

Package leaflet: Information for the patient

Bromhexin Krewel Meuselbach® Drops 8 mg/ml

Bromhexine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 to 5 days.

What is in this leaflet

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1. What Bromhexin Krewel Meuselbach® Drops 8 mg/ml are and what they are used for

Bromhexin Krewel Meuselbach® Drops 8 mg/ml are a mucolytic agent (a medicine that breaks up phlegm in respiratory diseases with thick mucus).

Bromhexin Krewel Meuselbach® Drops 8 mg/ml are used:

As mucolytic treatment in acute and chronic diseases of the lung and bronchial tubes, where thick mucus is present.

2. What you need to know before you take Bromhexin Krewel Meuselbach® Drops 8 mg/ml

Do not take Bromhexin Krewel Meuselbach® Drops 8 mg/ml

- if you are allergic to bromhexine hydrochloride, menthol or any of the other ingredients of this medicine (listed in section 6).

Because of the alcohol content, Bromhexin Krewel Meuselbach® Drops 8 mg/ml must not be used in patients suffering from alcoholism and children below 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml.

There have been reports of severe skin reactions associated with the administration of bromhexine. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using Bromhexin Krewel Meuselbach[®] drops and contact your doctor immediately.

Do not take Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml without first talking to your doctor if:

- you have a certain rare bronchial condition with excessive build up of mucus (e.g. malignant ciliary syndrome). In such cases, Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml should be used only under medical supervision, due to possible mucus congestion.

- you have poor kidney function or severe liver disease (in this case, Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml are used at longer dosing intervals or at a reduced dose). If kidney function is severely impaired, the metabolites (breakdown products) of Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml must be expected to accumulate in the liver.

Liver function should be occasionally monitored, especially during prolonged treatment.

Other medicines and Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml

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

Bromhexine / antitussives

In combined use of Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml and cough medicines (antitussive agents), a dangerous build-up of mucus may occur because the cough reflex is suppressed. For this reason, particular care should be taken when evaluating the need to use this combination treatment.

Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml with food and drink

There are no special points to consider.

Pregnancy and breast-feeding

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.

Pregnancy

There is no experience to date with the use of this medicine in human pregnancy. For this reason, Bromhexin Krewel Meuselbach[®] Drops 8 mg/ml may only be used during pregnancy after careful consideration of the benefits and risks by your doctor.

Breast-feeding

Bromhexine is excreted in human milk. As the effects on the infant have not been sufficiently studied, Bromhexin Krewel Meuselbach® Drops 8 mg/ml must not be taken during breast-feeding.

Driving and using machines

There are no special points to consider.

Bromhexin Krewel Meuselbach® Drops 8 mg/ml contain sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Bromhexin Krewel Meuselbach® Drops 8 mg/ml contain alcohol.

This medicinal product contains 41 vol % ethanol (alcohol), i.e. up to 0.36 g alcohol per ml. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy. The effect of other medicines may be reduced or enhanced.

3. How to take Bromhexin Krewel Meuselbach® Drops 8 mg/ml

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

If not prescribed otherwise by your doctor, the recommended dose is:

Adults and adolescents over 14 years of age should take 23 - 46 drops three times a day (equivalent to 24 – 48 mg bromhexine hydrochloride daily).

Adolescents aged 12 – 14 years and patients weighing less than 50 kg should take 23 drops three times a day (equivalent to 24 mg bromhexine hydrochloride daily).

For children under 12 years of age Bromhexin Krewel Meuselbach® Drops 12 mg/ml without alcohol are available.

Method of administration:

Bromhexin Krewel Meuselbach® Drops 8 mg/ml are taken with a sufficient amount of fluids (e. g. water).

Duration of administration:

The duration of treatment depends on the nature and severity of your condition and should be decided by your treating doctor.

If your symptoms get worse or do not improve after 4 – 5 days, you should consult a doctor.

If you take more Bromhexin Krewel Meuselbach® Drops 8 mg/ml than you should

In the event of an overdose, no symptoms beyond the usual side effects are generally to be expected. If severe symptoms occur, it may be necessary to monitor the blood circulation and, if necessary, administer treatment based on the symptoms.

Alcohol poisoning may result from taking relatively large amounts of this medicine, which may be life-threatening, especially in young children. In this case, a doctor should be consulted immediately. Approximately 9.9 g, 16.5g and 33 g alcohol would be ingested as a result of swallowing the entire pack contents of 30 ml, 50 ml and 100 ml Bromhexin Krewel Meuselbach® Drops 8 mg/ml, respectively.

If you forget to take Bromhexin Krewel Meuselbach® Drops 8 mg/ml

Do not take a double dose to make up for a forgotten dose.

If you stop taking Bromhexin Krewel Meuselbach® Drops 8 mg/ml

Please do not stop your treatment with Bromhexin Krewel Meuselbach® Drops 8 mg/ml without talking to your doctor first. Your disease might get worse as a result.

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.

Evaluation of undesirable effects and their probability:

Uncommon: may affect up to 1 in 100 people:

Nausea, abdominal pain, vomiting, diarrhoea.
Fever, allergic reaction (dyspnoea).

Rare: may affect up to 1 in 1,000 people:

Hypersensitivity reactions.
Rash, urticaria.

Not known: frequency cannot be estimated from the available data

Anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosal or submucosal tissues) and pruritus.
Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome / toxic epidermal necrolysis and acute generalized exanthematous pustulosis).

Measures to treat side effects

At the first signs of a hypersensitivity reaction (see above), you must stop taking Bromhexin Krewel Meuselbach® Drops 8 mg/ml. In this case, please contact your nearest doctor.

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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, 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 Bromhexin Krewel Meuselbach® Drops 8 mg/ml

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 and bottle after "EXP". The expiry date refers to the last day of that month.

Notes on shelf life after opening

After first opening Bromhexin Krewel Meuselbach® Drops 8 mg/ml can be used for 6 months.

Once opened, keep the bottle tightly closed, as this may otherwise affect the shelf life.

6. Contents of the pack and other information

What Bromhexin Krewel Meuselbach® Drops 8 mg/ml contain

The active substance is: bromhexine hydrochloride.

1 ml solution (= 23 drops) contains 8 mg bromhexine hydrochloride.

The other excipients are:

Purified water, ethanol 96%, sucrose (sugar), potassium dihydrogen phosphate, polysorbate 80, hydrochloric acid 36%, sodium monohydrogen phosphate dodecahydrate (Ph. Eur.), flavouring agents: star anise oil, bitter fennel oil, levomenthol, thyme oil, mint oil, eucalyptus oil.

Contains 41 vol % ethanol (alcohol).

What Bromhexin Krewel Meuselbach® Drops 8 mg/ml look like and contents of the pack

Bromhexin Krewel Meuselbach® Drops 8 mg/ml are a pale yellow, clear solution.

Bromhexin Krewel Meuselbach® Drops 8 mg/ml are available in packs of 30 ml, 50 ml and 100 ml oral drops, solution.

Marketing Authorisation Holder and Manufacturer

Krewel Meuselbach GmbH, Krewelstrasse 2, 53783 Eitorf, Germany

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