

Package leaflet: Information for the patient

Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 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® Cough Syrup 8 mg/10 ml is and what it is used for

Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml is a mucolytic agent (a medicine that breaks up phlegm in airway diseases with thick mucus).

Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml is used:

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

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

2. What you need to know before you take Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml

Do not take Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml

- if you are allergic to bromhexine hydrochloride 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[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 ml and contact your doctor immediately.

Children

In children under 2 years of age, Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml may only be used under medical supervision.

Do not take Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 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.

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[®] Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 ml must not be taken during breast-feeding.

Driving and using machines

There are no special points to consider.

Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml contains sorbitol.

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

3. How to take Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 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 10 - 20 ml three times a day (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 should take 10 ml three times a day (equivalent to 24 mg bromhexine hydrochloride daily).

Children below 6 years of age are given 5 ml three times a day (equivalent to 12 mg bromhexine hydrochloride daily).

A cup is supplied with each pack.

Method of administration:

Oral use.

Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml should be taken after meals with plenty of liquid.

Note:

Adequate hydration may be beneficial.

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® Cough Syrup 8 mg/10 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.

If a toddler has swallowed large amounts of Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml, please contact your nearest doctor.

If you forget to take Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml

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

If you stop taking Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 ml

Please do not stop your treatment with Bromhexin Krewel Meuselbach® Cough Syrup 8 mg/10 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[®] Cough Syrup 8 mg/10 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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 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 label 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[®] Cough Syrup 8 mg/10 ml can be used for 6 months.

6. Contents of the pack and other information

What Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml contains

The active substance is: bromhexine hydrochloride.

10 ml syrup contain 8 mg bromhexine hydrochloride.

The other excipients are:

Propylene glycol, glycerol, hyetellose, sorbitol solution 70% (non-crystallising) (Ph.Eur.), purified water, citric acid, raspberry flavouring.

What Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml looks like and contents of the pack

Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml is a clear, colourless solution.

Bromhexin Krewel Meuselbach[®] Cough Syrup 8 mg/10 ml is available in packs of 100 ml.

Each pack is supplied with a cup (marking of the medical device: CE 0123)

[To be completed nationally]

Marketing Authorisation Holder and Manufacturer

Krewel Meuselbach GmbH, Krewelstrasse 2, 53783 Eitorf, Germany

This leaflet was last revised in February 2016.