pressure falls too low. Care must be taken to ensure that the cannula does not come out of the vein as this medicine can irritate muscle tissue.

- You should not take other medicines when being treated with this medicine, particularly beta-blockers or drugs to regulate your heart beat (anti-arrhythmics).
- Phenoxybenzamine has been found to cause cancer in rats, and has been found to cause damage to unborn babies. There are no data about the safety of phenoxybenzamine during pregnancy or breast feeding infants. Your doctor will assess the risk versus the benefit of using this medicine to treat you, and you should discuss this with your doctor.

**Taking your medicine:**
- You will be given this medicine by an intravenous infusion via a cannula (needle) inserted in a vein.
- The medicine will have been diluted with sterile saline solution.
- The usual dose is 1mg/kg body weight, and this dose is infused into a vein over 2 hours.
- Only one dose will be given in 24 hours, and not more than two doses will be given in 48 hours.
- You will be lying down to be given the infusion.
- Your blood pressure will be measured every few minutes during the infusion.
- If your blood pressure falls to low, the infusion will be stopped, and you may be given other intravenous fluids.

**While taking your medicine:**
- Lie still while the infusion is given to you.
- Your blood pressure will be measured every few minutes.
- The infusion may be stopped if your blood pressure falls too low and you may be given a different intravenous fluid to counteract this.

**After having your medicine:** This medicine may cause unwanted effects in some people. If you experience any of the following, tell your doctor.
- You may become drowsy.
- You may feel dizzy.
- Your heart rate may increase.
- Your mouth may feel dry.
- Your nose may become stuffy.
- You may not sweat as much as normal.
- You may have an upset stomach.
- You may feel faint.
- You may notice that the pupil of your eye becomes smaller.

**Precautions:**
- This medicine should be protected from light.
- The infusion should be used immediately after dilution.
- The infusion must be kept out of reach and sight of children.
- This medicine should not be used after the expiry date printed on the pack. If you have any question about the use of this medicine, ask your doctor.

**Remember:** This medicine is only for you. Only a doctor can prescribe it for you.

**Other useful information:**
For further information about this product contact Goldshield Pharmaceuticals Ltd, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom.

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**Goldshield**

**Phenoxybenzamine Injection Concentrate 100mg/2ml (PHENOXYBENZAMINE HYDROCHLORIDE)**

**INSTRUCTIONS FOR PROFESSIONAL USE ONLY**

**Presentation**
Each 2 ml ampoule contains 100 mg Phenoxybenzamine Hydrochloride BP Excipients: Absolute ethyl alcohol, hydrochloric acid AR, and propylene glycol.

**Uses**
Phenoxybenzamine is a long-acting, non-competitive, α-adrenergic receptor antagonist. By intravenous infusion it is used as part of the investigational, pre-operative and operative management of phaeochromocytoma, and as an adjunct to the treatment of severe shock not responding to conventional therapy in the presence of an adequate circulating blood volume. ‘Phenoxybenzamine’ should only be used after careful consideration of the likely benefit of treatment compared with the mutagenic and carcinogenic risk. See **Precautions below**.

**Dosage and administration**
‘Phenoxybenzamine’ Injection Concentrate must be diluted before use. The dose selected should be added aseptically to 200-500 ml 0.9% sodium chloride immediately before use. **The intravenous route only must be used, preferably through a large vein.** Not more than one dose should be given in 24 hours, infused over at least two hours. It is suggested that one-third of the dose is given over the first hour, and the remaining two-thirds over the second hour if no precipitous fall in blood pressure has occurred.

**Adulthood:** Phaeochromocytoma. Where α-blockade is required as a preparation for investigation or operation in cases of phaeochromocytoma, a daily dose of 1 mg/kg body weight intravenously in 200 ml of physiological saline over two hours has been used, for several days preceding and during the procedure. This dose is a guide and it is often necessary to titrate the dose on a daily basis according to individual response. Concomitant β-receptor blockade may be necessary.

**Shock:** 1 mg/kg body weight in 200 to 500 ml of 0.9 per cent NaCl given over not less than two hours.

**Children:** There is little experience of use in children and none under the age of two years.

**Precautions**
The patient should be recumbent. Blood pressure must be determined every few minutes during the administration. Facilities for rapid infusion of intravenous fluid should be available. The ‘Phenoxybenzamine’ infusion should be slowed or stopped if there is a precipitous fall in blood pressure. This usually indicates an inadequate circulating blood volume, but occasionally may occur in the presence of an adequate blood volume in hypertensives or in patients with carbon dioxide retention, and in these cases is relatively unresponsive to the administration of intravenous fluids. If severe hypotension does occur, which is not correctable by adequate intravenous fluid administration, infusions of a vasopressor agent (e.g. noradrenaline) may be undertaken. Adrenaline must not be used for this purpose as it may cause a further fall in blood pressure. If blood pressure has been stabilised by the administration of appropriate fluids, the ‘Phenoxybenzamine’ infusion may be restarted under close supervision. The blockade produced is often still exerting an effect 24 hours after administration and, even in patients with a favourable response, close attention to their cardiovascular status should be maintained for at least this period. Little can be accomplished by a second administration of ‘Phenoxybenzamine’ within 24 hours and the drug should not be given more than twice during a 48-hour period. Special care should be taken if ‘Phenoxybenzamine’ is given to patients...
who have depressed cardiac function, or are receiving drugs which may depress it.
Care should be taken to avoid extravasation, as the diluted solution is irritant to muscle tissue.
Phenoxybenzamine is carcinogenic in the rat and has shown mutagenic activity in the bacterial Ames test and the mouse lymphoma assay. It should, therefore, be used only after very careful consideration of the risks, in patients in whom alternative treatment is inappropriate.
Avoid contamination of the hands with ‘Phenoxybenzamine’ as reactions may occur in sensitive skins.

Contra-indications, warnings, etc.
Contra-indications: Do not use in patients who have had a cerebrovascular accident; or in the recovery period (usually 3 to 4 weeks) after acute myocardial infarction. Do not use in the presence of hypovolaemia in patients with severe shock.

Precautions: Use with great caution in patients in whom a fall in blood pressure and/or tachycardia may be undesirable, such as elderly or those with severe ischaemic heart disease, congestive heart failure, extensive arteriosclerosis, cerebrovascular disease or renal damage. The adrenergic blocking effect may aggravate symptoms of respiratory infections. Alpha-sympathomimetics may be ineffective if used concomitantly with phenoxybenzamine. Care should be taken if phenoxybenzamine is used concomitantly with myocardial depressants e.g. beta-blockers and anti-arrhythmics.
Phenoxybenzamine is carcinogenic in the rat and has shown mutagenic activity in the bacterial Ames test and the mouse lymphoma assay. It should therefore be used only after very careful consideration of the risks, in patients in whom alternative treatment is inappropriate.
Use in pregnancy: There is no available evidence as to the safety of ‘Phenoxybenzamine’ in pregnancy and it should not be used in pregnancy or lactation unless essential.

Adverse reactions
‘Phenoxybenzamine’ given intravenously has a sedative effect and patients may become more drowsy or less responsive during the infusion. This may occur in spite of an excellent cardiovascular response and should not be confused with the decreased responsiveness associated with worsening of the shock syndrome.
Other side effects include orthostatic hypotension with dizziness and compensatory tachycardia, miosis, dry mouth, nasal congestion, decreased sweating and gastrointestinal upset. Convulsions have been reported after rapid infusion.
Some fall in blood pressure is a normal response, but an idiosyncratic profound hypotensive effect can occur, usually within five minutes of starting the infusion.
The effect of one dose of ‘Phenoxybenzamine’ on sympathetic motor responses may last 48 hours or more.
Constriction of the pupils, diminished sweating and nasal congestion may be encountered.

Pharmacological precautions
Protect the ampoules from light. Do not store above 25°C
‘Phenoxybenzamine’ solution should be made up immediately before administration.
A transient clouding of the solution, due to low aqueous solubility of ‘Phenoxybenzamine’ near neutral pH, is unimportant.
If markedly discoloured in the ampoule, the preparation should be discarded.

Package quantities
Ampoules of 2 ml in boxes of 5.

Legal category
POM.
PL 12762/0225 Date of last revision November, 2008

Manufactured by: Wülffing Pharma GmbH, Bethelner, Landstr. 18, 31028 Gronau, Germany for Goldshield Pharmaceuticals Ltd,
NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom.
10083/PL/A

PATIENT INFORMATION LEAFLET FOR
DIBENYLIN INJECTION CONCENTRATE/
PHENOXYBENZAMINE INJECTION CONCENTRATE
100mg/2ml

Please read this leaflet carefully before you start to have your medicine. This leaflet does not contain all the information about your medicine. If you have any questions, or you are not sure about anything ask your doctor or pharmacist.

The name of your treatment is:
Dibenylin Injection Concentrate/Phenoxybenzamine Injection Concentrate 100mg/2ml.

The active ingredient is: Phenoxybenzamine hydrochloride 100mg BP. The medicine which is presented in a clear colourless ampoule, is a clear colourless to mid-straw coloured liquid. It is sterile and is available in packs of 3, 5 or 10 ampoules.

What else is in your medicine: As well as phenoxybenzamine hydrochloride BP, the medicine also contains absolute ethyl alcohol, hydrochloric acid, and propylene glycol.

Your medicine is a long acting alpha adrenergic receptor antagonist (a drug which lowers high blood pressure).
It is made for the Product Licence Holder, Goldshield Pharmaceuticals Ltd, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, United Kingdom, by Wülffing Pharma GmbH, Bethelner, Landstr. 18, 31028 Gronau, Germany.

What is your medicine used for: Your medicine is given to lower high blood pressure associated with so called phaeochromocytoma (tumour of the kidney), and may be used together with another product in the treatment of severe shock not responding to conventional treatment.

Before you are given this medicine: If the answer is yes to any of the following questions, or you are not sure about the answer, tell your doctor.
• Have you ever been allergic to this medicine, or to any other medicine for lowering blood pressure, or to any of the ingredients in this medicine?
• Have you ever had a stroke?
• Have you had a heart attack (coronary thrombosis) within the last month?
• If you are being treated for shock, is your blood pressure abnormally low and unable to maintain an adequate supply to your tissues?
• Do you have angina (chest pain)?
• Do you have heart failure (e.g. swelling of the ankles)?
• Do you have arteriosclerosis (thickening of the arteries)?
• Have you ever had kidney problems which damaged your kidneys?

What precautions should you take:
• You will have to lie down to be given this medicine.
• Your blood pressure will be measured every few minutes when you are given this medicine.
• You will be given the medicine via a vein with a cannula (needle) inserted into one of your veins. This cannula can also be used to give other intravenous fluids as necessary, particularly if your blood