

Package leaflet: Information for the user

Damigra 10 mg nasal spray, solution Damigra 20 mg nasal spray, solution

sumatriptan

Read all of 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 only. 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 <Product name> is and what it is used for
2. What you need to know before you use <Product name>
3. How to use <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

Each <Product name> contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*).

<Product name> is used to treat migraine headache.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Sumatriptan is believed to reduce the widening of these blood vessels. This in turn helps to take away the headache and relieve other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and sensitivity to light and sound.

2. What you need to know before you use <Product name>

Do not use <Product name>

- If you're allergic to sumatriptan, or any of the other ingredients of this medicine (listed in section 6).
- If you have a heart problem such as narrowing of the arteries (*Ischaemic heart disease*) or chest pains (*angina*), or have already had a heart attack.
- If you have circulation problems in your legs that cause cramp-like pains when you walk (*peripheral vascular disease*).
- If you have had a stroke or a mini-stroke (*also called a transient ischaemic attack or TIA*).
- If you have high blood pressure. You may be able to use <Product name> if your high blood pressure is mild and is being treated.
- If you have serious liver disease.
- With other migraine medicines, including those which contain ergotamine, or similar medicines such as methysergide or any triptan/5-HT₁ receptor agonist (medicines which are also used for treating migraine).
- With anti-depressants called MAOIs (*monoamine oxidase inhibitors*), or if you have taken these medicines in the last 2 weeks.

If any of these apply to you:
Tell your doctor, and don't use <Product name> nasal spray.

Warnings and precautions

Talk to your doctor or pharmacist before using <Product name>.

If you have any extra risk factors

- If you are a heavy smoker, or are using nicotine replacement therapy, and especially
- If you are a man aged over 40, or
- If you are a woman who has been through the menopause.

In very rare cases, people have developed serious heart conditions after using <Product name>, even though they had no signs of heart disease before. If any of the points above applies to you it could mean you have a greater risk of developing heart disease - so:

Tell your doctor so that your heart function can be checked before <Product name> is prescribed for you.

If you have a history of fits (seizures)

Or if you have other conditions which might make it more likely that you'll have a fit – for example, a head injury or alcoholism:

Tell your doctor so that you can be supervised more closely.

If you have liver or kidney disease

Tell your doctor so that you can be supervised more closely.

If you are allergic to antibiotics called sulphonamides

If so, you may also be allergic to sumatriptan. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide:

Tell your doctor or pharmacist before using <Product name>.

If you are taking anti-depressants called SSRIs (*Selective Serotonin Reuptake Inhibitors*) or SNRIs (*Serotonin Noradrenaline Reuptake Inhibitors*)

Tell your doctor or pharmacist before using <Product name>. Also see *Other medicines and <Product name>*, below.

If you use <Product name> frequently.

Using sumatriptan too often may make your headaches worse.

Tell your doctor if this applies to you. He or she may recommend you stop using <Product name>.

If you feel pain or tightness in your chest after you use <Product name>

These effects may be intense but they usually pass quickly. If they don't pass quickly, or they become severe:

Get medical help immediately. Section 4 of this leaflet has more information about these possible side effects.

Other medicines and <Product name>

Tell your doctor or pharmacist if you're taking, have recently taken or might take any other medicines. This includes any herbal products or medicines you've bought without a prescription.

Some medicines must not be taken with <Product name> and others may cause adverse effects if they're taken with <Product name>. You must tell your doctor if you are taking:

- ergotamine also used to treat migraine, or similar medicines such as methysergide (see section 2 Don't use <Product name>.). Don't use <Product name> at the same time as these medicines. Stop taking these medicines at least 24 hours before using <Product name>. Don't take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using <Product name>.
- other triptans/5-HT₁ receptor agonists (such as naratriptan, rizatriptan, zolmitriptan), also used to treat migraine, (see section 2 Don't use <Product name>). Don't use <Product name> at the same time as these medicines. Stop taking these medicines at least 24 hours before using <Product name>. Don't take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using <Product name>.
- SSRIs (*Selective Serotonin Reuptake Inhibitors*) or SNRIs (*Serotonin Noradrenaline Reuptake Inhibitors*) used to treat depression. Using <Product name> with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heart beat and shaking). Tell your doctor immediately if you are affected in this way.
- MAOIs (*monoamine oxidase inhibitors*) used to treat depression. Don't use <Product name> if you have taken these in the last 2 weeks.
- St John's Wort (*Hypericum perforatum*). Taking herbal remedies that contain St John's Wort while you are using <Product name> may make side effects more likely.

Pregnancy and breast-feeding

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

There is only limited information about the safety of <Product name> for pregnant women, though up till now there is no evidence of any increased risk of birth defects. Your doctor will discuss with you whether or not you should use <Product name> while you are pregnant.

Don't breast-feed your baby for 12 hours after using <Product name>. If you express any breast milk during this time, discard the milk and don't give it to your baby.

Some breastfeeding women report breast and/or nipple pain after use of sumatriptan. The pain is usually temporary and disappears in 3 to 12 hours.

Driving and using machines

Either the symptoms of migraine or your medicine may make you drowsy. If you are affected, don't drive or operate machinery.

3. **How to use <Product name>**

Only use <Product name> after your migraine headache begins.
Don't use <Product name> to try to prevent an attack.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

There's a step-by-step guide to using the spray at the end of this leaflet (see section 6).

How much to use

Adults aged 18 to 65

The usual dose for adults aged 18 to 65 is one <Product name> 20 mg spray into just one nostril.

But one <Product name> 10 mg spray into one nostril is enough for some people.

Don't use more than two sprays in 24 hours.

Adolescents aged 12 to 17

The usual dose for adolescents aged 12 to 17 is one <Product name> 10 mg spray into one nostril.

Children under 12

<Product name> nasal spray is not recommended for children under 12 years old.

Older people (aged over 65)

<Product name> nasal spray is not recommended for people aged over 65.

When to use <Product name>

It's best to use <Product name> as soon as you feel a migraine coming on, although it can be used at any time during an attack.

If your symptoms start to come back

You can use a second <Product name> spray after 2 hours, but don't use more than two sprays in 24 hours.

If the first spray has no effect

Don't use a second spray, or any other Sumatriptan preparation for the same attack.

If <Product name> doesn't give you any relief:

Ask your doctor or pharmacist for advice.

If you use more <Product name> than you should

Don't use more than two <Product name> nasal sprays in 24 hours

Using too much <Product name> could make you ill. If you have used more than two sprays in 24 hours:

Contact your doctor for advice.

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

4. **Possible side effects**

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

Some symptoms may be caused by the migraine itself.

Adverse events reported in adults have also been observed in adolescents. These include very rare reports of heart attacks.

Allergic reaction: stop using <Product name> and get doctor's help or go to the emergency centre straight away

Allergic reactions have occurred but their exact frequency is not known.

The signs of allergy include rash, hives (itchy rash); wheezing; swollen eyelids, face or lips; complete

collapse.

Very common side effects

(may affect more than 1 in 10 people)

- Unpleasant taste.

Common side effects

(may affect up to 1 in 10 people)

- Pain, heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feelings of unusual sensations, including numbness, tingling and warmth or cold. These effects may be intense but generally pass quickly.

If these effects continue or become severe (especially the chest pain):

Get medical help urgently. In a very small number of people these symptoms can be caused by a heart attack.

Other common side effects include:

- Irritation or burning sensation in the nose or throat; nose bleeds.
- Feeling sick (nausea) or being sick (vomiting), although this may be due to the migraine itself.
- Tiredness or drowsiness.
- Dizziness, feeling weak, or getting hot flushes.
- Temporary increase in blood pressure.
- Shortness of breath
- Aching muscles.

Very rare side effects

(may affect up to 1 in 10,000 people)

- Liver function changes. If you have a blood test to check your liver function, tell your doctor or nurse that you are using <Product name>.

Other rare side effects include:

- Breast pain

Not known

(frequency cannot be estimated from the available data)

- Seizures/fits, tremors, muscle spasm, neck stiffness.
- Visual disturbances such as flickering, reduced vision, double vision, loss of vision, and in some cases even permanent defects (although these may be due to the migraine attack itself).
- Heart problems, where your heart beat may go faster, slower or change rhythm, chest pains (*angina*) or heart attack.
- Pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress (*Raynaud's phenomenon*).
- Feeling faint (blood pressure may go down).
- Pain in the lower left side of the stomach and bloody diarrhoea (*ischaemic colitis*).
- Diarrhoea.
- If you had a recent injury or if you have inflammation (like rheumatism or inflammation of the colon) you may experience pain or pain worsening at the site of injury or inflammation.
- Pain in the joints.
- Feeling anxious.
- Difficulty swallowing.
- Excessive sweating.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions. Do not freeze.

Don't use this medicine after the expiry (EXP) date shown on the carton and nasal spray. The expiry date refers to the last day of that month.

Don't throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Product name> contains

The active substance is sumatriptan.

Each <Product name> 10 mg nasal spray contains 10 mg sumatriptan.

Each <Product name> 20 mg nasal spray contains 20 mg sumatriptan.

The other ingredients are: sulfuric acid, disodium phosphate (anhydrous), dihydrogen potassium phosphate, sodium hydroxide and water for injection.

What <Product name> looks like and contents of the pack

This medicine is provided in a pre-filled single dose nasal spray device and contains sumatriptan in 0.1 ml of a transparent and colorless or yellow solution.

<Product name> is packed in cartons containing 1, 2, 4, 6, 12 or 18 pre-filled single use nasal spray devices. Each nasal spray contains one dose of <Product name>.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

<This medicinal product is authorised in the Member States of the European Economic Area under the following names:>

<To be completed nationally>

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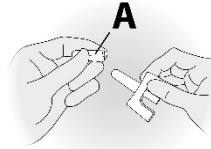
Step-by-step guide to using your <Product name> nasal spray

Each spray contains just one dose of <Product name>

Don't press the plunger too soon or you will lose the dose

A. The Protective Cover:

- This covers the nozzle to protect it.
- Remove it before you use the nasal spray.



B. The Nozzle:

- You put this part into your nose.
- The medicine comes out of a tiny hole in the top.



C. The Finger-grip:

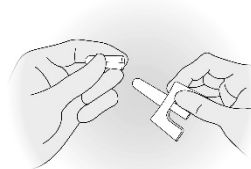
- You hold this part when you use the spray.

D. The Plunger:

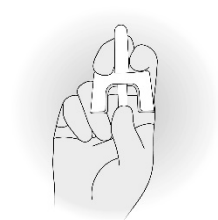
- You press this part once you have put the nozzle comfortably into your nose.
- The spray contains only one dose and works only once.

Do not press the plunger until you have put the nozzle in your nostril or you will lose the dose.

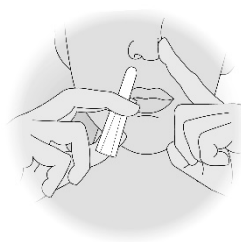
- 1**
- Blow your nose gently before use.
 - Remove the protective cover.



- 2**
- Hold the nasal spray gently with your fingers and thumb as shown in picture 2. Do not press the plunger yet!



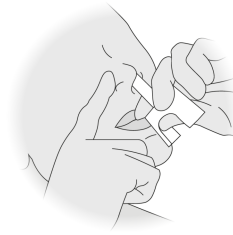
- 3**
- Block one nostril by pressing a finger on the side of your nose as shown in picture 3. It doesn't matter which nostril you choose.
 - Put the nozzle of the nasal spray into the other unblocked nostril as far as feels comfortable.



4 Breathe out gently through your mouth.

Tilt your head back slightly and close your mouth as shown in picture 4

4



- Breathe in gently through your nose and at the same time press the plunger firmly with your thumb. The plunger may feel stiff and you may hear it click. Keep breathing in while spraying.
- Keep your head slightly tilted back. Remove the nozzle from your nose.
- Keep your head upright for 10-20 seconds, breathing gently in through your nose and out through your mouth. This helps the medicine stay in your nose. You may feel liquid inside your nose. This does not mean that the dose is being lost or that the spray has failed. This is normal and will soon pass.
- Your nasal spray is now empty. Throw it away safely and hygienically.