

## **Information for the Patient**

Read carefully this package leaflet. It contains all important information on this drug. This drug was prescribed to you by your doctor or given to you without prescription by the pharmacist.

In order to obtain the best benefit, please use it following the leaflet or the indications of the doctor or pharmacist.

Keep this packing leaflet in order to read it again later if necessary.

### **What is Triofan and when is it used?**

Triofan is a local medication against cold promoting decongestion of the nasal mucous membranes by decreasing and liquefying nasal secretions. It so clears the upper respiratory pathways. Triofan is used treating congestive states of the nasal mucous membranes to free the nose in case of colds.

Following advice by a doctor or a pharmacist, it can also be applied in case of rhinitis, sinusitis, inflammation of the respiratory pathways, for example caused by an operative procedure. Triofan for infants and babies is to be used by infants only if advised by a doctor or a pharmacist. Triofan is available as drops and as a spray which does not contain a propellant gas (ensures that a precise dosage and a good distribution is achieved).

### **When is Triofan not to be used?**

If you underwent a surgery around the head/face area, the doctor will have to decide if you can use Triofan. This restriction is valid for all vasoconstrictors used in the nose.

Triofan is not to be used in case of

- hypersensitivity to its ingredients,
- dry nasal mucous membranes (rhinitis sicca),
- closed-angle glaucoma.

Do not use the drops or spray for adults for children under 6 years.

### **What are the precautions to observe when using Triofan?**

Triofan must not be used for more than 5 to 7 days without medical advice. A prolonged use can cause a drug-induced congestion of the nasal mucous membranes, whose symptoms are very close to those of a cold. Triofan is to be used with caution by patients suffering from hypertension, cardiovascular diseases, hyperthyroidism and diabetes mellitus.

As with other products against cold, Triofan can very rarely cause transient general effects (such as sleeping disorders, disturbed vision or dizziness), revealing an excessive sensitivity to one of the active ingredients.

You should inform your doctor or your pharmacist if you are suffering from other diseases, have any allergies or are taking or using other drugs (including as self medication!).

### **May Triofan be used during pregnancy and breast-feeding?**

Before using Triofan during pregnancy and breast-feeding, please take the advice of your doctor.

### **How to use Triofan?**

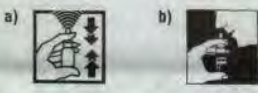
If not otherwise prescribed by your doctor:

**Adults and children from 6 years:** 3-4 times daily into each nostril, insert 2-3 drops of the nasal drops for adults and children or 1 squeeze with the nasal spray for adults and children.

**Children up to 6 years:** 2-3 times daily into each nostril, insert 1-2 drops of the nasal drops for infants and babies or 1 squeeze with the nasal spray for infants and babies.

**Babies:** 1-2 times daily into each nostril, insert 1 drop of the nasal drops for infants and babies or 1 squeeze with the nasal spray for infants and babies.

## Instructions for using the dosing bottle (spray)



Remove the protective cap. **Before the first use, the spray should be activated by priming the pump.** The bottle is then ready for subsequent administrations (a). During the application (b), the bottle should be held in an upright (vertical) position. Introduce the spray nozzle into the nostril and squeeze firmly once. Then remove the spray nozzle before releasing the pressure.

**Dosing spray:** to promote proper distribution of the mist, gently breathe in through your nose during the application.

**Dosing spray for infants and babies:** make sure the infant is seated when the medication is administered (do not give the medicine while the child is lying down).

Replace the protective cap after each use.

Keep to the dosage indicated in the package insert or that prescribed by your doctor.

Should you take a significant overdose, consult your physician.

If you think the effect of the drug is too weak or too strong, you should speak to your doctor or your pharmacist.

### What side effects can be caused by Triofan?

Following side effects can be caused by the use of Triofan: prickling or a transient burning of the nose or in the throat, as well as local irritation or a dryness of the nasal mucous membranes. Nausea, headaches and allergic reactions (skin rash, rare anaphylactic reactions) have been occasionally observed. If you note side effects not described in this leaflet, please inform your doctor or pharmacist.

### What else must be taken into account?

Keep Triofan at room temperature (15-25°C) and out of the reach of children. The drug must not be used after the date indicated with «EXP» on the container.

For further information, consult your doctor or pharmacist (they have detailed data at their disposal).

### What is contained in Triofan?

1 ml of the drops or spray or 1 g of gel contains as active ingredients xylometazoline hydrochloride (adults: 1.0 mg; infants: 0.5 mg) and carbocisteine (adults: 10.0 mg; infants: 5.0 mg). As antiseptic preservatives, Triofan also contains benzalkonium chloride and benzyl alcohol.

*1 drop of the solution for adults and children contains 25 µg xylometazoline hydrochloride and 250 µg carbocisteine.*

*1 drop of the solution for infants and babies contains 12.5 µg xylometazoline hydrochloride and 125 µg carbocisteine.*

*1 squeeze of the spray for adults and children contains 90 µg xylometazoline hydrochloride and 900 µg carbocisteine.*

*1 squeeze of the spray for infants and babies contains 25 µg xylometazoline hydrochloride and 250 µg carbocisteine.*

### Authorisation number (Switzerland)

46620, 46621 (Swissmedic)

### Where do you obtain Triofan? What pack sizes are available?

Available in pharmacies and drugstores without a medical prescription:

– *Dosing spray for adults and children from 6 years: 10 ml bottles.*

– *Nasal drops for adults and children from 6 years: 10 ml bottles.*

Available in pharmacies without a medical prescription:

– *Dosing spray for infants and babies up to 6 years: 10 ml bottles*

– *Nasal drops for infants and babies up to 6 years: 10 ml bottles.*

### Authorisation Holder (Switzerland)

#### and Manufacturer

Vifor SA, Villars-sur-Glâne (Switzerland)

This package insert was checked lastly by the drug regulatory authority (Swissmedic) in May 2011.

Vifor

103734/05