Please read this leaflet carefully before you start to take this medicine, even if you have just refilled the prescription or used this medicine before. Some of the information in the previous leaflet may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

NAZENE ADULT NASAL METERED SPRAY

1. WHAT DOES NAZENE ADULT NASAL METERED SPRAY CONTAIN:

Each 1 ml of solution contains:

Oxymetazoline hydrochloride 0,50 mg

Preservative:

Benzalkonium chloride 0,010 % m/v

This preparation also contains: disodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate (or monobasic sodium phosphate anhydrous), sodium chloride and sodium hydroxide or hydrochloric acid.

2. WHAT IS NAZENE ADULT NASAL METERED SPRAY USED FOR:

NAZENE ADULT NASAL METERED SPRAY is indicated for the temporary relief of a blocked nose due to hypersensitivity of the nasal mucous membranes, the common cold and hayfever. It is also indicated in other upper respiratory allergies and for the relief of blocked sinuses.

3. BEFORE USING NAZENE ADULT NASAL METERED SPRAY:

NAZENE ADULT NASAL METERED SPRAY should not be used if you are hypersensitive to any of the stated ingredients. It is not advisable to use NAZENE ADULT NASAL METERED SPRAY should the patient be using monoamine oxidase inhibitor treatment (a type of antidepressant), or has terminated

such treatment within the last 14 days. The safety of this medicine in pregnancy and lactation has not been established. The use of NAZENE ADULT NASAL METERED SPRAY is considered unsafe in porphyric patients (porphyria is an inherited disorder of blood pigment metabolism). NAZENE ADULT NASAL METERED SPRAY should not be used in children under 6 years of age.

Warnings and Precautions to be followed:

Do not use this medicine for more than 5 days without consulting your doctor. If the symptoms persist, consult a doctor. To reduce the chance of spreading infection, more than one person should not use the container. Children may be especially prone to the effects of these medicines, if the body absorbs the medicine. NAZENE ADULT NASAL METERED SPRAY should be used with care in patients with the following: cardiovascular disease such as cardiac disease, hypertension or angina, coronary artery disease, diabetes mellitus, enlarged prostate, narrow angle, glaucoma, hyperthyroidism, rhinitis, sicca. Prolonged use of these products may result in the medicines being less effective.

Interactions:

Certain medication such as tricyclic antidepressants, maprotiline or monamine oxidase inhibitors agents may cause interactions with NAZENE ADULT NASAL METERED SPRAY.

If your child is taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

5. HOW TO USE NAZENE ADULT NASAL METERED SPRAY:

For adults and children over 6 years of age:

Two to three sprays in each nostril in the morning and evening – or if necessary at 8 to 12 hour intervals.

Place the tip of the pump nozzle into one nostril, but do not completely occlude the nostril. While bending the head slightly forward, squeeze the pump spray two to three times and sniff simultaneously to ensure even distribution of the spray. Withdraw the nozzle from the nostril and repeat for the other nostril.

Do not exceed the recommended dosage or use continuously for longer than 5 days. Do not share medicines prescribed for you with others. Not recommended for children under 6 years of age.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

An overdosage may cause local stinging or burning of nasal mucosa, increase in nasal discharge, sneezing, dryness of mouth and throat and sweating as well as a severe increase in blood pressure.

6. SIDE-EFFECTS:

These include local stinging or burning of nasal mucosa, increase in nasal discharge, sneezing and dryness of mouth and throat.

Other side-effects that can occur are: blurred vision; fast, irregular, or pounding heartbeat; headache, dizziness, drowsiness, or lightheadedness; high blood pressure; nervousness; trembling; trouble in sleeping; weakness.

Not all side-effects reported for this medicine are included in this leaflet. Should you, or your child's general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional.

7. STORING AND DISPOSAL INFORMATION:

Store upright, at or below 25 ^{o}C. Protect from light. Keep tightly closed.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

8. PRESENTATION

A 20 ml white plastic bottle, containing 10 ml solution, with a white plastic screw-on spray pump closure.

9. IDENTIFICATION:

A clear, colourless solution, free from visible particulate matter and with a maximum of a faint odour.

10. REGISTRATION NUMBER:

A39/16.1/0211

11. NAME AND ADDRESS OF REGISTRATION HOLDER:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

11. DATE OF PUBLICATION

Registration date: 07/07/2006

Revision date: 20 November 2013

12. THE MANNER IN WHICH THE CORRESPONDING PROFESSIONAL INFORMATION MAY BE OBTAINED

The PI is included in the medicine package