

## Package leaflet: Information for the patient

### Benph 1 mg, 2 mg, 5 mg and 10 mg Tablets (terazosin)

**Read all of this leaflet carefully before you start taking 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 only. 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. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Benph is and what it is used for**

Your medicine contains terazosin, which belongs to a group of medicines called alpha-blockers. Benph is given to adult men suffering from an enlarged prostate gland (part of the male sexual organs found just below the bladder, which can place pressure on the bladder, causing problems, when passing water (urine)), as it can relax the muscles allowing urine to be passed more easily.

#### **2. What you need to know before you take Benph**

##### **Do not take Benph:**

- if you are allergic to terazosin or any of the other ingredients of this medicine (listed in section 6)
- if you have ever taken a similar medicine to terazosin (e.g. prazosin, alfuzosin, indoramin, tamsulosin, doxazosin) and you suffered an allergic reaction
- if you have heart failure which may be caused by heart valve disease, a blood clot in the lungs or the membrane (protective lining) around the heart being inflamed (pericarditis).
- if you have fallen over or fainted whilst passing water.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Benph:

- if you have had or are suffering from other heart conditions eg. heart disease, heart valve disease, angina, heart failure or stroke
- if you are taking other medication for high blood pressure. If a medicine for high blood pressure is started while you taking this medicine, then your doctor may need to adjust your dose.
- if you are taking medicines to treat erectile dysfunction (impotence) (e.g. sildenafil, tadalafil, vardenafil) (See section 'other medicines and Benph')
- if you are on a low salt (e.g. sodium) diet or are very dehydrated (e.g. you may have had severe diarrhoea or been sick)
- if you have liver or kidney problems
- if you have had or are currently suffering from eye problems due to high blood pressure

- if you have diabetes that requires insulin treatment

Terazosin must be used only after excluding other possible reasons in urinary track for abnormal/interrupted urinary flow. Terazosin should not be given to patients with bladder overflow (you do not feel the urge to urinate), anuria (your body is not producing any urine) or advanced renal failure.

Tell your doctor if any of the above apply to you.

#### During treatment

When taking this medicine you may experience a sudden drop in blood pressure when you stand up, shown by dizziness, weakness or sweating within a few hours of taking (this may occur especially after taking the first dose or during the early stages of treatment or when treatment is stopped and then restarted). If you experience a drop in blood pressure you should lie down with your legs and feet up in the air until the symptoms have disappeared. Usually, these effects last for only a short time.

This medicine can cause painful erections, which may last for hours and continue even after sex or masturbation (if left untreated this can cause problems with getting and maintaining an erection). If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately. (See section 4: possible side effects).

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are taking or have previously taken this medicine. This is because terazosin may cause complications during the surgery which can be managed if your specialist is prepared in advance.

#### **Other medicines and Benph**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription or the following:

- medicines to lower blood pressure (e.g. diltiazem), ACE inhibitors (e.g. ramipril) or other alpha-blockers (e.g. doxazosin, alfuzosin)
- diuretics (water tablets used to help your kidneys get rid of extra water and salt from your body and lower blood pressure) e.g. furosemide
- Some patients experience dizziness after taking medicines used to lower the blood pressure and terazosin due to the increased drop in blood pressure.
- medicine for erectile dysfunction (impotence) (e.g. sildenafil, tadalafil, vardenafil)

Some patients who take alpha-blocker therapy for the treatment of prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking medicines for erectile dysfunction (impotence) with alpha-blockers. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start medicines for erectile dysfunction.

#### **Benph with alcohol**

Alcohol can increase the effects of this medicine causing dizziness or fainting. **Do not** drink alcohol while taking this medicine if you are affected.

#### **Pregnancy and breast-feeding**

Benph is used to treat a condition found only in men. It should not be prescribed to women.

#### **Driving and using machines**

Benph may make you feel dizzy, light headed **and** drowsy. These side effects are more likely at the start of treatment, or in the case of missed doses and where treatment has been stopped and then

restarted again. You may also suffer from blurred vision or other eyesight changes. **Do not** drive, operate machinery or perform any hazardous tasks for 12 hours when you first start taking your medicine, or when your doctor increases the dose you are taking. After this time, make sure you are not suffering any of these side effects before carrying out these tasks.

### **Benph contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **Benph 5 mg and 10 mg tablets contain sunset yellow (E110)**

Sunset yellow (E110), may cause allergic reactions.

## **3. How to take Benph**

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

- Swallow the tablets whole with a full glass of water
- Take with or without food
- Do not chew, break or crush the tablets.

### **Adults and the elderly (over 65 years of age) only:**

The recommended starting dose is 1 mg of Benph. Take the very first dose at bedtime as Benph may make you feel dizzy or faint when taken for the first time.

Your doctor may adjust your dose depending on how you respond to the tablets. Response to treatment should be reviewed at four weeks of the treatment. If your doctor increases your dose, he or she may double your dose at intervals of one week or every two weeks. The usual maintenance dose is 5 to 10 mg once daily. The maximum daily dose is 10 mg of Benph.

### **Use in children and adolescents (under 18 years):**

Benph tablets are not recommended for use in children.

### **If you take more Benph than you should**

If you take more Benph than you should your blood pressure may suddenly drop and you may feel dizzy or even faint. If you begin to feel dizzy, lie down until you feel better. If the symptoms do not disappear, contact your doctor or nearest hospital casualty department immediately. Take any remaining tablets and the container with you.

### **If you forget to take Benph**

If you forget to take Benph, **do not** take a double dose to make up for a forgotten dose as this may cause a sudden drop in blood pressure, especially if you take blood pressure lowering medicines, just carry on as before. If for any reason, you have stopped taking Benph for several days, **do not** continue your treatment using the same dose. Contact your doctor as you may need to start taking your medicine at a lower strength than you have been used to taking.

### **If you stop taking Benph**

**Do not** suddenly stop taking your medicine as this may cause serious changes in your blood pressure. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

**If you experience any of the following, stop taking Benph and tell you doctor immediately or go to the nearest hospital emergency department:**

**Very rare (may affect up to 1 in 10,000 people):**

- itchy skin or a rash, difficulty breathing, feeling wheezy, or swelling of the face, mouth or throat, fast and uneven heartbeat, which may make you feel tired, dizzy and short of breath (atrial fibrillation)

**Rare (may affect up to 1 in 1,000 people):**

- if you suffer from a painful, prolonged erection which continues even after sex or masturbation which lasts for more than 4 hours, you should contact doctor immediately. This can lead to permanent impotence (failure to get and maintain an erection) if not treated.

When taking Benph for the first time or when starting to take higher dose tablets dizziness, light-headedness or fainting may occur. These effects may also occur when standing up quickly from a lying or sitting position. If you are affected by this, you should lie down until you feel better then you should sit for a few minutes before standing again to prevent these effects returning. These side effects usually go away and should not return once you have become used to taking your tablets.

**Other possible side effects:**

**Common (may affect up to 1 in 10 people):**

- feeling dizzy, light-headed or weak
- sleepiness
- feeling nervous
- constipation, diarrhoea, feeling or being sick
- swelling of the ankles or hands
- itchy skin or skin rash
- uneven or rapid heart beat
- breathlessness
- headache
- impotence
- chest pain
- tingling or numbness in the hands and feet
- fainting on standing
- blurred vision or decreased vision (lazy eye)
- pain in the extremities (hands and feet)
- back pain
- feeling weak
- nose bleeds, sinusitis or blocked nose

**Uncommon (may affect up to 1 in 100 people):**

- depression
- weight gain
- loss of sexual desire
- fainting

**Rare (may affect up to 1 in 1,000 people):**

- bladder (urinary tract) infection or loss of control of passing water (incontinence), mostly in women who have been through the menopause

**Very rare (may affect up to 1 in 10,000 people):**

- unusual bruising or bleeding of the skin

**Not known (frequency cannot be estimated from the available data):** anxiety, difficulty sleeping, abnormal vision, infection causing redness and swelling of the thin layer covering the front of the eye (conjunctivitis), ringing in the ears, spinning sensation, irregular heartbeat, bronchitis, flu symptoms, sore throat, cold symptoms, cough, dry mouth, indigestion, wind, swelling of the face, sweating, stomach, neck and shoulder pain, gout, painful joints or muscles, changes in urinary frequency, fever, dilation of the blood vessels which may cause redness of the skin.

If you are undergoing eye surgery because of cataract and you are taking or have taken this medicine in the past, there may be complications during the surgery (please see "Warnings and precautions").

The use of this medicine may affect the results of some blood tests. Always tell your doctor that you are taking this medicine.

### **Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Benph**

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the blister 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 Benph contains**

- The active substance is terazosin hydrochloride dihydrate (equivalent to 1 mg, 2 mg, 5 mg and 10 mg of terazosin).
- The other ingredients are talc, magnesium stearate, povidone, pregelatinised starch, lactose monohydrate (see section 2. "Important information about some of the ingredients of Benph"). In addition, the 2mg tablet contains quinoline yellow (E104). The 5 mg and 10 mg tablets contain sunset yellow (E110) (see section 2 "Benph 5 mg and 10 mg tablets contain sunset yellow [E110]").

### **What Benph looks like and contents of the pack**

The 1mg tablets are white, round, flat bevel-edged tablets imprinted 'E' and '451' on one side.

The 2 mg tablets are yellow, round, flat bevel-edged tablets imprinted 'E' and '452' on one side.

The 5 mg tablets are light orange, round, flat bevel-edged tablets imprinted 'E' and '453' on one side.

The 10 mg tablets are orange, round, flat bevel-edged tablets imprinted 'E' and '454' on one side.

They are available in PVC/PVDC/ aluminium blister packs of:

1 mg: 7, 10, 14, 20, 28, 50 and 100 tablets \*

2 mg: 7, 10, 14, 20, 28, 50, 84, 98 and 100 tablets \*

5 mg: 14, 20, 28, 30, 50, 84, 98 and 100 tablets \*

10 mg: 28, 50, 84, 98 and 100 tablets \*

\* Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

### **Manufacturer**

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

EGIS Pharmaceuticals PLC, H-1165 Budapest Bökényföldi út. 118-120., Hungary

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Italy: Terazosina Mylan Generics 2 mg, 5 mg compresse

United Kingdom: Benph 1 mg, 2 mg, 5 mg, 10 mg Tablets

**This leaflet was last revised in: September 2017**