Package leaflet: Information for the user

Bisolaclar 600 mg bruistabletten

Acetylcysteine

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 8 to 10 days.

What is in this leaflet

1. What Bisolaclar is and what it is used for

Acetylcysteine breaks down and loosens thick mucus making it runny and easy to cough up.
Acetylcysteine is indicated in adults for the treatment of airway diseases in which a reduction in the viscosity of the bronchial secretions is required to facilitate expectoration, especially during periods of acute bronchitis.

You must talk to a doctor if you do not feel better or if you feel worse after 8 to 10 days.

2. What you need to know before you take Bisolaclar

Do not take Bisolaclar
- if you are allergic to acetylcysteine or any of the other ingredients of this medicine (listed in section 6).
- Children aged under 2 years must not use this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Bisolaclar.

If you have asthma or experienced episodes of bronchospasm (narrowing / cramping of the airways) in the past Bisolaclar should be taken with special caution as your condition can aggravate under the treatment with Bisolaclar. If this happens, a doctor has to be consulted immediately.

If you have a stomach ulcer or a history thereof special care is advised, because Bisolaclar may irritate your stomach wall, particularly if you use other medicines known to irritate the stomach wall.

There have been very rare reports of serious hypersensitivity reactions with (high) fever, red marks on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome) and acute hypersensitivity reactions associated with fever and blisters on the skin or peeling of the skin (Lyell syndrome) which may be associated with the use of acetylcysteine. If new changes to the skin or mucous membranes occur, you should immediately consult a doctor and stop taking Bisolaclar.

If you are unable to cough up fluid mucus effectively (e.g. elderly or frailed patients with impaired cough reflex). Especially at the beginning of treatment you need to take special care because the mucus secretion may increase in volume as it becomes more fluid.

When opening the pack a slight smell of sulphur (the smell of rotten eggs) may be observed. This is a property of the active ingredient and is normal. It does not indicate any abnormality in the medicine.

Children and adolescents
Bisolaclar may block the airways of children aged under 2 years, since their ability to cough up mucus is restricted. For this reason, Bisolaclar must not be used by children aged under 2 years.

Bisolaclar is not suitable for children and adolescents.

Other medicines and Bisolaclar
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
If you are using other medicines, do not dissolve them together with Bisolaclar.
If you must use other medicines to combat or prevent infections (antibiotics), you are advised to take these two hours before or after Bisolaclar.
Bisolaclar may increase the blood pressure-lowering effect of nitro-glycerine (a medicine used for a heavy, painful feeling in the chest (angina pectoris). Caution is required.
If you use activated charcoal (a medicine for traveller's diarrhoea), the effect of Bisolaclar may decrease.
Acetylcysteine can bind metal-salts like gold-, iron- and potassium salts and reduces their effect in the body. Do not take these salts together with Bisolaclar or keep a time lag between the administrations.

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 or pharmacist for advice before taking this medicine.

Pregnancy
There is a limited amount of data from the use of acetylcysteine in pregnant women. You should only use acetylcysteine during pregnancy if your doctor finds it necessary.

Breast-feeding
It is not known whether acetylcysteine is excreted in breast milk. Ask your doctor for advice before using acetylcysteine if you are breast-feeding.

Fertility
Based on available data, there are no indications for possible effects of the use of acetylcysteine on fertility.

Driving and using machines
Bisolaclar has no or negligible influence on the ability to drive or use machines.

Bisolaclar contains sodium, lactose and sorbitol

This medicine contains 138.8 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 6.94% of the recommended maximum daily dietary intake of sodium for an adult. This has to be taken into consideration by patients on a controlled sodium diet.

This medicine contains 70 mg lactose in each tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains up to 40 mg sorbitol in each tablet.

3. How to take X

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.

The recommended dose is:

Adults
Take one 600 mg effervescent tablet once daily.

Use in children
Bisolaclar must not be given to children under the age of 2 years and is not recommended in children and adolescents.

Dissolve the effervescent tablet in half a glass of water. Drink the solution straight away.
The score line is only there to help you break the tablet for ease of dissolving.

Do not take this medicine for longer than 8 to 10 days without consulting a doctor.

If you take more Bisolaclar than you should
If you have taken too many Bisolaclar, contact your doctor or pharmacist immediately.
You may experience nausea, vomiting and diarrhoea.

If you forget to take Bisolaclar
If you have forgotten to take an effervescent tablet and it is almost time for the next dose, skip the forgotten effervescent tablet and continue the schedule as given under “How to take this medicine”. Do not take a double dose to make up for a forgotten tablet.

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

4. Possible side effects

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

If any of the following very serious side effects occur, stop the use of Bisolaclar straight away and contact your doctor or go to the emergency department of a nearby hospital immediately. These side effects are very rare (may affect up to 1 in 10,000 people):

- Shock (rapid drop in blood pressure, pallor, agitation, weak pulse, clammy skin, reduced consciousness) due to a sudden widening of the blood vessels as a result of severe hypersensitivity to specific substances (anaphylactic shock).

- Sudden accumulation of fluid in the skin and mucous membranes (e.g. throat or tongue) with difficulty breathing and/or itching and skin rash, often as a result of an allergic reaction (angioedema).

Tell your doctor if you experience any of the following side effects. These side effects are part of a hypersensitivity reaction to the active substance of this medicine and are uncommon (may affect up to 1 in 100 people):

- Tightness due to cramping of the muscles in the airways (bronchospasms)
- Difficulty breathing, shortness of breath or tightness in the chest (dyspnoea)

Other side effects
Uncommon (may affect up to 1 in 100 people):

- Hypersensitivity reactions like increase in heartbeat (tachycardia), itching (pruritus), skin rash with severe itching and formation of spots (urticaria)
- Headache
- Ringing in the ears (tinnitus)
- Inflammation of the mucous membrane in the mouth (stomatitis)
- Belly ache (abdominal pain)
- Nausea, vomiting
- Diarrhoea
- Fever (pyrexia)
- Decrease in blood pressure

Rare (may affect up to 1 in 1,000 people)

- Impaired digestion with heartburn (dyspepsia)

Very rare (may affect up to 1 in 10,000 people)

- Bleeding

Not known (frequency cannot be estimated from the available data)

- Swelling of the face

If you develop gastric or intestinal ulcers, or have had these in the past, acetylcysteine may have an unfavourable effect on your gastrointestinal mucous membrane.

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 national reporting system <to be completed nationally>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bisolaclar

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 package after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Laminated aluminium paper foil package
No special temperature storage conditions required.

Polypropylene tubes with polyethylene stoppers containing desiccant package
Do not store above 30°C.

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 Bisolaclar contains

- The active substance is acetylcysteine. Each effervescent tablet contains 600 mg acetylcysteine.
- The other ingredients are citric acid (E330), anhydrous, ascorbic acid (E300), sodium citrate (E331), sodium cyclamate (E952), saccharin sodium (E954), mannitol (E421), sodium hydrogen carbonate (E500), sodium carbonate (E500), lactose, anhydrous, magnesium stearate and lemon flavour (consisting of: natural lemon oil, natural / nature identical lemon oil, mannitol (E421), maltodextrin, gluconolactone (E575), sorbitol (E420), silica, colloidal anhydrous (E551)).

What Bisolaclar looks like and contents of the pack

Bisolaclar are round, white tablets with faultless surface, a score line on one side and diameter of 20 mm.

Each effervescent tablet is either sealed separately into an aluminium paper foil packed in a folding box, into which 10 or 20 effervescent tablets are packed, or is unsealed and tablets are packed into a plastic polypropylene tube with polyethylene desiccant stoppers filled with molecular sieve.

Pack sizes:
Boxes with 10 and 20 tablets.
Polypropylene tubes with 10, 20 and 25 tablets.

Not all pack sizes may be marketed.

When opening the pack, you will sometimes notice a slight smell of sulphur. This is normal and not harmful.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine
Frankrijk

Voor correspondentie en inlichtingen
Healthypharm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Fabrikant:
HERMES PHARMA GmbH
Hans-Urmiller-Ring 52
82515 Wolfratshausen
Duitsland

In het register ingeschreven onder: RVG 115427

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Finland	Bisolaclar 600 mg poretabletti
Netherlands	Bisolaclar 600 mg bruistabletten
Norway	Bisolaclar
Italy	Bisolmonus600 mg compresse effervescenti

Deze bijsluiter is voor het laatst goedgekeurd in juli 2023.