

BUTALINE SYRUP

Terbutaline sulphate 1.5mg/5ml

What is in the leaflet?

1. What Butaline is used for
2. How Butaline works
3. Before you use Butaline
4. How to use Butaline
5. While you are using it
6. Side effects
7. Storage and Disposal of Butaline
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Butaline is used for

Butaline is used to open up the airways in people with asthma, bronchitis (inflammation of the mucous membrane in the bronchial tubes) and other breathing problems so that they can breathe more easily.

How Butaline works

Butaline syrup contains terbutaline sulfate. Terbutaline is a bronchodilator and belongs to a group of medicines called beta-2-agonists. It works by relieving bronchospasm (constriction of the air passages of the lung), and reducing airway resistance.

Before you use Butaline

- When you must not take it

Do not use Butaline if you have an allergy to:

- any medicine containing terbutaline
- any of the ingredients at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any of the following medical conditions:

- heart problems
- hypertension (high blood pressure)
- diabetes
- thyroid problems
- closed-angle glaucoma (increased pressure within the eye)
- phaeochromocytoma (a rare tumor of adrenal gland tissue)
- history of seizures.

It may not be safe for you to take Butaline if you have any of these conditions.

Tell your doctor if you are pregnant or plan to become pregnant, or breastfeeding.

Your doctor will advise you of the risks and benefits of using Butaline during pregnancy and while breastfeeding.

- Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Butaline may interfere with each other. These include:

- Anaesthetics such as chloroform,

- cyclopropane, halothane or trichloroethylene
- Tricyclic antidepressants and monoamine oxidase inhibitors (MAOI) for the treatment of depression
- Thyroid hormones
- Enflurane, isoflurane, methoxyflurane
- medicines used to treat heart problems or high blood pressure
- medicines to treat asthma, bronchitis or breathing problems

These medicines may be affected by Butaline, or may affect how well it works.

You may need different amounts of your medicine, or you may need to use a different medicine. Your doctor or pharmacist will advise you.

How to use Butaline

- How much to use

Adults

Bronchodilator :

2.5 – 5 mg 3 times daily

Labour (premature) inhibitor-maintenance :

2.5mg 4-6 hourly OR 5mg 3 times daily until term

Usual adult prescribing limit : 15mg daily

Children 12-15years :

2.5mg 3 times daily

Children up to 12 years :

Dosage has not been established.

- When to use it

Take Butaline Syrup as your doctor has prescribed.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much Butaline.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

- Things you must do

If you find that the usual dose of Butaline is not giving you as much relief as before, or you need to use it more often, please contact your doctor so that your condition can be checked.

This is important to ensure your breathing problem is controlled properly.

See your doctor regularly for check-up and to ensure that your asthma is not getting worse.

Tell any other doctors, dentists and pharmacists who are treating you that you are using Butaline.

If you are about to be started on a new medicine, tell your doctor or pharmacist that you are using Butaline.

If you become pregnant while using Butaline, tell your doctor or pharmacist.

- Things you must not do

Do not use Butaline to treat any other complaints unless your doctor tells you to.

Do not give Butaline to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful of driving or operating machinery until you know how Butaline affects you.

Side effects

Like all medicines, Butaline can cause side effects, although not everyone gets them.

Tell your doctor if you notice any of the following and they worry you:

- headache
- tremor (shaky hands)
- nervousness
- increased heart rate or palpitations
- nausea (feeling sick), vomiting or diarrhoea
- sweating, muscle cramps
- drowsiness or dizziness
- restlessness or disturbed sleep

These side effects are usually mild.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Butaline

- Storage

Keep your Butaline Syrup in a cool dry place where the temperature stays below 30°C.

Keep the Butaline Syrup in its bottle until it is time to take it.

Do not store Butaline or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Butaline Syrup is a colourless clear fruity flavoured syrup.

Ingredients

Active ingredient:

- Terbutaline sulphate

Inactive ingredients:

- Sorbitol 70% Solution
- Sodium Benzoate
- Pineapple essence
- Strawberry flavour
- Glycerin
- Trisodium Citrate
- Citric Acid

MAL number

- MAL19880212AZ

Manufacturer

DUOPHARMA
MANUFACTURING
(BANGI) SDN. BHD.
Lot No. 2 & 4, Jalan P/7,
Section 13, Bangi Industrial
Estate 43650 Bandar Baru
Bangi, Selangor Darul Ehsan

Product Registration Holder

DUOPHARMA
MANUFACTURING
(BANGI) SDN. BHD.
Lot No. 2, 4, 6, 8 & 10, Jalan
P/7, Section 13, Bangi
Industrial Estate 43650 Bandar
Baru Bangi, Selangor Darul
Ehsan

Date of Revision

28/04/2021

Serial number

BPFK (R4/1)111114/0048