

Momate™ Nasal Spray

Mometasone Furoate 50 mcg/ Spray

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

1. What MOMATE is used for
2. How MOMATE works
3. Before you use MOMATE
4. How to use MOMATE
5. While you are using it
6. Side Effects
7. Storage and Disposal of MOMATE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

WHAT IS MOMATE AND WHAT IS IT USED FOR?

MOMATE contains mometasone furoate, one of a group of medicines called corticosteroids. Momate is used in adults, adolescents and children between the ages of 3 and 11 years to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis. In adults and adolescents aged 18 and over, MOMATE is also used to treat nasal polyps. In patients aged 12 and over without signs or symptoms of severe bacterial infection, MOMATE is used to treat acute rhinosinusitis.

What is hayfever and perennial rhinitis?

Hayfever, 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 rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods. These allergies cause a runny nose and sneezing, and make the lining of the nose swell, causing a stuffy blocked-up feeling. Momate reduces the swelling and irritation in your nose and so relieves sneezing, itching and blocked-up or runny nose.

What are nasal polyps?

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. Momate Nasal Spray reduces the inflammation in the nose, causing the polyps to gradually shrink, thereby relieving a blocked feeling in the nose

which may affect breathing through the nose. Watering from the nose, a feeling of something running down the back of the throat and loss of taste and smell may also occur. MOMATE reduces the inflammation in the nose, causing the polyps to gradually shrink.

What is Rhinosinusitis?

Rhinosinusitis is the inflammation and blockage of the sinuses behind the nose. Symptoms can include a stuffy or runny nose, feeling of something running down the back of the throat; and facial pressure or pain. MOMATE relieves these symptoms by reducing the inflammation in the nose in patient with adequate rhinosinusitis, without signs and symptoms of severe bacterial infection.

HOW MOMATE WORKS

When tiny amounts of mometasone furoate are sprayed into the nose, it can help to relieve inflammation, sneezing, itching and blocked up or runny nose.

BEFORE YOU USE MOMATE

When you must not use it

- If you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine
- If you have an infection in your nose. You should wait until the infection is resolved before you start using the nasal spray.

- If you have bleeding tendency or recurring nose bleeds

- If you have recently had an operation on your nose or you have injured your nose. You should wait until it has healed before you start using the nasal spray

Before you start to use it: Tell your doctor or pharmacist any medical problems, such as

- if you have or have ever had tuberculosis.
- If you have herpes simplex (virus) infection of the eye
- if you have any other infection
- if you are taking other corticosteroid medicines, either by mouth or by injection.
- If you had recent nasal surgery or trauma

Discuss them with doctor before taking MOMATE.

If you are taking other corticosteroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using MOMATE. A few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, weakness and depression. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects and you are worried, you should see your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including that you

buy without a prescription from a pharmacy, supermarket or health food shop.

Pregnancy and breast-feeding

You should not use MOMATE if you are pregnant unless your doctor has told you to. Tell your doctor if you are pregnant before you start using this medicine. You should not breast feed when you are using this medicine unless your doctor has told you to.

HOW TO USE MOMATE?

How much to use

Always use MOMATE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not use a larger dose or use the spray more often or for longer than your doctor tells you to.

a) Hayfever and Perennial Rhinitis

Adults and children over 12 years old:

The usual dose is two sprays into each nostril once a day for adults (including the elderly) and adolescents over the age of 12 years.

- Once your symptoms are under control, your doctor may advise you to decrease the dose.
- If you do not start to feel any better, you should see your doctor and he or she may tell you to increase the dose to the maximum daily dose of four sprays into each nostril once a day. Once your symptoms are controlled your doctor may advise you to reduce the dose.

Children aged 3 to 11 years:

The usual dose is one spray into each nostril once daily.

Long term use of nasal steroids at high doses may cause slowing of growth in children. Your doctor may check your child's height at intervals during treatment and reduce the dose if any effects are seen.

If you suffer badly from hayfever, your doctor may tell you to start using MOMATE two to four weeks before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring. At the end of pollen season your hayfever should get better and treatment may then not be needed.

b) Nasal Polyps:

The usual dose for adults and adolescents aged 18 and over is two sprays into each nostril twice daily.

- Once symptoms are under control, your doctor should ask you to decrease your dose to two sprays into each nostril once daily.

c) Acute Rhinosinusitis:

The usual dose for adults and adolescents aged 12 and over is two sprays into each nostril twice daily.

- If symptoms get worsen during treatment or no improvement seen after 15 days, you should contact your doctor.

When to use it

Use as directed by your doctor or pharmacist

How long to use it

Do not use the spray for longer than your doctor tells you to.

How should I use MOMATE?

i) Preparing your nasal spray for use

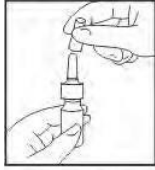
Your Momate Nasal Spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use.

If you are using the spray 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.
2. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle. **DO NOT PIERCE THE NASAL APPLICATOR.**
3. Point the nozzle away from you and then press down with your fingers to pump the spray. If you have not used the spray for 7 days or more, you need to "re-prime" the bottle by pumping the spray 2 times or until a fine mist is produced, before next use.

ii) How to use your nasal spray

1. Remove the plastic cap (Figure 1).



(Figure 1)

2. Before you use *Momate Nasal Spray* for the first time prime the pump by pressing downward on the shoulders of the white nasal applicator using your index finger and middle finger while holding the base of the bottle with your thumb (Figure 2). Do not pierce the nasal applicator. Press down and release the pump 10 times or until a fine spray appears. Do not spray into eyes. The pump is now ready to use. The pump may be stored unused for upto 1 week without repriming. If unused for more than 1 week, reprime by spraying 2 times or until a fine spray appears.



(Figure 2)

3. Gently blow your nose to clear the nostrils. Close 1 nostril. Tilt your head forward slightly, keep the bottle upright, and carefully insert the nasal applicator into the other nostril (Figure 3). Do not spray directly onto the nasal septum (the wall between the two nostrils.)



(Figure 3)

4. Then breath out through the mouth.
5. Repeat in the other nostril.
6. Wipe the nasal applicator with a clean tissue and replace the plastic cap (Figure 4).

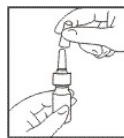


(Figure 4)

iii) Cleaning your nasal spray

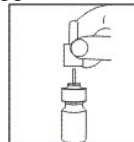
It is important to clean your nasal spray regularly; otherwise it may not work properly.

1. To clean the nasal applicator, remove the plastic cap (Figure 1).



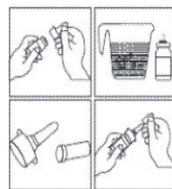
(Figure 1)

2. Pull gently upward on the white nasal applicator to remove (Figure 2).



(Figure 2)

3. Soak the Nozzle and Dust Cap in **warm water for few minutes** and then rinse thoroughly spray tip and dust cap in **warm water** and finally rinse under clean running water. Repeat the procedure if the mist is not coming out.

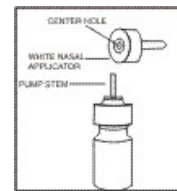


(Figure 3)

Note:

Incase during usage for the first time if the actuator is observed to be blocked condition due to accidental pressing during transit or during handling which prompts release of miniscule contents, never use a pin or any sharp objects to pierce to unblock the nozzle instead subject the actuator for cleaning.

4. Put the nasal applicator back together making sure the pump stem is reinserted into the applicator's center hole (Figure 4).



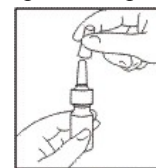
(Figure 4)

5. Reprime the pump by pressing downward on the shoulders of the white nasal applicator using your index and middle fingers while holding the base of the bottle with your thumb. Press down and release the pump 2 times or until a fine spray appears. Do not spray into eyes. The pump is now ready to use. The pump may be stored unused for upto 1 week without repriming. If unused for more than 1 week, reprime by spraying 2 times or until a fine spray appears (Figure 5).



(Figure 5)

6. Replace the plastic cap (Figure 6).



(Figure 6)

If you forget to use it

If you forget to use your nasal spray at the right time, use it as soon as you remember, then carry on as before. Do not take a double dose to make up

for a forgotten dose.

If you use too much (overdose)

Tell your doctor if you accidentally use more than you were told.

If you use steroids for a long time or in large amounts they may, rarely, affect some of your hormones. In children this may affect growth and development.

If you stop using MOMATE

In some patients MOMATE should begin to relieve symptoms 12 hours after the first dose. It is very important that you use your nasal spray regularly. Do not stop your treatment even if you feel better unless told to do so by your doctor.

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

WHILE YOU ARE USING MOMATE

See '*How much to use, When to use it, How long to use it*' Things you must do

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you plan to have or have had a recent nasal surgery or trauma.

Things you must not do

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

MOMATE is for intranasal use only. Avoid getting it into your eyes. Do not use it to treat anything other than the condition for which it was prescribed.

Things to be careful of

While using MOMATE, avoid coming into contact with anyone who has measles or chickenpox. You should tell your doctor if you do come into contact with anyone who is suffering from these interactions.

POSSIBLE SIDE EFFECTS

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

Rarely, immediate hypersensitivity (allergic) reactions may occur after use of this product. Very rarely, these reactions may be severe. If you have any wheezing or have trouble breathing, get immediate medical help.

In very rare cases, treatment with corticosteroid nasal sprays like MOMATE has led to an increase in pressure in the eye (glaucoma), causing visual disturbances and damage to the partition in the nose which separates the nostrils. Contact your doctor if you notice any of these side effects.

Other side effects

Most people do not have any problems after using the nasal spray. However, some people, after using mometasone furoate or other corticosteroid nasal sprays may find that they suffer from:

- headache
- sneezing
- nose bleeds
- sore nose or throat
- alterations in taste or smell which may occur very rarely

Children

When used at high doses for long periods of time, corticosteroids nasal sprays may cause certain side effects, such as growth reduction in children. It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by

visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

HOW TO STORE MOMATE?

Keep this medicine out of reach of children. Store below 30°C, Do not Freeze.

Protect from light, Shake well before use.

Do not use this medicine after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

PRODUCT INFORMATION

What Momate contains:

Composition

Mometasone Furoate Monohydrate equivalent to Mometasone Furoate 0.05% w/w
Each spray delivers: Mometasone Furoate monohydrate equivalent to Mometasone Furoate 50 mcg
Preservative: Benzalkonium Chloride BP 0.02% w/w
Excipients q.s

Inactive ingredients:

Microcrystalline Cellulose and Carmellose Sodium BP Glycerol BP Citric Acid Monohydrate BP Sodium Citrate BP Polysorbate 80 BP Benzalkonium Chloride BP Water for injections BP

What Momate looks like and contents of the pack:

White to off white translucent thick suspension filled in a off white opaque HDPE Bottle crimped with Nasal Spray Pumps and fitted with an actuator and Cap

MAL15015062AZ

Product Registration Holder :

Glenmark Pharmaceuticals
(Malaysia) Sdn Bhd (660397-W)
D-31-02, Menara Suezcap 1, No. 2,
Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

Manufacturer:

Glenmark Pharmaceuticals Ltd
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai Road,
Mumbai – 400 026, (INDIA).
At: (Unit III) Village Kishanpura
Baddi – Nalagarh Road, Tehsil
Baddi, Dist Solan .(H.P.) -173 205.\

TMTrade Mark

Date of Revision: 07.07.2023

NPRA(R2/2)230503/1058