1. **What Kalymin is and what it is used for**

Kalymin is an indirect parasympathomimetic and inhibits the enzyme cholinesterase.

**Uses of Kalymin**

Pyridostigmine AWD 60 mg is used to treat pathological muscular weakness (myasthenia gravis, myasthenic syndrome). In treating myasthenic syndrome it is combined with guanidine.

2. **Before you take Kalymin**

*In the following cases do not take Kalymin:*

- if you are hypersensitive (allergic) to pyridostigmine bromide or any of the other ingredients of Kalymin
- if you suffer from mechanical occlusion of the gastrointestinal and urinary tracts
- if you suffer from diseases with an increased tone of the bronchial muscles (e.g. bronchial asthma and spastic bronchitis)
- if you suffer from an eye inflammation
- if you are breast-feeding (see section "Pregnancy and breast-feeding period")

*Take special care with Kalymin in the following cases:*

Carefully weigh the benefits against the risks before using Kalymin in the treatment of gastric ulcers (ulcus ventriculi), hyperactivity of the thyroid (thyrotoxicosis), decompensated cardiac insufficiency and myocardial infarction.

Special care should also be taken in administering Kalymin to patients with an abnormally low rate of heartbeat (bradycardia), patients suffering from diabetes (pancreatic diabetes), kidney failure (the dose may have to be adjusted), Parkinson’s disease and after gastrointestinal surgery.
The treatment of patients exposed to one or several of these risk factors should be carefully watched (and the dose adjusted, if necessary).

Patients with pathological muscular weakness (myasthenia gravis) require strictly individual dosing of Kalymin, depending on the severity of the disease and their response to the treatment (see Section 3: "How to take Kalymin").

**Combining Pyridostigmin AWD 60 mg with other medicinal products**

*Please inform your doctor or pharmacist, if you are taking - or have taken until recently - any other medicinal products, including drugs sold without a prescription.*

The effect of Kalymin is intensified by combination with drugs of the same active principle (cholinesterase inhibitors) or drugs activating the parasympathetic nervous system. The parasympathetic nervous system is part of the nervous system and controls body functions as well as the conscious exercise of will power. Kalymin may intensify the action of morphine and its derivatives (potent analgesics) and prolong the action of certain muscle relaxants (agents for muscle relaxation such as succinylcholine).

Antimuscarinics (such as atropine) inhibit the effects of Kalymin on the salivary glands, the eyes, the heart, the bronchial muscles and the intestine. The effects on the skeletal muscles are not affected. Combination with methyl cellulose or charcoal tablets interferes with the uptake of Kalymin from the gastrointestinal tract.

The effect of Kalymin may be impaired by substances interfering with the nerve-muscle transmission, such as some antibiotics (agents for treatment of bacterial infections, such as streptomycin, neomycin, kanamycin, gentamycin, polymyxin, colistin, oxytetracycline, clindamycin and lincomycin), some antiarrhythmics (agents for treatment of cardiac arrhythmias, such as quinidine, procainamide and propranolol), penicillamine, lithium, tranquilizers of the benzodiazepine type as well as phenothiazines (such as chlorpromazine). Large doses of corticosteroids may also adversely affect the action of Kalymin.

*Please note that the above may also apply to medicinal products taken in the recent past.*

**Pregnancy and breast-feeding period**

*Please consult your doctor or pharmacist before taking any medicines.*

As Kalymin has not been sufficiently studied in pregnant women, it should not be used during pregnancy, unless your doctor considers this absolutely necessary. The intravenous administration of acetylcholinesterase inhibitors – the group of substances that includes Kalymin – may trigger premature labour during pregnancy. The danger is greatest towards the end of pregnancy.

As the active substance of Kalymin passes into the mother’s milk, you should stop breast-feeding during treatment with Kalymin. If this treatment is absolutely essential, the baby has to be weaned (see section: "In the following cases do not take Kalymin").

**Effects on the ability to drive and to operate machines**

If your basic disease has not been sufficiently improved by the use of this medicine or if a relative overdose causes undesirable (cholinergic) effects, your vision and reactivity as well as your general judgement may be impaired (see also Section 4. "Possible side effects"). Your reaction to sudden and unexpected events is no longer fast and specific enough. In that case do not drive a vehicle or operate electric tools and make sure that you are well supported while you work.

3. **How to take Kalymin**

*Always take Kalymin exactly as prescribed by your doctor. Check with your doctor or pharmacist if you are not quite sure.*

**The usual dosage, unless otherwise prescribed by your doctor**

The dosage prescribed by your doctor has to be strictly adhered to. Never change your dosage without consulting your doctor first.

*Pathological muscular weakness (myasthenia gravis):*

For symptomatic treatment of myasthenia gravis in adults, take 1 to 3 tablets of Kalymin 3 to 4 times a day (equivalent to 180 mg up to a maximum of 720 mg of pyridostigmine bromide a day).
Myasthenic (Lambert-Eaton) syndrome:
For treatment of myasthenic (Lambert-Eaton) syndrome, Kalymin is combined with guanidine. To start with, take Kalymin on its own (1 to 3 tablets, to be taken 3 or 4 times a day). If this dosage does not produce satisfactory results, the therapy may be supplemented by guanidine, which should be administered in between the usual administration times of Kalymin. Your doctor will individually determine your dose, depending on your response to the therapy.

Note:
Patients suffering from myasthenia gravis require strictly individual dosing of pyridostigmine bromide, depending on the severity of the disease and their response to the treatment. The recommended dose is therefore only an approximate guideline. But the maximum daily dose of pyridostigmine bromide should not be exceeded in general. Tablets containing 10 mg of pyridostigmine bromide are also available for smaller doses.

Patients suffering from kidney diseases:
In patients with severely impaired kidneys or kidney failure, the action of Kalymin may be prolonged. If you suffer from those conditions, please tell your doctor.

Method of administration
Take the tablets with some liquid (such as half a glass of water). Your doctor will generally divide your individual daily dose into 2 to 6 single doses. Being provided with a break notch, the tablets can be divided into two equal halves so that half tablets can be taken as well.

Duration of treatment
The duration of treatment depends on the particular disease and will be decided by the attending physician.

If the effect of Kalymin seems to be too strong or not strong enough, please tell your doctor.

If you have taken more Kalymin than you should
Immediately contact your doctor in any case. Taking large doses (overdoses) of Kalymin may trigger a cholinergic crisis (a crisis caused by an overdose of cholinesterase inhibitors, which include Kalymin). Among other symptoms (see Section 4. "Possible side effects"), this crisis is accompanied by a distinct or even increasing muscular weakness up to the point of paralysis. Danger of life-threatening respiratory paralysis! Other concomitant effects may be a drop in blood pressure leading to circulatory collapse as well as a slowing down of heartbeat resulting in cardiac arrest or – paradoxically – in an acceleration of heartbeat (reflex tachycardia). After discontinuing the preparation, the physician has to take immediate emergency measures (by slow intravenous administration of 1 or 2 mg of atropine sulphate, which may have to be repeated after 2 to 4 hours, depending on the behaviour of the pulse rate).

If you have forgotten to take Kalymin
If you have taken too little Kalymin or have forgotten to take a dose, do not take a larger dose to make up for the forgotten one but keep to your dosaging scheme. When in doubt, consult your doctor.

If you want to stop taking Kalymin
Do not stop taking this medicinal product without consulting your doctor first, as otherwise your symptoms may recur.

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

4. Possible side effects
Like all medicinal products, Kalymin may cause side effects, although they are not bound to occur in every case.

Possible side effects
Rare (occurring in fewer than 1 in 1,000 but more than 1 in 10,000 patients treated): skin rash.
Other possible side effects whose frequency cannot be deducted

Disorders of the cardiovascular system
- an abnormally slow heartbeat (bradycardia)
- an undesirable drop in blood pressure (hypotension)

Eye disorders
- disturbance of the eye adaptability to near vision (accommodation disturbances)

Respiratory, thoracic and mediastinal disorders
- increased formation of mucus in the bronchial tubes

Gastrointestinal disorders
- nausea
- vomiting
- diarrhoea
- abdominal cramping due to increased intestinal peristalsis

Renal and urinary disorders
- increased urinary urgency

Musculoskeletal and connective-tissue disorders
- muscular weakness
- tremor
- muscular cramps

Skin and subcutaneous-tissue disorders
- sweating

General disorders and administration site conditions
- salivation and lacrimation

These side effects may be symptoms of an overdose. Please cf. Section 3: "If you have taken more Kalymin than you should".

If any of the side effects listed here hampers you seriously, or if you notice any side effects in yourself that are not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store Kalymin

Keep medicinal products out of reach of children
Do not use this medicinal product after the expiry date ("Exp.") indicated on the label and carton. The expiry date refers to the last day of the month indicated.

Storage conditions
No special storage conditions are required for this medicinal product.

Shelf life after the vial has been opened or the product prepared
After the vial has been opened, Kalymin still has a shelf life of 6 months. This medicinal product should not be disposed of in the sewage or domestic waste. Ask your pharmacist how you can dispose of medicines no longer required. This helps to protect your environment.

6. Further information

What Kalymin contains
Its active substance is pyridostigmine bromide.

One tablet contains 60 mg of pyridostigmine bromide.
Other ingredients are herbal magnesium stearate (Ph.Eur.), povidone (K 25), glutamic acid hydrochloride, precipitated silica, highly disperse silica, maize starch, microcrystalline cellulose, and purified water.

What Kalymin looks like and contents of the pack
Pyridostigmin AWD 60 mg tablets are white, oblong tablets with a break notch, of about 17 mm length.
They are available in amber-glass vials with pressure caps in 50-tablet and 100-tablet packs.
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