergic reaction

- Lack of water in the body (dehydration)
- Tingling or numbness of the skin (pins and needles)
- Change in taste sensation
- Daytime sleepiness
- Problems controlling movements of the body or limbs (extrapyramidal disorder)
- Blurred vision
- Ringing in the ears that does not go away (tinnitus)
- Low blood pressure
- Hot flashes
- Feeling like vomiting (gagging)
- Excessive sweating
- Weak muscles
- Increased amount of liver enzymes in the blood

Rare (occur in less than 1 in 1000 people):

- Inflamed liver (hepatitis)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and the blister strip after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 30°C.

Store in the original package to protect from moisture.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. Proper disposal of medications ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is galantamine.
8 mg: Each hard extended-release capsule contains 8 mg galantamine (as hydrobromide).
16 mg: Each hard extended-release capsule contains 16 mg galantamine (as hydrobromide).
24 mg: Each hard extended-release capsule contains 24 mg galantamine (as hydrobromide).

- The other substances in this medicine in the extended-release tablet core are sodium lauryl sulfate, ammonium methacrylate copolymer (type B), hypromellose, carbomers, hydroxypropyl cellulose, magnesium stearate, and talc. See section 2 “Bergal SR contains sodium”.
- The other substances in this medicine in the 8 mg capsule shell are gelatin, titanium dioxide (E171), and black printing ink (shellac, propylene glycol, concentrated ammonia solution, black iron oxide (E172), potassium hydroxide).
- The other substances in this medicine in the 16 mg and 24 mg capsule shells are gelatin, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), and black printing ink (shellac, propylene glycol, concentrated ammonia solution, black iron oxide (E172), and potassium hydroxide).

What does Bergal SR look like and what is in a package?

8 mg: White capsules, size 2 (capsule length: 17.6 – 18.4 mm) with a G8 inscription on the capsule cap. The content of the capsule is a white oval extended-release tablet core. 16 mg: Pink capsules, size 1 (capsule length: 19.0 – 19.8 mm) with a G16 inscription on the capsule cap. The content of the capsule is two white, oval extended-release tablet cores. 24 mg: Orange pink capsules, size 0 el (capsule length: 23.8 – 24.6 mm) with a G24 inscription on the capsule cap. The content of the capsule is three white, oval extended-release tablet cores.

Capsules are available in blister packs containing 10, 14, 28, 30, 56, 60, 84, 90, and 100 hard extended-release capsules packed in a box.

Not all mentioned pack sizes are marketed.

Marketing authorization holder

Marketing authorization holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, Novo mesto, Slovenia

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Registered under

RVG 107504 Bergal SR 8 mg hard capsules with prolonged release

RVG 107505 Bergal SR 16 mg hard capsules with prolonged release

RVG 107506 Bergal SR 24 mg hard capsules with prolonged release

This medicine is registered in member states of the European Economic Area under the following names:

Name of the member state	Name of the medicine
Slovenia	Galema SR
Germany	Galidurel
Netherlands	Bergal SR
Spain	Galnora

This leaflet was last approved in July 2024.