

BROPHYLE CAPSULE

Please read this leaflet carefully before you start using 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. 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.

What is in this leaflet

1. What Brophyle is and what it is used for
2. What you need to know before you use Brophyle
3. How to use Brophyle
4. Possible side effects
5. How to store Brophyle
6. Contents of the pack and other information

1. What Brophyle is and what it is used for

Brophyle Capsules contain the active substance acebrophylline, which is used to treat chronic obstructive pulmonary disease (COPD), bronchial asthma, and bronchitis. It helps to relax the muscles in the airways and reduces inflammation, making it easier to breathe.

2. What you need to know before you take Brophyle

Do not take Brophyle Capsules if you:

- Are allergic to acebrophylline, ambroxol, theophylline, or any other xanthine derivative.
- Have had a recent heart attack.
- Suffer from low blood pressure, unstable blood circulation, or irregular heartbeats.
- Have severe kidney or liver disease.

Warnings and precautions:

- Inform your doctor if you have heart failure, chronic alcoholism, liver dysfunction, or viral infections.
- Use with caution if you have heart arrhythmias, cardiovascular diseases, hyperthyroidism, hypertension, stomach ulcers, or convulsive disorders.
- Patients with liver or kidney insufficiency should use this medicine with caution.

Other medicines and Brophyle Capsules:

- **Allopurinol, cimetidine, ciprofloxacin, corticosteroids, diltiazem, erythromycin, frusemide, isoprenaline, oral contraceptives, thiabendazole, and verapamil:** These medicines can reduce the clearance of acebrophylline, potentially increasing the risk of side effects. Your doctor may need to adjust your dose.
- **Doxycycline and amoxicillin:** These antibiotics can interact with acebrophylline, requiring careful monitoring.
- **Beta2-agonists, steroids, diuretics, and hypoxia:** Xanthines like acebrophylline can potentiate hypokalaemia (low potassium levels) caused by these treatments. Monitoring of serum potassium levels is recommended, especially in severe asthma.
- **No clinically relevant unfavourable interactions** with other medications have been reported, but always inform your doctor about all the medicines you are taking.

Pregnancy and breastfeeding:

- Brophyle Capsules are not recommended during pregnancy or breastfeeding.

Driving and using machines:

- No studies have been conducted on the effects of Brophyle Capsules on the ability to drive or use machines. Use caution until you know how the medicine affects you.

Important Precautions

- You have been prescribed Acebrophylline for prevention and treatment of asthma and chronic obstructive pulmonary disease (COPD).
- It should be taken at the same time each day, preferably in the evening after food.
- It does not work right away and should not be used to relieve sudden breathing problems. Always keep a fast-acting (rescue) inhaler with you.
- Your doctor may take regular blood test to monitor potassium level and the level of this medicine in your body.
- Notify your doctor if you have ever been diagnosed with kidney, liver or heart disease, or if you have a smoking history. Your dose may need to be adjusted.
- Do not discontinue use without consulting your doctor, even if you feel better.

3. How to take Brophyle

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

Adults:

- The usual dose is one capsule twice daily, preferably in the evening after food.

Elderly:

- Dosage may need to be adjusted.

Children:

- Not recommended for children who may have difficulty swallowing capsules.

If you use more Brophyle than you should

Tell your doctor if you accidentally use more than you were told.

If you forget to use Brophyle

If you forget to take at the right time, use it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop using Brophyle

Do not stop your treatment even if you feel better unless told to do so by your doctor.

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

4. Possible side effects

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

Common side effects:

- Abdominal discomfort, stomach distension, vomiting, abdominal pain, diarrhea, constipation, heartburn, loss of appetite, esophageal bleeding, rashes, urticaria, itching, drowsiness, difficulty breathing, leukocytosis, nasal inflammation.

Rare side effects:

- Headache, numbness, insomnia, tachycardia, fatigue, hypertension, albuminuria, glycosuria, hypotension, hyperglycemia.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.com in and click the tab "Safety Reporting" located on the top end of the home page. Website link: <https://www.zuventus.co.in/drug-safety-reporting>. By reporting side effects, you can help provide more information on the safety of this medicine. You can also report the side effect with the help of your treating physician.

5. How to store Brophyle

- Keep this medicine out of the sight and reach of children.
- Store below 30°C. Protect from light & moisture.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
- The expiry date refers to the last day of that month.

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 Brophyle Capsules contain:

- The active substance is acebrophylline 100 mg.