

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Nasonex® 50 micrograms/actuation
Nasal Spray, Suspension
(mometasone furoate)**

Please read this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT NASONEX IS AND WHAT IT IS USED FOR

What is Nasonex?

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

What is Nasonex used for?

Hayfever and perennial rhinitis

Nasonex is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 3 and older.

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. Nasonex reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial rhinitis.

Nasal polyps

Nasonex is used to treat nasal polyps in adults aged 18 and over.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. Nasonex 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NASONEX

Do not use Nasonex

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6).
- if you have an untreated infection in your nose. Use of Nasonex during an untreated infection in your nose, such as herpes, can worsen the infection. You should wait until the infection is resolved before you start using the nasal spray.
- if you have recently had an operation on your nose or you have injured your nose. You should not use the nasal spray until your nose has healed.

Warnings and precautions

Talk to your doctor or pharmacist before using Nasonex

- if you have or have ever had tuberculosis.
- if you have any other infection.
- if you are taking other corticosteroid medicines, either by mouth or by injection.
- if you have cystic fibrosis.

While you are using Nasonex, talk to your doctor

- 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 has these infections.
- if you have an infection of the nose or throat.
- if you are using the medicine for several months or longer.
- if you have persistent irritation to the nose or throat.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

If your eyes are itching or irritated, your doctor may recommend that you use other treatments with Nasonex.

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side effects, such as 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 any changes are noted, their doctor should be notified.

Other medicines and Nasonex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 Nasonex. 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, you should contact your doctor.

Some medicines may increase the effects of Nasonex and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

There is little or no information on the use of Nasonex in pregnant women. It is not known if mometasone furoate is found in breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There is no known information on the effect of Nasonex on the ability to drive or use machinery.

Nasonex contains benzalkonium chloride

Nasonex contains benzalkonium chloride which may cause nasal irritation.

3. HOW TO USE NASONEX

Always use Nasonex 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.

Treatment of Hayfever and Perennial Rhinitis

Use in adults and children over 12 years old

The usual dose is two sprays into each nostril once a day.

- 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; the maximum daily dose is four sprays into each nostril once a day.

Use in children aged 3 to 11 years

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

In some patients Nasonex begins to relieve symptoms within 12 hours after the first dose; however full benefit of treatment may not be seen in the first two days. Therefore, you should continue regular use to achieve full benefit of treatment.

If you or your child suffer badly from hayfever, your doctor may tell you to start using Nasonex some days before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring.

Nasal Polyps

Use in adults over 18 years old

The usual starting dose is two sprays into each nostril once daily.

- If symptoms are not controlled after 5 to 6 weeks, the dose may be increased to two sprays in each nostril twice daily. Once symptoms are under control, your doctor may advise you to decrease your dose.
- If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, you should contact your doctor.

Preparing your nasal spray for use

Your Nasonex 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 10 times until a fine mist is produced.

If you have not used the spray for 14 days or more, you need to 're-prime' the bottle by pumping the spray 2 times until a fine mist is produced.

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 as shown. (Figure 2). Tilt your head forward slightly, keeping the bottle upright.
4. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
6. Remove the nozzle from this nostril and breathe out through the mouth.
7. Repeat steps 3 to 6 for the other nostril (Figure 3).

After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.



Cleaning your nasal spray

- It is important to clean your nasal spray regularly, otherwise it may not work properly.
- Remove the dust cap and gently pull off the nozzle.
- Wash the nozzle and dust cap in warm water and then rinse under a running tap.
- **Do not** try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.
- Allow the dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

If you use more Nasonex than you should

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 forget to use Nasonex

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 stop using Nasonex

In some patients Nasonex should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. 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.

4. POSSIBLE SIDE EFFECTS

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

Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should stop taking Nasonex and get immediate medical help if you experience symptoms such as:

- swollen face, tongue or pharynx
- trouble swallowing
- hives
- wheezing or trouble breathing

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

Other side effects

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

Common side effects (may affect up to 1 in 10 people):

- headache
- sneezing
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving Nasonex two sprays in each nostril twice a day]
- sore nose or throat
- ulcers in the nose
- respiratory tract infection

Not known (frequency cannot be estimated from the available data):

- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances,
- damage to the partition in the nose which separates the nostrils
- changes in taste and smell
- difficulty in breathing and/or wheezing

Reporting of side effects

If you get any 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 directly via
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE NASONEX

- Do not store the nasal spray above 25°C. Do not freeze.
- Discard unused spray within 2 months of first opening. Only open one bottle at a time.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (Exp) which is printed on the outer packaging and inner label. The expiry date refers to the last day of that month.
- If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist for safe disposal.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help protect the environment.
- If you have any left-over/unused nasal spray, please return it to your pharmacist for safe disposal.
- If your medicine appears to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nasonex contains

The active substance in Nasonex Nasal Spray is mometasone furoate. Each metered actuation (spray) delivers 50 micrograms of mometasone furoate (as the monohydrate).

The following other ingredients are also contained in the nasal spray: dispersible cellulose, glycerol, sodium citrate dihydrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride and purified water.

What Nasonex looks like and contents of the pack

Nasonex is supplied in packs of 1 nasal spray.
Nasonex is a nasal spray suspension.
Each bottle contains 140 actuations.

Manufacturer

Manufactured by Schering-Plough Labo NV, Heist-op-den-Berg, Belgium.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/62/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Nasonex aquosum – Nasenspray
Belgium, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Slovenia, Sweden, UK	Nasonex
Bulgaria, Czech Republic, Romania, Slovak Republic	NASONEX
Latvia	Nasonex 50 mikrogrami/deva deguna aerosols,suspensija
Portugal	Nasomet
Spain	NASONEX 50 microgramos suspensión para pulverización nasal

Leaflet revision and issue date (Ref): 10.07.17

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)
Please be ready to give the following information:
Product name: Nasonex 50 micrograms/actuation Nasal Spray, Suspension
Reference No: 1151/62/1

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1. WHAT NASONEX IS AND WHAT IT IS USED FOR

What is Nasonex?

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What is Nasonex used for?

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Nasonex is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 3 and older.

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. Nasonex reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial rhinitis.

Nasal polyps

Nasonex is used to treat nasal polyps in adults aged 18 and over.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. Nasonex 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NASONEX

Do not use Nasonex

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6).
- if you have an untreated infection in your nose. Use of Nasonex during an untreated infection in your nose, such as herpes, can worsen the infection. You should wait until the infection is resolved before you start using the nasal spray.
- if you have recently had an operation on your nose or you have injured your nose. You should not use the nasal spray until your nose has healed.

Warnings and precautions

Talk to your doctor or pharmacist before using Nasonex

- if you have or have ever had tuberculosis.
- if you have any other infection.
- if you are taking other corticosteroid medicines, either by mouth or by injection.
- if you have cystic fibrosis.

While you are using Nasonex, talk to your doctor

- 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 has these infections.
- if you have an infection of the nose or throat.
- if you are using the medicine for several months or longer.
- if you have persistent irritation to the nose or throat.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

If your eyes are itching or irritated, your doctor may recommend that you use other treatments with Nasonex.

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side effects, such as 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 any changes are noted, their doctor should be notified.

Other medicines and Nasonex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 Nasonex. 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, you should contact your doctor.

Some medicines may increase the effects of Nasonex and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

There is little or no information on the use of Nasonex in pregnant women. It is not known if mometasone furoate is found in breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

There is no known information on the effect of Nasonex on the ability to drive or use machinery.

Nasonex contains benzalkonium chloride

Nasonex contains benzalkonium chloride which may cause nasal irritation.

3. HOW TO USE NASONEX

Always use Nasonex 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.

Treatment of Hayfever and Perennial Rhinitis

Use in adults and children over 12 years old

The usual dose is two sprays into each nostril once a day.

- 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; the maximum daily dose is four sprays into each nostril once a day.

Use in children aged 3 to 11 years

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

In some patients Nasonex begins to relieve symptoms within 12 hours after the first dose; however full benefit of treatment may not be seen in the first two days. Therefore, you should continue regular use to achieve full benefit of treatment.

If you or your child suffer badly from hayfever, your doctor may tell you to start using Nasonex some days before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring.

Nasal Polyps

Use in adults over 18 years old

The usual starting dose is two sprays into each nostril once daily.

- If symptoms are not controlled after 5 to 6 weeks, the dose may be increased to two sprays in each nostril twice daily. Once symptoms are under control, your doctor may advise you to decrease your dose.
- If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, you should contact your doctor.

Preparing your nasal spray for use

Your Nasonex 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 10 times until a fine mist is produced.

If you have not used the spray for 14 days or more, you need to 're-prime' the bottle by pumping the spray 2 times until a fine mist is produced.

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 as shown. (Figure 2). Tilt your head forward slightly, keeping the bottle upright.
4. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
6. Remove the nozzle from this nostril and breathe out through the mouth.
7. Repeat steps 3 to 6 for the other nostril (Figure 3).

After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.



Cleaning your nasal spray

- It is important to clean your nasal spray regularly, otherwise it may not work properly.
- Remove the dust cap and gently pull off the nozzle.
- Wash the nozzle and dust cap in warm water and then rinse under a running tap.
- **Do not** try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.
- Allow the dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

If you use more Nasonex than you should

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 forget to use Nasonex

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 stop using Nasonex

In some patients Nasonex should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. 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.

4. POSSIBLE SIDE EFFECTS

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

Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should stop taking Nasonex and get immediate medical help if you experience symptoms such as:

- swollen face, tongue or pharynx
- trouble swallowing
- hives
- wheezing or trouble breathing

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

Other side effects

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

Common side effects (may affect up to 1 in 10 people):

- headache
- sneezing
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving Nasonex two sprays in each nostril twice a day]
- sore nose or throat
- ulcers in the nose
- respiratory tract infection

Not known (frequency cannot be estimated from the available data):

- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances,
- damage to the partition in the nose which separates the nostrils
- changes in taste and smell
- difficulty in breathing and/or wheezing

Reporting of side effects

If you get any 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 directly via

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971 Fax: +353 1 6762517

Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

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6. CONTENTS OF THE PACK AND OTHER INFORMATION

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The following other ingredients are also contained in the nasal spray: dispersible cellulose, glycerol, sodium citrate dihydrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride and purified water.

What Nasonex looks like and contents of the pack

Nasonex is supplied in packs of 1 nasal spray.

Nasonex is a nasal spray suspension.

Each bottle contains 140 actuations.

Manufacturer

Manufactured by Schering-Plough Labo NV, Heist-op-den-Berg, Belgium.

Procured from within the EU and repackaged by:

Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/62/1

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Austria	Nasonex aquosum – Nasenspray
Belgium, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Slovenia, Sweden, UK	Nasonex
Bulgaria, Czech Republic, Romania, Slovak Republic	NASONEX
Latvia	Nasonex 50 mikrogrami/deva deguna aerosols,suspensija
Portugal	Nasomet
Spain	NASONEX 50 microgramos suspensión para pulverización nasal

Leaflet revision and issue date (Ref): 10.07.17

Nasonex® is a registered trademark of the Merck Sharp & Dohme Corp.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:

Product name: Nasonex 50

micrograms/actuation Nasal Spray,

Suspension

Reference No: 1151/62/1