

Package leaflet: Information for the patient

Bromhexin Krewel Meuselbach® Drops 12 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 - 5 days.

What is in this leaflet

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1. What Bromhexin Krewel Meuselbach® Drops 12 mg/ml are and what they are used for

Bromhexin Krewel Meuselbach® Drops 12 mg/ml are a medication that liquefies and dissolves mucus in diseases of the respiratory tract (airways), especially those associated with the protracted production of thick mucus.

It is indicated in acute and chronic diseases of the bronchi and lungs associated with the production of viscous mucus.

You must talk to a doctor if you do not feel better or if you feel worse after 4 - 5 days.

2. What you need to know before you take Bromhexin Krewel Meuselbach® Drops 12 mg/ml

Do not take Bromhexin Krewel Meuselbach® Drops 12 mg/ml

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Bromhexin Krewel Meuselbach® Drops 12 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 12 mg/ml and contact your doctor immediately.

Do not take Bromhexin Krewel Meuselbach® Drops 12 mg/ml without 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 12 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 12 mg/ml is 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 12 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 12 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

Concurrent use of products that suppress cough (antitussives) may lead to the dangerous accumulation of mucus due to the suppression of the cough reflex. This is why special care must be taken in the case of such therapeutic combinations and the physician's advice must be followed carefully.

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 12 mg/ml must not be taken during breast-feeding.

Driving and using machines

There are no special points to consider.

3. How to take Bromhexin Krewel Meuselbach® Drops 12 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 15 – 30 drops 3 times daily (equivalent to 24 - 48 mg bromhexine hydrochloride daily).

Use in children and adolescents

Children and adolescents aged 6 – 14 years and patients weighing less than 50 kg take 15 drops 3 times daily (equivalent to 24 mg bromhexine hydrochloride daily).

Children aged 2 – 6 years of age are given 8 drops 3 times daily (equivalent to 12 mg bromhexine hydrochloride daily).

Method of administration:

Oral use.

Note:

Adequate hydration may be beneficial.

Duration of administration:

The duration of treatment depends on the severity of the disease and should be decided by your treating physician.

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

If you have the impression that the effect of Bromhexin Krewel Meuselbach® Drops 12 mg/ml are too strong or too weak, please contact your doctor or pharmacist.

If you take more Bromhexin Krewel Meuselbach® Drops 12 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, treatment depends on the symptoms.

If a toddler has swallowed large amounts of Bromhexin Krewel Meuselbach® Drops 12 mg/ml, please contact your nearest physician.

If you forget to take Bromhexin Krewel Meuselbach® Drops 12 mg/ml

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

If you stop taking Bromhexin Krewel Meuselbach® Drops 12 mg/ml

Please do not stop your treatment with Bromhexin Krewel Meuselbach® Drops 12 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, shortness of breath (hypersensitivity reaction).

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 12 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 12 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 box and label. The expiry date refers to the last day of that month.

Storing Bromhexin Krewel Meuselbach® Drops 12 mg/ml

Do not freeze.

Shelf life after first opening:

After first opening Bromhexin Bromhexin Krewel Meuselbach® Drops 12 mg/ml can be used for 6 months.

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 Bromhexin Krewel Meuselbach® Drops 12 mg/ml contain

The active substance is: bromhexine hydrochloride.

1 ml solution (= 23 drops) contains 12 mg bromhexine hydrochloride.

The other excipients are:

propylene glycol, glycerol, levomenthol, mint oil, bitter fennel oil, star anise oil.

What Bromhexin Krewel Meuselbach® Drops 12 mg/ml look like and contents of the pack

Bromhexin Krewel Meuselbach® Drops 12 mg/ml are a clear, slightly yellowish solution.

Bromhexin Krewel Meuselbach® Drops 12 mg/ml are available in packs of 30 ml, 50 ml oral drops, solution.

Marketing Authorisation Holder and Manufacturer

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