PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription

Alrin® for Babies

Salt Solution Nasal drops/Metered dose nasal spray

nposition:

Composition: Sodium chloride 0.74% w/v

For the list of inactive ingredients in the preparation, se section 6 – "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

You must use the medicine in the correct manner. Consult a pharmacist if you need further information. Refer to the doctor if the symptoms worsen or do not improve after 3 days.

1. WHAT IS THE MEDICINE INTENDED FOR:

The medicine is intended for the relief of nasal congestion, particularly in infants. BEFORE USING THE MEDICINE

Special warnings regarding use of the medicine Before treatment with Alrin® for Babies Salt Solution, tell the doctor if:

- You or your child are suffering, or have suffered in the past, from impaired function of the liver, the heart and/or blood vessels, hypertension.
 You are sensitive to any food or medicine.
 Do not use this medicine frequently or for a prolonged period without consulting the doctor.
- Do not use this medicine if the solution has become discolored or becomes cloudy.

Hif you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Important info of the medicine ome of the ingredients

This preparation contains benzalkonium chloride, which may cause irritation of the nasal mucosa.

Pregnancy and breastfeeding
This medicine can be used during pregnancy or when This medicine breastfeeding.

HOW SHOULD YOU USE THE MEDICINE? neck with the doctor or pharmacist if

Check with the uncertain. you are

The usual dosage is generally:
Drops: 2 drops in each nostril, up to 4 times a day.
Spray: 1-2 sprays in each nostril, 3-4 times a day.
Refer to the doctor if there is no improvement in the condition within 3 days.

Do not exceed the recommended dose

Directions for using the preparation:<u>Attention!</u> Do not swallow! This medicine is intended for external use only.

Nasal drops:

Remove the bottle cover. Blow the child's nose gently. Tilt the child's head back or lie him down on a bed. Instill the drops into each nostril and keep the child's head tilted back for a few minutes, to allow the medicine to spread throughout the nose.

Nasal sprav: Nasai spray:

Remove the bottle cover. Before the first use, press on the pump a few times until spray comes out.

Blow the child's nose gently. With the child's head upright, spray the preparation into each nostril while simultaneously blocking the other nostril with a finger. If possible, it is recommended to breathe in short inhalations while rapidly and sharply squeezing the bottle.

The number of squeezes will be according to the recommended dosage. Wait 3-5 minutes and gently blow the nose again. Rinse the tip of the spray bottle with hot water, taking care not to let water into the bottle. Dry with a clean paper tissue and close tightly.

To avoid spreading of infection, do not use the same bottle for more than one child. If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine on time, do not take a double dose; rather, take the next dose at the regular time and consult the doctor. Never take two doses together to compensate for a forgotten dose.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

SIDE EFFECTS:

As with any medicine, use of Alrin® for Babies Salt Solution may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

In addition to the desired effect of the medicine, side effects such as: temporary nasal irritation or burning may occur when using it.

Stop treatment and refer to the doctor as soon as possible if any of the following effects occur:

Hypertension
Rash or local inflammation that did not exist before using the preparation (rare)

the preparation to the preparation to the preparation to the saide effect occurs, if any or if you are suffering from a sansult the doctor if any of the side effects worsen,

or it you are suffering from a side effect not mentioned in the leaflet, consult the doctor. Parent must inform the attending doctor of all side effects as well as any other medicine being given to the child. Side effects can be reported to the distry of Health via the online form at the following link: http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il

- HOW SHOULD THE MEDICINE BE STORED?

 Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants. Do not induce vomiting without explicit instruction from the doctor.
- e preparation for up to one month from first Use the opening.

- Do not start using the preparation after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Store this preparation below 25°C. Do not discard medicines in the waste water or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment. waste

FURTHER INFORMATION

n addition to the active ingredient, Alrin[®] for alt Solution also contains:

Benzalkonium chloride 50% sol., dibasic sodium chosphate dihydrate, edetate disodium, hydrogenatec astor oil, monobasic sodium phosphate monohydrate purified water. Benzalkonium sodium

What the medicine looks like and the contents of the package: package:
The medicine is provided as a spray or drops. Manufacturer and license holder and addre

Ltd., Teva Pharmaceutical Industries Petach Tikva P.O.B.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132-50-31095 This leaflet was chec Health on 31.5.2015. ecked and approved by the Ministry of

3190.