

BUTAMIRATE CITRATE**ATUSSIN™**

50 mg Film-Coated Sustained-Release Tablet

ANTITUSSIVE

FORMULATIONEach film-coated sustained-release tablet contains:
Butamirate Citrate 50 mg**NAME OF THE PRODUCT**

Butamirate Citrate (Atussin) 50 mg Film-Coated Sustained-Release Tablet

DESCRIPTION OF THE PRODUCT

White, round, biconvex shaped film-coated tablets having 'ORION' mark on one side and breakline on the other side.

WHAT IS IN THE MEDICINE?

Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet contains the active ingredient butamirate citrate, which belongs to a group of medicines called antitussives.

STRENGTH OF THE MEDICINE

50 mg

WHAT IS THIS MEDICINE USED FOR?

Butamirate citrate is used for symptomatic treatment of dry, irritant cough of any etiology, pre- and post- operative cough and whooping cough.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?Butamirate Citrate (Atussin) should be taken orally.
The recommended dose is:

Adolescents over 12 years: 1 to 2 tablets daily

Adults: 2 to 3 tablets daily at 8 to 12-hour intervals

If the symptoms worsen or do not improve within 5 days (3 days in children below 12 years of age), a doctor must be consulted. If fever or any other symptoms occur during the treatment, consult your doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet:

- 1.) If you are allergic to Butamirate Citrate or any of the other ingredients of this medicine
- 2.) Children under 3 years of age
- 3.) If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet during the first three months of pregnancy. From the fourth month of pregnancy, you should only take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet if your doctor has explicitly advised you to do so.
- 4.) If you are breastfeeding you should take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet after doctor's advice.
- 5.) When driving and using machines Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet may cause rarely drowsiness in some people. Caution is required while driving or using machines.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

Before taking Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet, contact your doctor if:

1. You suffer from liver problems (liver function impairment or failure).
2. You suffer from kidney problems (kidney function impairment or failure).

Talk to your doctor or pharmacist before taking Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet if:

1. You are pregnant, might become pregnant or think you may be pregnant.
2. Allergy

It is important to ask your doctor or pharmacist if Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet is safe for you when you are taking any other medicines, including medicines obtained without prescription.

Take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet with or without food.

UNDESIRABLE EFFECTS OF THIS MEDICINE

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur in rare cases (they may affect 1 to 10 patients in 10,000):

1. Drowsiness
2. Nausea
3. Diarrhea
4. Urticaria (itchy skin rash)

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Do not use this product with other cough medicines called "expectorants" since the combination of these medicines may lead to the build-up of mucus in the airways.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you forget to take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet, take it as soon as you remember. However, if it is almost time for the next dose, wait until that is due and then continue as normal.

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

SIGNS AND SYMPTOMS OF OVERDOSE

Butamirate overdose may lead to the following symptoms: drowsiness, dizziness, nausea, vomiting, diarrhea, hypotension.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have used or taken too much Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet, the usual emergency assistance should be taken: activated charcoal, saline laxative and symptomatic treatment must be given or contact your doctor, pharmacist or the poison unit at your nearest hospital casualty department immediately.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C. Protect from light.

Keep out of reach of children.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. It is not known whether Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet affects the way other medicines work, or whether Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet is affected by other medicines.

You should not take Butamirate Citrate (Atussin) Film-Coated Sustained-Release Tablet

If you are taking medicines known as strong enzyme inhibitors or medicines known to have 'a narrow therapeutic index'. Your doctor or pharmacist will be able to confirm whether this applies to you.

ADVERSE DRUG REACTION REPORTING STATEMENTFor suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-UNILAB-1 (+632-8-864522-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph.

By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Alu/Alu Blister Pack x 10's (Box of 30's)

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