

BURINEX[®] TABLET 1MG

Bumetanide (1mg)

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What Burinex[®] tablet is used for

Burinex[®] is used as a diuretic for treatment of oedema and/or high blood pressure.

How Burinex[®] tablet works

Bumetanide, the active ingredient in Burinex[®] tablet is a diuretic (water tablet). They help your kidneys produce more urine over a short period of time. This helps your body to quickly get rid of more water.

Before you use Burinex[®] tablet

- When you must not use it

Do not use Burinex[®] if:

- you are allergic to the active substance or one or more of the other ingredients
- you have serious disturbances in fluid and salt balance (electrolyte disturbance)
- you have kidney failure, where the production of urine has ceased
- you have a severe liver disease
- you have too little sodium in your blood

Pregnancy

Pregnancy: You should only take Burinex[®] tablet if advised by your doctor.

- Before you start to use it

Before you take Burinex[®] tablet, tell your doctor if:

- you are allergic to medicine for urinary tract infections (sulphonamides) or diuretics

(thiazides), as there is a risk that you will also be allergic to Burinex[®] tablet

- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Burinex or other sulphonamides, such as loop diuretics
- you have metabolism disorders (porphyria)
- you have diabetes
- you have gout, as Burinex[®] tablet may worsen this condition
- you have low blood pressure
- you have a tendency to infection or bleeding due to reduced number of white blood corpuscles and blood platelets
- you take antibiotics (amino glycosides) or take other medicine which may impair your hearing
- you are pregnant

When having blood and urine tests, always inform that you are receiving treatment with Burinex[®] tablet.

The tablets contain lactose. Consult your doctor before taking them, if your doctor has informed you that you cannot tolerate certain types of sugar.

- Taking other medicines

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

Burinex[®] tablet can alter the effect of other medicines, just as other medicines can alter the effect of Burinex[®] tablet. Contact your doctor if you take:

- digitalis therapy (medicine for heart failure and abnormal heart rhythm)

- lithium salts
- non-steroidal antirheumatics

How to use Burinex[®] tablet

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults: ½-1 tablet (0.5-1 mg) daily.

Children: Burinex[®] tablet may only be given to children if advised by the doctor.

Elderly: Follow the doctor's instructions.

Reduced liver function: It is necessary to adjust the dose. Follow the doctor's instructions.

- When to use it

Use as directed by your doctor or pharmacist.

Burinex[®] tablet must be taken with a glass of water.

- How long to use it

Continue taking Burinex[®] tablet for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you have forgotten to take Burinex[®] tablet, do not take a double dose, just continue with the normal dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even

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if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken too much Burinex[®] tablet you may:

- experience severely increased urination
- experience fluid deficiency
- experience thirst and dryness in the mouth
- feel weak
- feel lethargic, drowsy, confusion
- experience digestive disorders, restlessness, muscular pains and cramps

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Burinex[®] tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Burinex treatment. Stop using Burinex and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section "Side Effects".

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Burinex[®] tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Burinex[®] tablet can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. Tell your doctor if you notice any of the following:

- muscle cramps or pain
- skin rash,
- abdominal discomfort

Stop using Burinex and seek medical attention immediately if you notice any of the following symptoms:
- Reddish, non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

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.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Burinex[®] tablet

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

Do not use Burinex[®] tablets after the expiry date, printed on the package.

- 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

Burinex[®] tablet are white round flat tablets, scored and imprinted on one side with the number 133.

- Ingredients

- Active ingredient(s)
Bumetanide

- Inactive ingredients
Agar; lactose monohydrate; povidone; magnesium stearate; corn starch; polysorbate 80; colloidal anhydrous silica and talcum.

- MAL number:

MAL19913216ACZ

Manufacturer

allphamed PHARBIL
Arzneimittel GmbH Hildebrandstr. 10-12
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Product Registration Holder

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