BURINEX® TABLET 1MG

Bumetanide (1mg)

What is in this leaflet

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

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 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 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.

- <u>Things you must not do</u>
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.

- <u>Things to be careful of</u> 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

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, and imprinted with the image of a lion on the other side.

- Ingredients
 - Active ingredient Bumetanide
 - Inactive ingredients Agar; lactose monohydrate; povidon; magnesium stearate; corn starch; polysorbate 80; colloidal anhydrous silica and talcum.
- *MAL number:* MAL19913216A

Manufacturer

LEO Pharmaceutical Products Ltd. A/S (LEO Pharma A/S) 55 Industriparken 2750 Ballerup Denmark

Product Registration Holder

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Date of revision

14/03/2014