

**PACKAGE LEAFLET**

## **Package leaflet:Information for the user**

### **Afrin 0.5mg/ml Nasal Spray Solution Afrin 0.5mg/ml Nasal Spray Solution Menthol Afrin 0.5mg/ml Nasal Spray Solution Glycerol Afrin 0.5mg/ml Nasal Spray Solution Chamomile**

Oxymetazoline hydrochloride

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

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

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

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

The full name of your medicine is  
Afrin 0.5mg/ml Nasal Spray Solution  
Afrin 0.5mg/ml Nasal Spray Solution Menthol  
Afrin 0.5mg/ml Nasal Spray Solution Glycerol  
Afrin 0.5mg/ml Nasal Spray Solution Chamomile

#### **What Afrin is**

Afrin nasal spray solution contains the active substance oxymetazoline hydrochloride.

#### **How Afrin works**

Afrin is a decongestant, which relieves a blocked nose by constricting the blood vessels in the nose. It acts within a few minutes and lasts for hours.

#### **When Afrin should be taken**

Afrin is used for the symptomatic relief of nasal congestion due to hay fever, common cold and sinusitis. It can be taken every 12 hours.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **2. What you need to know before you use Afrin**

##### **Do not use Afrin**

- if you are allergic to oxymetazoline hydrochloride or any of the other ingredients of this medicine (listed in section 6) if you are taking monoamine oxidase inhibitors (MAO inhibitors, used in the treatment of Parkinson's disease and depression). MAO inhibitors may increase the hypertensive effects of oxymetazoline

- if you have narrow angle glaucoma
- if you have had trans-sphenoidal hypophysectomy
- if you have inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca)
- if you have acute coronary disease or cardiac asthma

### **Warnings and precautions**

Talk to your doctor if you have:

- coronary artery disease
- hypertension
- hyperthyroidism
- diabetes mellitus
- difficulty in urination due to enlargement of the prostate gland

If used over a longer period Afrin may cause a blocked nose. It is not recommended to use for longer than one week. Contact your doctor if symptoms worsen or do not improve after 7 days.

### **Children**

Do not use Afrin in children under 6 years of age (See Section 3 How to use Afrin)

### **Other medicines and Afrin**

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

The hypertensive effects of oxymetazoline may increase when used together with:

- some types of antidepressants: tricyclic antidepressants, maprotiline, monoamine oxidase inhibitors (MAO inhibitors)

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

#### ***Pregnancy***

Oxymetazoline has not been associated with adverse pregnancy outcome. Afrin can be used in pregnant women if used as recommended. Caution should be exercised in patients with hypertension or signs of reduced placental perfusion. Frequent or prolonged use of high doses may reduce placental perfusion.

#### ***Breast Feeding***

It is not known if oxymetazoline is excreted into breast milk. In view of the lack of data on the use of oxymetazoline during lactation, Afrin should not be used during breast feeding.

### **Driving and using machines**

No effect on ability to drive or use of machines has been observed.

### **Afrin contains benzalkonium chloride; Afrin Nasal Spray Menthol and Afrin Nasal Spray Chamomile contain propylene glycol.**

- Benzalkonium chloride (a preservative) is an irritant and may cause skin reactions.
- Propylene glycol may cause skin irritation

## **3. How to use Afrin**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

#### ***Dosage***

Adults and children > 10 years; 1-2 sprays in each nostril, every 12 hours.

Children 6-10 years 1 spray in each nostril, every 12 hours.

Not more than a total of 8 sprays for adults (4 for children) should be given in any 24 hours.

Do not exceed the stated dose.

Afrin should not be used for longer than 7 days unless prescribed by your doctor. An interval of several days should elapse before re-administration of the product.

#### *Administration*

Shake well before use. Before first use, prime the unit by depressing the pump several times until the first full spray is achieved.

Whilst holding upright the spray nozzle should be inserted into each nostril in turn and squeezed firmly one or two times whilst breathing in.

After use wipe nozzle clean. Use of this product by more than one person may spread infection.

#### **If you use more Afrin than you should**

If you use more Afrin than you should, you should contact your doctor or go to a hospital immediately and take the bottle with you.

#### **If you forget to use Afrin**

Do not take a double dose to make up for a forgotten dose.

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

### **4. Possible side effects**

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

Possible side effects are:

**Uncommon** (occurring in less than 1 in 100 people), sneezing, dryness or irritation in the nose, mouth or throat and blocked nose.

**Rare** (occurring in less than 1 in 1000 people), anxiety, fatigue, irritability, disturbed sleep in children, rapid heart beat, palpitations, raised blood pressure, , swelling of the nasal lining, headache, nausea, flushing, rash and visual disturbances.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Afrin**

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. Do not refrigerate or freeze.
- Do not use this medicine after the expiry date which is stated on the bottle after Exp: The expiry date refers to the last day of that month.
- Use within 30 days of first opening.
- 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 to protect the environment.

### **6. Contents of the pack and other information**

#### **What Afrin contains**

##### **Afrin**

- The active substance is oxymetazoline HCl 0.5 mg/ml
- The other ingredients are disodium edetate, disodium phosphate anhydrous, sodium phosphate monobasic monohydrate, povidone K29-32, benzalkonium chloride, PEG 1450, purified water,

benzyl alcohol, microcrystalline cellulose and carmellose sodium, lemon flavour, including natural and artificial flavours, alcohol and DL-alpha tocopherol.

#### **Afrin Menthol**

- The active substance is oxymetazoline HCl 0.5 mg/ml
- The other ingredients are disodium edetate, disodium phosphate anhydrous, sodium phosphate monobasic monohydrate, povidone K29-32, benzalkonium chloride, PEG 1450, propylene glycol, purified water, benzyl alcohol, microcrystalline cellulose and carmellose sodium, cineole, camphor, levomenthol.

#### **Afrin Glycerol**

- The active substance is oxymetazoline HCl 0.5 mg/ml
- The other ingredients are disodium edetate, disodium phosphate anhydrous, sodium phosphate monobasic monohydrate, povidone K29-32, benzalkonium chloride, PEG 1450, purified water, benzyl alcohol, microcrystalline cellulose and carmellose sodium, glycerol, lemon flavour, including natural and artificial flavours, alcohol and DL-alpha tocopherol.

#### **Afrin Chamomile**

- The active substance is oxymetazoline HCl 0.5 mg/ml
- The other ingredients are disodium edetate, disodium phosphate anhydrous, sodium phosphate monobasic monohydrate, povidone K29-32, benzalkonium chloride, PEG 1450, purified water, benzyl alcohol, microcrystalline cellulose and carmellose sodium, glycerol, chamomile flavour, including natural and artificial flavours, propylene glycol and corn syrup.

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

Afrin is a white to off white gel like solution in a white light-resistant 15 ml high density plastic bottle with a white plastic pump.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorization Holder:  
[To be completed nationally]

Manufacturer:  
Berlimed S.A., C/Francisco Alonso no.7, Poligono Industrial Santa Rosa Alcalá de Henares;  
28806 Madrid; Spain

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

AFRIN: Czech Republic, Estonia, Latvia, Lithuania, Netherlands, Slovakia, Slovenia, Spain, Romania

AFRIN Comfort: Hungary

AFRIN ND: Bulgaria, Poland

NASAROX: Portugal

Rhinacept: Greece

**This leaflet was last revised in {MM/YYYY}.**