

**Patient leaflet in accordance with the  
Pharmacists' Regulations (Preparations) – 1986**

The medicine is dispensed according to a physician's prescription only

## **Imitrex Nasal Spray 20 mg**

Each nasal spray unit (0.1 ml of solution) contains a single dose of sumatriptan 20 mg.

For the list of inactive and allergenic ingredients, see section 6 "Additional information".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

### **1. What is the medicine intended for?**

Imitrex Nasal Spray 20 mg is indicated for the acute treatment of migraine attacks with or without aura.

#### **Therapeutic group**

Selective 5-HT<sub>1</sub> receptor agonists.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Imitrex Nasal Spray 20 mg 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 nausea or vomiting and sensitivity to light and sound.

### **2. Before using the medicine**

#### **Do not use the medicine:**

- **If you are sensitive (allergic)** to sumatriptan or to any of the additional ingredients contained in the 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 Imitrex Nasal Spray 20 mg 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-HT<sub>1</sub> receptor agonist (medicines which are also used for treating migraine).

- **With anti-depressant medicines 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 physician, and don't use Imitrex Nasal Spray 20 mg.**

### **Special warnings regarding the use of the medicine**

**Before the treatment with Imitrex Nasal Spray 20 mg, tell the physician:**

#### **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 Imitrex Nasal Spray 20 mg, even though they had no signs of heart disease before. If any of the points above apply to you, it could mean you have a greater risk of developing heart disease – so:

- **Tell your physician so that your heart function can be checked** before Imitrex Nasal Spray 20 mg 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 physician so that you can be supervised more closely.**

#### **If you have liver or kidney disease**

- **Tell your physician so that you can be supervised more closely.**

#### **If you are allergic to antibiotics called sulphonamides**

If so, you may also be allergic to Imitrex Nasal Spray 20 mg. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide:

- **Tell your physician or pharmacist before using Imitrex Nasal Spray 20 mg.**

**If you are taking anti-depressant medicines called SSRIs** (Selective Serotonin Reuptake Inhibitors), SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) or TCAs (Tricyclic anti-depressants)

- **Tell your physician or pharmacist before using Imitrex Nasal Spray 20 mg.** Also see “Drug interactions”, below.

#### **If you use Imitrex Nasal Spray 20 mg frequently**

Using Imitrex Nasal Spray 20 mg too often may make your headaches worse.

- **Tell your physician if this applies to you.** Your physician may recommend you stop using Imitrex Nasal Spray 20 mg.

**If you feel pain or tightness in your chest after you use Imitrex Nasal Spray 20 mg**

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.

### **Drug interactions:**

Some medicines must not be taken with Imitrex Nasal Spray 20 mg and others may cause adverse effects if they're taken with Imitrex Nasal Spray 20 mg.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.** Especially if you are taking:

- **ergotamine** also used to treat **migraine**, or similar medicines such as methysergide (see section 2 "Do not use the medicine"). Don't use Imitrex Nasal Spray 20 mg at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imitrex Nasal Spray 20 mg. Don't take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Imitrex Nasal Spray 20 mg.
- **other triptans/5-HT<sub>1</sub> receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine** (see section 2 "Do not use the medicine"). Don't use Imitrex Nasal Spray 20 mg at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imitrex Nasal Spray 20 mg. Don't take another triptan/5-HT<sub>1</sub> receptor agonist again for at least 24 hours after using Imitrex Nasal Spray 20 mg.
- **SSRIs** (*Selective Serotonin Reuptake Inhibitors*), **SNRIs** (*Serotonin Noradrenaline Reuptake Inhibitors*) or **TCAs** (*Tricyclic anti-depressants*) used to treat **depression**. Using Imitrex Nasal Spray 20 mg with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heartbeat and shaking). Tell your physician immediately if you are affected in this way.
- **MAOIs** (*monoamine oxidase inhibitors*) used to treat **depression**. Don't use Imitrex Nasal Spray 20 mg if you have taken these in the last 2 weeks.
- ***Hypericum perforatum*** (St. John's Wort). Taking herbal remedies that contain *Hypericum perforatum* while you are using Imitrex Nasal Spray 20 mg may make side effects more likely.

### **Pregnancy and breast-feeding**

- **If you are pregnant, think you may be pregnant or are planning to become pregnant**, consult the physician before using the medicine. There is only limited information about the safety of Imitrex Nasal Spray 20 mg for pregnant women, though up till now there is no evidence of any increased risk of birth defects. Your physician will discuss with you whether or not you should use Imitrex Nasal Spray 20 mg while you are pregnant.
- **Don't breast-feed your baby for 12 hours after using Imitrex Nasal Spray 20 mg.** If you express any breast milk during this time, discard the milk and

don't give it to your baby.

### **Driving and using machines**

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

## **3. How should you use the medicine?**

Always use the preparation according to the physician's instructions.

You should check with the physician or the pharmacist if you are unsure about the dosage and treatment regimen of the preparation.

**Only use Imitrex Nasal Spray 20 mg after your migraine headache begins. Don't use Imitrex Nasal Spray 20 mg to try to prevent an attack.**

**There's a step-by-step guide** to using the spray at the end of this leaflet.

**The dosage and treatment regimen will be determined only by the physician. The usual dosage is generally:**

### **Adults aged 18 to 65**

- **The usual dose for adults aged 18 to 65** is one spray (single dose) of Imitrex Nasal Spray 20 mg into just one nostril.  
Don't use more than two spray units in 24 hours.

### **Children under the age of 18**

- **Imitrex Nasal Spray 20 mg is not intended** for children under the age of 18 years.

### **Older people (aged over 65)**

- **Imitrex Nasal Spray 20 mg is not intended** for use in people over the age of 65.

### **Do not exceed the recommended dose**

### **When to use Imitrex Nasal Spray 20 mg**

- **It's best to use Imitrex Nasal Spray 20 mg 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 spray unit of Imitrex Nasal Spray 20 mg after 2 hours, but **don't use more than two spray units in 24 hours.**

### **If the first spray (single dose) has no effect**

- **Don't use a second spray unit**, or any other Imitrex preparation for the same attack.

If Imitrex Nasal Spray 20 mg doesn't give you any relief:

→ **Ask your physician or pharmacist for advice.**

### **If you have accidentally taken a higher dosage**

- **Don't use more than two spray units of Imitrex Nasal Spray 20 mg in 24**

**hours.**

Using too much Imitrex Nasal Spray 20 mg could make you ill. If you have used more than two spray units in 24 hours:

→ **Contact your physician for advice.**

**If you took an overdose**, or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

Adhere to the treatment regimen as recommended by the physician.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.**

## **4. Side effects**

As with any medicine, use of Imitrex Nasal Spray 20 mg may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Some symptoms may be caused by the migraine itself.

**Allergic reaction: get a physician's help straight away**

The following side effects have occurred but their frequency is not known.

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

If you get any of these symptoms soon after using Imitrex Nasal Spray 20 mg:

→ **Don't use the medicine any more. Contact a physician straight away.**

**Very common side effects – effects that affect more than 1 in 10 users**

- **Unpleasant taste.**

**Common side effects – effects that affect up to 1 in 10 users**

- **Heaviness, pressure, tightness or pain in the chest**, throat or other parts of the body, or 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.
- **Nausea** or vomiting, although this may be due to the migraine itself.
- **Tiredness** or drowsiness.
- **Dizziness**, feeling weak, or hot flushes.
- **Temporary increase in blood pressure.**
- **Shortness of breath.**

- **Aching muscles.**

**Very rare side effects – effects that affect up to 1 in 10,000 users**

- Liver function changes. If you have a blood test to check your liver function, tell your physician or nurse that you are using Imitrex Nasal Spray 20 mg.

**Some patients may have the following side effects but it is not known how often they occur**

- 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 vision defects (although these may be due to the migraine attack itself).
- Heart problems, where your heartbeat 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.

**If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- Keep this medicine in the sealed blister in the carton to protect it from light.

- Don't store above 30°C.
- Don't freeze.

## 6. Additional information

- In addition to the active ingredient the medicine also contains:  
Sulphuric acid, monobasic potassium phosphate, dibasic sodium phosphate anhydrous, sodium hydroxide, purified water
- What the medicine looks like and the contents of the pack:  
This medicine is provided in a pre-filled nasal spray device and contains a single dose of sumatriptan in 0.1 ml of a yellow-coloured solution.  
Imitrex Nasal Spray 20 mg is packed in a carton containing 2 nasal spray units individually sealed in blisters. Each nasal spray unit contains one dose for single use.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Manufacturing S.p.A, Verona, Italy.
- Revised in January 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 113-98-29573-00

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## Step-by-step guide to using your Imitrex Nasal Spray 20 mg

**Don't open a blister until you are ready to use a spray.** Each spray unit is sealed in a blister to keep it clean and safe. If you carry a spray unit without a blister, or in an open blister, it may not work properly when you need it.

**Each spray unit (0.1 ml) contains just one dose of Imitrex Nasal Spray 20 mg, for single use.**

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

**Imitrex Nasal Spray 20 mg has three parts:**

### The nozzle

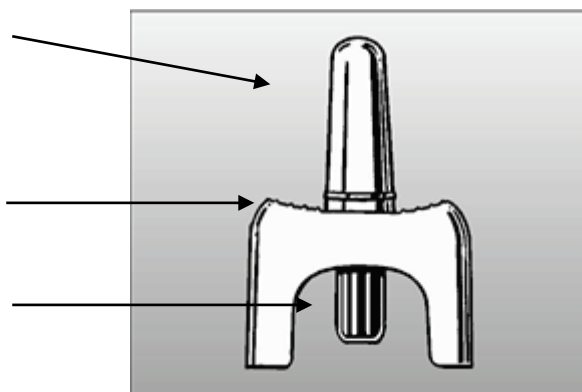
The part that you put into your nostril.  
The spray comes out of a tiny hole in the top.

### The finger-grip

Hold it when you use the spray unit.

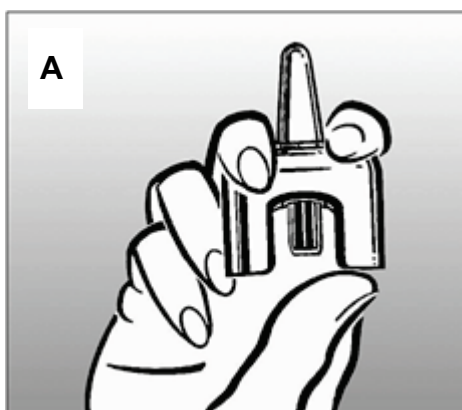
### The blue plunger

Press it to spray the whole dose into your nostril in one go. This only works once – **don't press the plunger until you have put the nozzle into your nostril or you will lose the dose.**



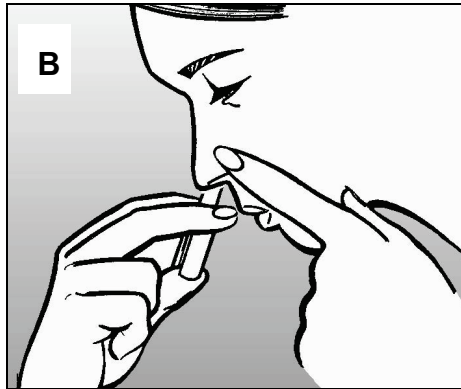
## How to use the nasal spray

- 1 Remove the nasal spray** from the blister packaging just before you want to use it.
- 2 Find a comfortable position.** You may prefer to sit down.
- 3 Blow your nose** if it feels blocked, or if you have a cold.
- 4 Hold the nasal spray** gently with your fingers and thumb, as shown in picture A.  
**Don't press the blue plunger yet.**

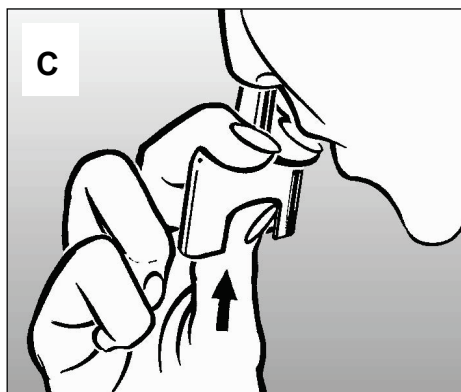




- 5 **Block one nostril** by pressing a finger firmly on the side of your nose. It doesn't matter which nostril you choose.



- 6 **Put the nozzle of the nasal spray unit into the other nostril**, as far as feels comfortable – about 1 cm (picture B).  
**Breathe out gently through your mouth.**  
Hold your head upright and close your mouth.



- 7 **Start to breathe in gently through your nose.**  
As you breathe in:  
**Press the blue plunger firmly with your thumb.**  
The plunger may feel a bit stiff and you may hear it click. Keep breathing in while spraying (picture C).
- 8 **Remove the spray unit and remove your finger from the side of 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 that your nose is wet inside and you may notice a slight taste after using the spray – this is normal and will soon pass.
- 9 **Your nasal spray unit is now empty.** Throw it away safely and hygienically.