

EFRIN-10[®] STERILE OPHTHALMIC DROPS

Patient package insert in accordance with the Pharmacists' Regulations (Preparations) 1986.

The dispensing of this medicine requires a doctor's prescription.

Read this leaflet carefully in its entirety before using this medicine.

The format of this bulletin was determined by the Ministry of Health who has reviewed and approved its content.

Composition:

Active Ingredient: Phenylephrine Hydrochloride 10%.

Inactive Ingredients: Benzalkonium Chloride, Boric Acid, Disodium

EDTA, Purified Water, Sodium Bisulfite.

Therapeutic Activity: Mydriasis and Vasoconstriction.

When this preparation should not be used:

Do not use this preparation if you have a known sensitivity to any of its ingredients or if you suffer from Glaucoma.

This preparation must not be used without consulting a doctor before commencing treatment. Do not use this preparation if you are pregnant or nursing, or if you suffer or have suffered from a heart complaint, vascular or eye disorders, dysfunction of the thyroid gland, diabetes or hypertension.

Warnings: If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. The product contains the preservative Benzalkonium Chloride that could be absorbed by soft contact lenses. This product should not be used if you wear soft contact lenses. The lenses should be removed before using the product and should only be replaced 15 minutes following application of the medication to the eyes.

Drug Interaction: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially true in connection with drugs in the following groups: anti-depressants from the TRICYCLINE and MAOI groups, and within 21 days of completing a course of: RESERPINE, METHYLDOPA, GUANETHIDINE or/and Beta Blockers for the heart and blood pressure.

Side Effects: Apart from the desirable activity of this drug, side effects might appear such as: headache, stinging in the eyes and sensitivity to light. Consult your doctor if these symptoms continue and/or disturb you.

Side effects that require special attention: Signs of systemic absorption - trembling, accelerated pulse beat, disturbances of heart rhythm (arrhythmia), pain in the eyes, excessive perspiration, irritation, rash or local inflammation (that did not exist prior to treatment); in which case, cease treatment and immediately consult your doctor. Any time you experience side effects that are not listed in this leaflet or if you feel any change in your general health, consult your doctor immediately.

Dosage: Only according to a doctor's instructions. Do not exceed the stated dose. This drug is not generally recommended for infants or children. This drug should be used at the allotted times as determined by your attending doctor. If you have forgotten to apply the drops at the allotted time, you should apply a dose immediately you remember, however on no account should two doses be applied at the same time!

ATTENTION: **Do not swallow**. This medicine is intended for external use only.

Directions for use: Wash your hands thoroughly. Tilt back your head or lie down on a bed and with the aid of a finger pull the lower eyelid away slightly from the eye. Instill the drops into the gap keeping the eyes closed for 1-2 minutes. In order to prevent contaminating the solution, keep the bottle well closed when not in use and avoid touching the bottle opening to any surfaces including the fingers and the eyes. Use is limited to one month from the time the bottle is first opened.

Avoid Poisoning! This medicine and all other medicines must be stored in a safe place and out of the reach of children and/or infants to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not take medicines in the dark! Check the label and dose each time you take your medicine. Wear your glasses if you need them. This medicine has been prescribed for your condition, in another patient it may cause harm. Do not give this medicine to your relatives, neighbours or acquaintances.

Storage: Up to 25°c. Close firmly to prevent penetration of air and humidity. Even if kept in the original container and stored as recommended, medicine may be kept for a limited period only. Please note the expiry date of the medicine! In the case of doubt consult the pharmacist who dispensed the medicine to you.

Do not store different medication in the same package.

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