Package leaflet: Information for the patient

Kaliumbromid DESITIN 850 mg tablets

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 Kaliumbromid DESITIN 850 mg tablets is and what it is used for

Kaliumbromid DESITIN 850 mg tablets is a medicine for seizure disorders (antiepileptic) from the group of bromine salts.

Therapeutic indications
Kaliumbromid DESITIN 850 mg tablets is used to treat major seizures with loss of consciousness and spasms in the arms and legs (primary and secondary generalised tonic-clonic seizures in early childhood grand mal epilepsy) and major seizures with spasms in the arms and legs (severe myoclonic syndromes) in childhood (e.g. in the presence of Dravet syndrome).

Kaliumbromid DESITIN 850 mg tablets is particularly suitable when other antiepileptics are ineffective or not effective enough on their own.

Note: As the dosage must be adjusted very precisely, it is recommended that Kaliumbromid DESITIN 850 mg tablets be used only under the supervision of a specialist experienced in the treatment of seizure disorders (epilepsy) and bromide therapy.

Kaliumbromid DESITIN 850 mg tablets is not effective for the following seizures:
- seizures with a sudden lapse of consciousness (absence seizures)
- seizures with sudden muscle twitches (myoclonic seizures)
- seizures with increased muscle tension or stiffness (tonic seizures).

In these cases, further epileptic seizures could be triggered.
There is no sufficient information about the clinical effectiveness of giving Kaliumbromid DESITIN 850 mg tablets alone without co-treatment with other antiepileptics.

2. What you need to know before you take Kaliumbromid DESITIN 850 mg tablets

Do not take Kaliumbromid DESITIN 850 mg tablets
- if you are allergic to potassium bromide or any of the other ingredients of this

medicine (listed in section 6)
- if you have a known intolerance to bromides
- if you have kidney failure (renal insufficiency)
- during pregnancy and breast-feeding.

Do not take Kaliumbromid DESITIN 850 mg tablets without consulting your doctor
The following describes when Kaliumbromid DESITIN 850 mg tablets should be taken only under certain conditions and only with special caution: if you have
- bronchial asthma
- malnutrition or nutritional disorders

Please consult your doctor. This also applies if this information has ever applied in the past.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Kaliumbromid DESITIN 850 mg tablets.

- Before using this medicine for the first time, standard measurements of kidney function should be made and electrolyte imbalances should be ruled out.
- During therapy with this medicine, care should be taken to ensure an average salt intake and sufficient fluid intake. Any changes in the salt balance within the body affect the level of bromide, a component of this medicine.
  Increased salt intake leads to increased excretion of bromide.
  A reduced salt intake leads to increased accumulation of bromide in the body.
  Patients with severe vomiting, diarrhoea or severe dehydration through sweating may also experience increased side effects due to the active substance potassium bromide.
  In some cases, the dose may have to be adjusted by the treating doctor.
- During therapy with this medicine, regular examinations are required to measure bromide concentrations in the blood: at least every 4 weeks in the first 3 months, then every 3 months thereafter.
  It is therefore most important that you attend the check-ups arranged with your doctor.
- During therapy with this medicine, measurement of chloride concentrations in the blood may show falsely high values (pseudohyperchloraemia).
- In people on a low-potassium diet (see dosage instructions), caution is advised when using this medicine. Due to the potassium bromide content, there is a risk of excess potassium with stomach problems and diarrhoea.
- A small number of people being treated with anti-epileptics have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Other medicines and Kaliumbromid DESITIN 850 mg tablets:
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Which other medicines affect how Kaliumbromid DESITIN 850 mg tablets works?
Interactions with other medicines for epilepsy (antiepileptics) do not occur.

Co-administration of other sedative medicines can lead to increased tiredness or drowsiness.

Increased salt intake and diuretics (medicines used to increase urine output) cause increased excretion of bromide via the kidneys and thus lower the concentration of

bromide in the blood. The duration of action of Kaliumbromid DESITIN 850 mg tablets is reduced.
The resulting bromide excretion is dependent on the diuretic mechanism of action. Co-administration of ethacrynic acid (a very strong diuretic) has a potent effect.

Kaliumbromid DESITIN 850 mg tablets with food and alcohol
You should aim to keep your dietary salt intake consistent.
Alcohol should be avoided during treatment.

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 for advice before taking this medicine.
Kaliumbromid DESITIN 850 mg tablets must not be given during pregnancy or breast-feeding, as potassium bromide (the active substance of Kaliumbromid DESITIN 850 mg tablets) passes through the placenta and is excreted in human milk. Harmful effects on the unborn child, as well as on newborns and infants, cannot be ruled out.

Driving and using machines
Depending on individual sensitivity and bromine concentrations in the blood, Kaliumbromid DESITIN 850 mg tablets may, even when used as directed, alter reaction skills to such an extent that the ability to drive or use machines is impaired. This particularly applies in interaction with alcohol.

Kaliumbromid DESITIN 850 mg tablets contains potassium.
One sachet contains 1.68 mmol (65.7 mg) potassium. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to take Kaliumbromid DESITIN 850 mg tablets

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

Unless otherwise prescribed by the doctor, the usual dose is:
Right from the outset, treatment can be started with the average dose for long-term therapy (maintenance dose).

Depending on the nature and severity of the clinical picture and tolerability, the dose is adjusted individually and set by the doctor. Dose determination should be guided by measurement of blood values, especially in combination therapy with other medicines for epilepsy.

In individual cases, the required dose may differ significantly from the starting or maintenance dose stated (e.g. due to accelerated or delayed excretion of the active substance caused by changes in the salt balance).

Treatment must be monitored by a specialist experienced in epilepsy treatment and bromide therapy.

When switching from another epilepsy medicine to treatment with Kaliumbromid DESITIN 850 mg tablets, the dose of the medicine to be discontinued must be reduced gradually, if possible under hospital conditions.

The following general dosage regimen is recommended for the treatment of generalised tonic-clonic seizures:

Age	Weight in kg	Daily dose in mg per kg body weight	Daily dose in mg*	Number of tablets per day. To be divided over 2-3 single doses
Children				
[½ ¬ 3 years]	7 ¬ 15	50 ¬ 70	350 ¬ 1050	½ to 1½
[4 ¬ 8 years]	16 ¬ 28	40 ¬ 60	640 ¬ 1680	1 to 2
[9 ¬15 years]	29 ¬ 58	40 ¬ 60	1160 ¬3500	1½ to 4
Adults		30 – 50	up to 4 000	Up to 4½

* The mg values expressing the daily dose are for rough guidance only.

Children may outgrow the dose per kg of body weight. In this respect, the dose may need to be adjusted to body weight instead of dose adjustment according to age, in which case EEG findings (measuring electrical activity in the brain) should not deteriorate.

If seizure disorders persist into adulthood, the use of Kaliumbromid DESITIN 850 mg tablets can also be continued in adults.

During an infection, children are given half the usual prescribed dose to prevent the active substance from accumulating in the body and the thus associated side effects.

A total daily dose of 4 000 mg must not be exceeded, as side effects can increasingly occur at higher doses.

Please talk to your doctor or pharmacist if you have the impression that the effect of Kaliumbromid DESITIN 850 mg tablets is too strong or too weak.

Method of administration
Kaliumbromid DESITIN 850 mg tablets is taken after meals with plenty of liquid (approx. 100 – 150 ml).
The daily dose is taken in 2 - 3 individual doses spread over the day (for example, morning and evening, or morning, noon and evening).
Kaliumbromid DESITIN 850 mg tablets can be divided. This means that half and whole tablets can be taken alternately to achieve the calculated daily dose.
It is possible to allow the tablets to dissolve in lukewarm water or tea while stirring gently.

Duration of use
In principle, antiepileptic therapy is generally a long-term therapy.
With regard to adjustment, duration of treatment and discontinuation of this medicine, it is up to a specialist with experience in epilepsy treatment and bromide therapy to decide in each individual case.
In general, a dose reduction or discontinuation of this medicine should be considered no sooner than after two or three years of freedom from seizures. Treatment must be discontinued by gradual reduction of the dose.

If you take more Kaliumbromid DESITIN 850 mg tablets than you should
In the event of overdose with Kaliumbromid DESITIN 850 mg tablets, the symptoms listed under side effects may become more pronounced.

In cases of <u>acute overdose</u>, nausea and vomiting regularly occur. Notwithstanding this,

you can try to empty the stomach contents by induced vomiting. In one case, a severe blistering skin disease (epidermal necrolysis) was reported to occur.

Chronic poisoning (bromism) with very high blood levels can occur if too high doses are taken over a prolonged period of time or if excretion is impaired.

The following signs may occur: Very common: tiredness, slowness, apathy and drowsiness occur. Uncommon: wasting syndrome (cachexia), dehydration, weakened or pathologically altered reflexes, sensory disorders, involuntary muscle twitches, slurred speech, unsteady gait (ataxia), muscle tremors, paralysis and impaired pupil movement occur. Rare: aggressiveness, states of confusion and even mental illness (psychoses) and loss of consciousness (coma) occur. Increased brain pressure has been described in individual cases.

If there are signs of an acute overdose or chronic poisoning (bromism), a doctor should be consulted, who must decide on the necessary measures depending on the symptoms that occur.

In the event of a mild overdose, the daily dose can be reduced after consultation with the treating doctor or treatment can be suspended for 1 - 2 days (so-called “bromine pause”). A high-salt diet may speed up the excretion of bromine.

For further information, professionals can request a Summary of Product Characteristics if required.

If you forget to take Kaliumbromid DESITIN 850 mg tablets
If a dose of Kaliumbromid DESITIN 850 mg tablets has been missed, the prescribed dose should be taken at the next scheduled time. Do not take a double dose.

If you stop taking Kaliumbromid DESITIN 850 mg tablets
If you wish to interrupt your treatment, discuss this first with your doctor. Do not stop treatment with this medicine on your own initiative without medical advice. You may be putting the success of treatment at risk.

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

4. Possible side effects

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

The following frequency statements are used for evaluating side effects:

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1 000 people
Very rare:	may affect up to 1 in 10 000 people
Not known:	frequency cannot be estimated from the available data

Side effects of treatment with Kaliumbromid DESITIN 850 mg tablets can affect various organs:

Central Nervous System
The desired and undesirable effects of potassium bromide lead to a slowing of central nervous processes, with large differences in individual bromide sensitivity.

- Low bromide levels (below 1.0 mg/mL, determined via photometry):
  Rarely fatigue, prolonged reaction times, less spontaneous speech, headache.
- Medium bromide levels (1.0 - 1.5 mg/mL, determined via photometry):
  Increasing signs of delays in terms of reaction time, concentration, fine motor skills, speech and thinking. More frequent tiredness, increased need for sleep, headache.
- High bromide levels (up to 2.25 mg/mL, determined via photometry):
  Tiredness, poor concentration, delayed reactions and impaired speech. Possibly persistent headache. Signs of bromine poisoning (bromine intoxication, bromism) possible.
- Bromide levels above 2.25 - 2.5 mg/mL (determined via photometry):
  Bromine intoxication, bromism (see section “If you take more Kaliumbromid DESITIN 850 mg tablets than you should”).

Note: Even when the dose has been properly adjusted, there is a tendency for bromide to accumulate (accumulation tendency) and a possibility that signs of a relative chronic overdose (bromism) may develop if accompanying illnesses with fluid loss occur.

Eyes
- Inflammation of the conjunctiva (conjunctivitis) with watery eyes

Airways
- Increased secretion of mucus by the glands in the respiratory tract: Bromine-induced rhinitis (serous rhinitis), mucus, bronchitis, inflammation of the paranasal sinuses and worsening of bronchial asthma. In particular, this applies if you already have an allergic predisposition.

Gastrointestinal tract
- At high single doses: bloating, stomach pains and vomiting.
  These symptoms can usually be controlled by taking this medicine with plenty of liquid after meals and by administering it as 2 - 3 single doses spread over the day.
- Rare: Coated tongue, bad breath, inflamed changes in the mouth lining (aphthous ulcers), constipation or diarrhoea
- Very rare: Inflammation of the stomach lining, ulcers (and even perforation), inflammation of the pancreas

Note: Impaired appetite at medium and high bromide levels can cause gradual bromine poisoning due to reduced salt intake.

Skin and skin appendages
- Very common: Bromine acne (nodular skin changes or pus-filled blisters), sometimes independent of the dose. Severe forms may require discontinuation of treatment.
- Rare: Brown to blackish-red, flaccid, granular or ulcerated skin changes (bromoderma tuberosum) or painful nodules in the subcutaneous fatty tissue (halogen panniculitis; initially, this may resemble erythema nodosum; possibly with fever, increased signs of inflammation or diarrhoea in patients with a general (systemic) bromide intolerance). These are skin manifestations probably due to bromine allergy.
- Discontinuation of Kaliumbromid DESITIN 850 mg tablets leads to rapid healing, possibly with scarring (in the case of bromoderma tuberosum). Resumption of

therapy with Kaliumbromid DESITIN 850 mg tablets will lead to a return of these symptoms of bromide intolerance.

Musculoskeletal system
- Very rare: Bromine-induced joint inflammation (arthritis)

Whole body
- Weight loss, abnormally increased feeling of thirst (polydipsia)
- In one case, bromine-related hypothyroidism (underactive thyroid) was reported to occur.

What to do in case of side effects?
If side effects occur, please talk to your doctor about possible ways to deal with them.

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 *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kaliumbromid DESITIN 850 mg tablets?

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 carton after “EXP”. The expiry date refers to the last day of that month.

Kaliumbromid DESITIN 850 mg tablets can no longer be used even before the expiry date if the tablets have become moist due to improper storage and their appearance has changed significantly.

Storage conditions:
Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater (e.g. down the toilet or sink). Ask your pharmacy how to throw away medicines you no longer use. These measures will help protect the environment. You will find further information at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Kaliumbromid DESITIN 850 mg tablets contains:
The active substance is potassium bromide.
1 tablet contains 850 mg potassium bromide.

The other ingredients are:
Crospovidone, microcrystalline cellulose, povidone K25, stearic acid, highly dispersed silicon dioxide.

What Kaliumbromid DESITIN 850 mg tablets looks like and contents of the pack:
White tablet with break line. The tablet can be divided into equal doses.

Kaliumbromid DESITIN 850 mg tablets is available in blister packs of 30 and 60 tablets.
Not all pack sizes may be marketed.

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Note on this package leaflet:
Package leaflets of medicinal products are continuously revised and adapted to the current state of scientific knowledge. The present version of this package leaflet may also have been updated in the meantime.
The current package leaflet of this medicinal product is published at https://www.gebrauchsinformation4-0.de/ by Rote Liste Service GmbH on behalf of our company and can also be accessed by scanning the data matrix code or barcode on the medicinal product packaging with a smartphone using the GI 4.0® app.