

**SCHEDULING STATUS:** S2

**MOMETASONE NS KIARA** (Aqueous nasal spray 0,05 % w/w)

Mometasone furoate

Sugar free

**Read all of this leaflet carefully because it contains important information for you**

MOMETASONE NS KIARA is available without a doctor's prescription, for you to treat a mild condition. Nevertheless, you still need to use MOMETASONE NS KIARA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MOMETASONE NS KIARA with any other person
- Ask your healthcare provider or pharmacist if you need more information of advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

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

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

### **1. What MOMETASONE NS KIARA is and what it is used for**

MOMETASONE NS KIARA contains mometasone furoate, one of a group of medicines called corticosteroids. When MOMETASONE NS KIARA is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked or runny nose.

MOMETASONE NS KIARA is used in adults, adolescents, and children between the ages of 2 and 11 years to treat the symptoms of hay fever (also called seasonal allergic rhinitis) and also over the long term for a blocked or runny nose throughout the year (perennial allergic rhinitis).

If you normally suffer badly from hay fever, your doctor may tell you to start using MOMETASONE NS KIARA two to four weeks before the start of the pollen season, as this will help to prevent your hay fever symptoms from occurring.

Hay fever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen (from trees, grasses, weeds) and also moulds and fungal spores.

Perennial allergic rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including dust mites, animal hair, feathers, and certain foods.

## **2. What you need to know before you use MOMETASONE NS KIARA**

### **Do not use MOMETASONE NS KIARA:**

- if you are hypersensitive (allergic) to mometasone furoate, or to any of the ingredients of MOMETASONE NS KIARA (see section 6).
- if you are pregnant or breastfeeding your baby.
- in children under 2 years, as its safety has not been established in this age group.

## Warnings and precautions

### Take special care with MOMETASONE NS KIARA:

MOMETASONE NS KIARA should not be used:

- if you have an infection in your nose that is not being treated.
- if you have recently had an operation on your nose or have injured your nose.

You should wait until your nose has healed before starting treatment with MOMETASONE NS KIARA.

If you have any of the following conditions before starting treatment with MOMETASONE NS KIARA, or develop any of them during treatment, your doctor may need to either reduce your dose of MOMETASONE NS KIARA or you may need extra treatment to control them.

Once advised, your doctor will decide whether any change in your treatment is needed. In some cases, it may be necessary to stop the treatment.

- If you develop a nose injury.
- If you have tuberculosis.
- If you have any other infection (fungal, bacterial, or viral).
- If you have herpes simplex (virus) infection of the eye.
- If your immune system is not functioning well (if you have difficulty in fighting infection) and you come into contact with anyone with measles or chickenpox. You should avoid coming into contact with anyone who have these infections.
- If f you have an infection of the nose or throat.
- If you have been using the medicine for several months or longer.
- If you are taking other corticosteroid medicines, either by mouth or by injection your doctor may advise you to stop taking them once you begin using MOMETASONE NS KIARA.

- If you have persistent irritation to the nose or throat as your doctor may need to discontinue your treatment.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to absorption of the corticosteroid, such as mometasone, by the body. Side effects may include weight gain, increased fat at the base of the neck, puffy face, eye and vision disorders, growth retardation in children, hyperactivity, depression or aggression (especially in children) and sleep disorders.

If your eyes are itching/irritated or your eyesight is blurred, your doctor may recommend that you use other treatments with MOMETASONE NS KIARA. Contact your doctor if you experience blurred vision or other visual disturbances.

When changing from an oral or injectable corticosteroid to MOMETASONE NS KIARA, some people may find that they suffer from some side effects such as joint and/or muscle pain, weakness, and depression. Other allergies, such as itchy, watering eyes, blurred vision or patches of red and itchy skin may develop. If any of these side effects occur, you should contact your doctor who will advise about the continued use of MOMETASONE NS KIARA.

**Children:**

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side effects, such as a slowed growth rate in children.

It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if there is concern about slow growth, their doctor should be notified.

## **Other medicines and MOMETASONE NS KIARA**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

If you are taking other antihistamines or corticosteroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using MOMETASONE NS KIARA.

Some medicines may increase the effects of MOMETASONE NS KIARA and your doctor may wish to monitor you carefully, especially if you are taking such medicines (including some medicines for HIV, e.g., ritonavir, cobicistat).

## **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare professional for advice before using MOMETASONE NS KIARA.

You should not use MOMETASONE NS KIARA if you are pregnant or breastfeeding your baby. It is not known if mometasone furoate is found in breast milk.

## **Driving and using machines:**

MOMETASONE NS KIARA may make you feel dizzy. If MOMETASONE NS KIARA affects you in this way, do not drive, operate machinery, or do anything that requires you to be alert.

It is not always possible to predict to what extent MOMETASONE NS KIARA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the

above activities until they are aware of the measure to which MOMETASONE NS KIARA affects them.

### **MOMETASONE NS KIARA contains benzalkonium chloride**

MOMETASONE NS KIARA contains benzalkonium chloride which may cause nasal irritation.

### **3. How to use MOMETASONE NS KIARA**

Do not share medicines prescribed for you with any other person. Always use MOMETASONE NS KIARA exactly as described in this leaflet or as your doctor, pharmacist or nurse told you. Check with your doctor, pharmacist, or nurse if you are not sure.

The usual dose is:

*Adults (including the elderly) and children over 12 years of age:*

The usual dose is two sprays of MOMETASONE NS KIARA into each nostril once a day.

Once your symptoms are under control, your doctor may advise you to decrease your dose.

If you do not start to feel better, you should see your doctor who may tell you to increase your dose up to a maximum of four sprays into each nostril once a day. Once your symptoms are controlled, your doctor may reduce your dose back to two sprays into each nostril once a day.

*Children between the ages of 2 and 11 years:*

The usual recommended dose is 1 spray into each nostril once daily.

Administration to young children should be aided by an adult.

Your doctor will tell you how long your treatment with MOMETASONE NS KIARA will last. Do not stop treatment early because your hay fever symptoms may return.

If you have the impression that the effect of MOMETASONE NS KIARA is too strong or too weak, tell your doctor or pharmacist.

### **Preparing MOMETASONE NS KIARA for use:**

If you are using MOMETASONE NS KIARA for the first time, you need to 'prime' the bottle, by pumping the spray 10 times until a fine mist is produced.

1. Gently shake the bottle, then remove the dust cap.
2. Place your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle.
3. Point the nozzle away from you and then press down with your fingers to pump the spray.

If you have not used MOMETASONE NS KIARA for more than 14 days, you need to 're-prime' the bottle by pumping the spray 2 times until a fine mist is produced. If you use MOMETASONE NS KIARA regularly, you do not need to 're-prime' it.

Shake the bottle well before each use.

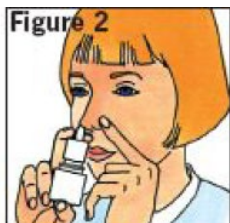
### **How to use your nasal spray:**

1. Shake the bottle gently and remove the dust cap (Figure 1).



2. Gently blow your nose.

3. Close one nostril and put the nozzle into the other nostril (Figure 2). Tilt your head slightly forward, keeping the bottle upright.



4. Start to breathe in through your nose, and at the same time press down with your fingers once to spray a fine mist into your nose.
5. Breathe out through your mouth. Repeat steps 4 and 5 if your doctor has told you to spray more than once into each nostril.
6. Repeat steps 3, 4 and 5 for the other nostril (Figure 3).
7. After using the spray, wipe the nozzle carefully with a clean cloth and replace the dust cap.



### **How to clean MOMETASONE NS KIARA:**

It is important to clean your nasal spray at least once a week, to ensure it works properly.

1. Remove the dust cap and gently pull off the nozzle.
2. Wash the nozzle and dust cap in warm water. Shake off excess water and leave to dry in a warm place.
3. When dry, replace the nozzle and the dust cap.

If the nozzle becomes blocked, remove as above and soak in warm water. Rinse under a cold tap, allow to dry and re-fit. Do not use a pin or other sharp object to unblock the nozzle as this may cause damage.



The spray will need to be 're-primed' with 2 sprays when first used after cleaning.

The bottle should be discarded after the labelled number of actuations or within 2 months of first use.

**If you use more MOMETASONE NS KIARA than you should:**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Possible consequences of overdose:

- It may very rarely affect your hormones.
- In children, overdose may affect growth and development.

**If you forget to use MOMETASONE NS KIARA:**

If you forget to use MOMETASONE NS KIARA, use a dose as soon as you remember, then continue to use MOMETASONE NS KIARA at the usual times. Do not use a double dose to make up for a forgotten dose.

**If you stop using MOMETASONE NS KIARA**

Even if you feel better, do not alter or discontinue the daily dose of MOMETASONE NS KIARA without first consulting your doctor as your hay fever symptoms may return.

**4. Possible side effects**

MOMETASONE NS KIARA can have side effects.

Not all side effects reported for MOMETASONE NS KIARA are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using MOMETASONE NS KIARA, please consult your healthcare provider for advice.

If any of the following happens, stop using MOMETASONE NS KIARA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MOMETASONE NS KIARA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- increase in pressure behind the eyes (glaucoma) causing visual disturbances.
- damage to the part of the nose which separates the nostrils (septum).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- respiratory tract infection – sore throat (pharyngitis).
- nose bleeds, burning sensation in the nose, nose irritation, or nose ulcers.
- headache.

Less frequent side effects:

- dizziness.
- conjunctivitis (pink eye), dry eyes.

- cough, itchy nose, sneezing.
- changes in taste and smell, nausea.

The following side effects have been reported but the frequency at which they occur is not known:

- cataracts causing visual disturbances.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get 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 to SAHPRA via the “**6.04 Adverse Drug Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MOMETASONE NS KIARA.

### **5. How to store MOMETASONE NS KIARA**

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

Use within 2 months of opening.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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

### **What MOMETASONE NS KIARA contains**

The active substance is mometasone furoate.

Each 100 mg actuation contains mometasone furoate monohydrate, equivalent to 50 µg mometasone furoate.

### **The other ingredients are:**

Benzalkonium chloride, citric acid monohydrate, glycerol, microcrystalline cellulose, carboxyl methyl cellulose sodium, polysorbate 80, purified water and sodium citrate dihydrate.

### **What MOMETASONE NS KIARA looks like and contents of the pack**

MOMETASONE NS KIARA is a white homogeneous aqueous suspension.

MOMETASONE NS KIARA is packed into a 26 ml white HDPE bottle with a crimped, metered dose micro pump, nasal adaptor and transparent dust protective cap. Each bottle contains 140 actuations and is packed in an outer carton together with a leaflet.

### **Holder of Certificate of Registration**

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**Access to the corresponding Patient Information**

To access the corresponding Professional Information, scan the QR code below (SAHPRA Online OTC Directory) or email [customercare@kiarahealth.com](mailto:customercare@kiarahealth.com).

