

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Vividrin®**

*Preservative Free SDU 2% w/v Eye Drops solution*

### **Sodium cromoglicate**

The name of your medicine is Vividrin Preservative Free SDU 2% w/v Eye Drops solution and it is called Vividrin Preservative Free in this leaflet.

### **Please read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However you still need to use Vividrin Preservative Free carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

### **In this leaflet:**

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

### **1. WHAT VIVIDRIN PRESERVATIVE FREE IS AND WHAT IT IS USED FOR**

Your drops contain the active ingredient sodium cromoglicate, which belongs to a group of medicines called antiallergics. Your drops are used to prevent and treat chronic allergic conjunctivitis and hay fever (acute allergic conjunctivitis).

Allergic conjunctivitis is an inflammation of the thin skin that covers the white parts of the eyes and the inside of the eyelids. The most common cause is an allergy to pollen during the hay fever season. Other causes are less common such as allergies to house dust mites, cosmetics or problems with contact lenses. You may have red, watery and itchy eyes.

The sodium cromoglicate in your drops works to stop the allergic reaction in your eyes and has a soothing effect.

These drops can be used in children, adults and the elderly.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE VIVIDRIN PRESERVATIVE FREE**

#### **Do NOT use these drops**

- If you have been told, or know, that you are allergic (hypersensitive) to any of the ingredients (see Section 6).

#### **Taking other medicines**

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- Use these drops only if necessary, and then only on your doctor's advice, if you are pregnant or breast-feeding.
- Vividrin Preservative Free should not be used during the first 3 months of pregnancy.

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

- All eye drops can cause a short term blurring of vision when first used so you should wait until your eyes are clear before driving or using machines.

### 3. HOW TO USE VIVIDRIN PRESERVATIVE FREE

To work best, these drops should be used every day that you are in contact with the allergen (pollen, house dust, cosmetics) even when you are not suffering from any symptoms. If your symptoms are caused by pollen, you should continue to use your drops until the end of the hayfever season.

If you have used sodium cromoglicate before, you may have to take it for a few days before you obtain the maximum effect.

Always use your drops exactly as your doctor or pharmacist has told you to. You should check with your doctor or pharmacist if you are not sure.

The medicine is to be used only as drops applied into the eye.

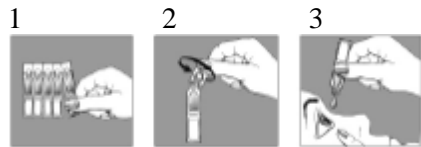
#### **Dosage**

The usual dose is one drop in each eye, 4 times each day. Your doctor may tell you to use your drops more often if you are in contact with high pollen levels.

You may find it easier to remember to take them if you use them at meal times and before going to bed.

#### **Directions for use**

- Wash your hands before using your drops
- Sit down in front of a mirror so that you can see what you are doing
- Wipe your eyes to clear any residual wateriness or discharge
- Holding the unit by the label end, remove a single-dose unit from the pack (see picture 1)
- Twist the cap off the single-dose unit (see picture 2)
- Pull your lower eyelid gently down, and then carefully place one drop in the space between the eyelid and eye (see picture 3)
- Take care not to touch the dropper with your eye or fingers
- Release the lower eyelid, and blink a few times to make sure the eye is covered by the liquid
- Repeat the procedure for your other eye
- This product is for single use only - when you have finished, throw away the single-dose unit (see Section 5).



#### ***If you use more Vividrin Preservative Free than you should***

If you accidentally use too much, do not worry.

#### ***If you forget to use Vividrin Preservative Free***

Use your drops as soon as you remember then carry on in the usual way. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Vividrin Preservative Free can cause side effects, although not everybody gets them.

Like all eye drops you may briefly have blurred vision or a slight stinging feeling after using your drops.

There is also a slight possibility that irritation of the eye may occur in a very small number of people.

Very rarely, an allergic reaction can occur. Symptoms include facial rash or swelling around the eye, and very rarely, difficulty breathing.

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:

HPRA Pharmacovigilance.

Website: [www.hpra.ie](http://www.hpra.ie)

## **5. HOW TO STORE VIVIDRIN PRESERVATIVE FREE**

Keep out of the reach and sight of children.

- **Do not use this medicine after its expiry date.**
- **Check the expiry date on the label before you begin to use your medicine.**
- **The expiry date refers to the last day of that month.**
- **If the expiry date has passed, take the medicine back to your pharmacist.**
- Do not store your eye drops above 25°C.
- Keep the single-dose units in the outer box.
- Your eye drops are sterile until first opened. It is important to keep the drops as clean as possible during use.
- Your drops come in single-use, single-dose units, which should be thrown away immediately after use.
- 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.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Vividrin Preservative Free contains**

- The active ingredient is: sodium cromoglicate 2% w/v. Each 0.5ml of solution contains 10mg of sodium cromoglicate.
- The other ingredients are: sorbitol, hypromellose, hydrochloric acid and water for injection.

### **What Vividrin Preservative Free looks like and contents of the pack**

These eye drops are a colourless to slightly yellow clear, sterile solution and are supplied in plastic single-dose units. Each single-dose unit has a volume of 0.5 ml. Your drops contain no preservative and therefore each unit is for single-use only. Each pack contains 20, 30 or 60 single-dose units. Not all pack sizes may be marketed.

Your drops do not contain a preservative and can be used if your eyes are sensitive to preservatives or if you wear contact lenses.

### **Marketing Authorisation Holder**

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