

**PATIENT LEAFLET IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**
The medicine is dispensed according to a physician's prescription only

Imitrex Injection

Solution for Injection 6 mg/0.5 ml

Each 0.5 ml pre-filled syringe contains:

sumatriptan (as succinate) 6 mg

For the list of inactive and allergenic ingredients in the medicine, see section 6 “Additional information” and in section 2 “Important information about some of the ingredients of the medicine”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further 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 subcutaneous Injection is indicated for the acute relief of migraine attacks, with or without aura, and for the acute treatment of cluster headache. Imitrex Injection should only be used where there is a clear diagnosis of migraine or cluster headache.

Migraine and cluster headache symptoms may be caused by the temporary widening of blood vessels in the head. Imitrex Injection is believed to reduce the widening of these blood vessels. This in turn helps to take away the headache and relieve other symptoms such as nausea or vomiting and sensitivity to light and sound.

Therapeutic group:

Analgesics: triptans - selective 5-HT₁ receptor agonists.

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 Injection 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 maleate; or any triptan or 5-HT₁ agonist (such as naratriptan or zolmitriptan).
- **With any of the following anti-depressant medicines:**
 - **Monoamine oxidase inhibitors (MAOIs)** or if you have taken an MAOI in the last 2 weeks.

If any of these apply to you:

→ **Tell the physician, and do not use Imitrex Injection.**

Special warnings regarding use of the medicine

Before the treatment with Imitrex Injection, 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 menopause**

In very rare cases, people have developed serious heart conditions after using Imitrex Injection, 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 the physician** so that your heart function can be checked before Imitrex Injection 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 the physician so that you can be supervised more closely.**

If you have had high blood pressure, Imitrex Injection may not be suitable for you

- **Tell the physician or pharmacist before using Imitrex Injection.**

If you have liver or kidney disease

If either of these apply to you:

- **Tell the physician or pharmacist before using Imitrex Injection.**

If you are allergic to antibiotics called sulphonamides

You may also be allergic to Imitrex Injection. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide:

- **Tell the physician or pharmacist before using Imitrex Injection.**

If you are taking anti-depressant medicines called SSRIs

(Selective Serotonin Reuptake Inhibitors), or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) or TCAs (Tricyclic Anti-depressants)

- **Tell the physician or pharmacist before using Imitrex Injection.** Also see

“Drug interactions”, below.

Imitrex Injection syringe may contain latex

The syringe needle shield may contain latex

→ **Tell the physician if you are allergic to latex.**

If you use Imitrex Injection frequently

Using Imitrex Injection too often may make your headaches worse.

→ **Tell the physician if this applies to you.** The physician may recommend you stop using Imitrex Injection.

If you feel pain or tightness in your chest after you use Imitrex Injection

These effects may be intense but they usually pass quickly. If they do not pass quickly, or they become severe:

→ **Get medical help immediately.** Section 4 (below) has more information about these possible side effects.

Drug interactions

Some medicines must not be taken with Imitrex Injection and others may cause adverse effects if they are taken with Imitrex Injection.

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 under “Do not use the medicine”). Do not use Imitrex Injection at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imitrex Injection. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Imitrex Injection.
- **other triptans/5-HT₁ receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine** (see section 2 under “Do not use the medicine”). Do not use Imitrex Injection at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imitrex Injection. Do not take another triptan/5-HT₁ receptor agonist for at least 24 hours after using Imitrex Injection.
- **MAOIs** used to treat **depression**. If you have taken these in the last 2 weeks, do not use Imitrex Injection.
- **SSRIs, SNRIs and TCAs (tricyclic anti-depressants)** used to treat **depression**. Using Imitrex Injection 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 the physician immediately if you are affected in this way.
- ***Hypericum perforatum* (St. John’s Wort)**. Taking herbal remedies containing *Hypericum* while using Imitrex Injection may make side effects more likely.

Pregnancy, breast-feeding and fertility

- **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 Injection for pregnant women, though up until now there is no evidence of any increased risk of birth defects. The physician will discuss with you whether or not you should use Imitrex Injection while you are pregnant.
- **Do not breast-feed your baby for 12 hours after using Imitrex Injection.** If you express any breast milk during this time, discard the milk and do not 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, do not drive or operate machinery.**

Important information about some of the ingredients of the medicine

- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per syringe; therefore, it is considered "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

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

Check with the physician or the pharmacist if you are unsure about the dosage and treatment regimen of the medicine.

Imitrex Injection is usually injected into the thigh.

Imitrex Injection is intended for subcutaneous injection. Never inject Imitrex Injection into a vein.

There is a step-by-step guide to using Imitrex Injection at the end of this leaflet (see section 7).

When to use Imitrex Injection

- It is best to use Imitrex Injection **as soon as you feel a migraine or a cluster headache coming on**, although you can use it at any time during an attack.
- **Do not use Imitrex Injection** to try to prevent an attack - only use it after your migraine symptoms start.

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

Adults aged 18 to 65

- **The usual dose for adults aged 18 to 65** with migraine or a cluster headache is one 6 mg injection.

Children under the age of 18

- **Imitrex Injection** is not intended for use in children under 18 years old.

Older people (aged over 65)

- **Imitrex Injection** is not intended for use in adults over the age of 65.

Do not exceed the recommended dose.

If your symptoms start to come back

- You can use a second Imitrex Injection if at least 1 hour has passed since the first injection, but **do not use more than two injections in 24 hours.**

If the first injection has no effect

- **Do not use a new injection** or any other Imitrex medicine for the same attack.

If Imitrex Injection does not give you any relief:

- **Ask the physician or pharmacist for advice.**

If you use more Imitrex Injection than you should

- **Do not use more than two Imitrex injections in 24 hours.**

Using too much Imitrex Injection could make you ill. If you have used more than two injections in 24 hours:

- **Contact the 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 further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Imitrex Injection may cause side effects in some 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: refer to a physician straight away

The following side effects 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.**

If you get any of these symptoms soon after using Imitrex Injection:

- **Do not use any more of the medicine. Contact a physician straight away.**

Very common side effects (affect more than **1 in 10** users)

- Temporary pain at the site of injection
- Stinging or burning, redness, swelling, bruising and bleeding at the site of injection.

Common side effects (affect up to **1 in 10** users)

- Pain, heaviness, pressure or tightness 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:

- 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 (affect up to **1 in 10,000** users)

- Changes in liver function blood test values. If you have to do a liver function blood test, tell the physician that you are using Imitrex Injection.

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

- Seizures/fits, tremors, short-lived/temporary muscle spasm (which may affect jaw movement), 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 be faster, slower or irregular, chest pains (*angina*) or heart attack
- Pale, blue-tinged skin and/or pain in the 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 occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the physician.

Reporting of suspected adverse reactions

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) 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 unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- You may wish to carry Imitrex Injection with you in case of a migraine attack.
- Always keep your injections in the case provided to protect them from the light. Store below 30°C.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:
sodium chloride, water for injection.

- What the medicine looks like and contents of the pack:
Each Imitrex Injection treatment pack comes with an injection device (Pen) and a cartridge pack which contains two pre-filled syringes. Each pre-filled syringe is for single use.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations (UK) Limited, Barnard Castle, UK.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 055-92-26920.

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7. STEP-BY-STEP GUIDE TO USING YOUR IMITREX INJECTION SYSTEM

This leaflet shows you how to load the injection pen and how to use it to give a dose of Imitrex Injection.

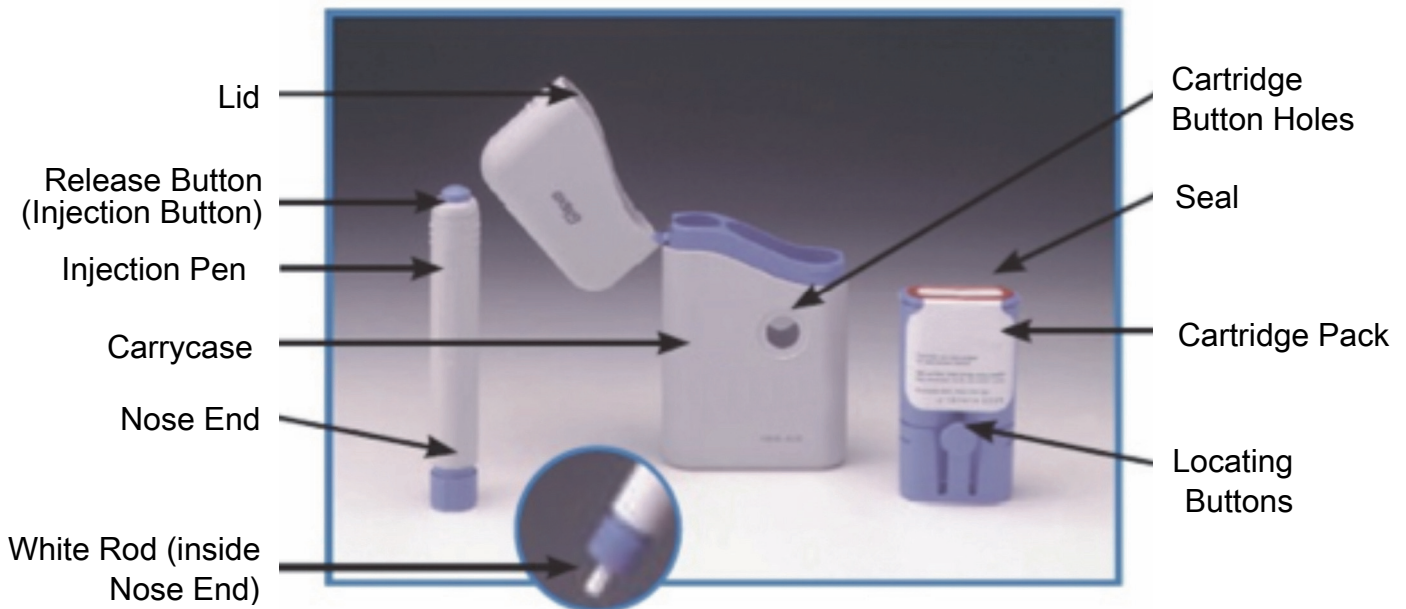
Please read this leaflet before using the injection system.

The GlaxoSmithKline Imitrex Injection system is designed for use with the medicine Imitrex Injection.

Each injection system comes with an Imitrex cartridge pack.
The cartridge pack contains two pre-filled syringes.

Keep out of the sight and reach of children.

Description of parts:



How to give an injection using the Imitrex Injection pen

- Read the leaflet fully and carefully before using the Imitrex Injection pen.
- Each Imitrex Injection system includes a cartridge pack which contains two syringes pre-filled with Imitrex Injection. Each pre-filled syringe is for single use.
- Use the photo above to help you identify the different parts of the injection system.
- **Do not load the pen until you are ready to give the injection.**

- 1 Swing open the lid of the carrycase.



- 2 Remove the red seal from one of the syringes. Open the blue lid underneath the seal.
- 3 Take out the Imitrex Injection pen from the carrycase. Check that the white rod is not sticking out beyond the end of the pen (see picture in section 11 of this guide). If it is sticking out, place the pen back inside the carrycase, push it firmly and the rod should click into place. The pen is now ready for use.



- 4 Push the Imitrex Injection pen firmly into the opened cartridge pack and gently screw it clockwise (about half a turn) until it will twist no further.



- 5 Keep your finger away from the blue release button (injection button) and pull the Lomitrex Injection pen out of the cartridge pack. You may have to pull quite hard to do this. A safety catch stops accidental injection until you are ready.



- 6 The loaded pen is now ready for immediate use.
Do not try to put the loaded pen back into the carrycase until after you have used the injection, or the needle may be damaged and the pen will not inject correctly.
- 7 Press the pen with the long blue nose end firmly against a clean area of skin - usually the outside of the thigh (as in picture) - so the grey part slides down to cover part of the blue nose. This releases the safety catch.



- 8 Hold the pen firmly and press the blue release button at the top of the Imitrex Injection pen. Count slowly to 10, keeping the Imitrex Injection pen very still and the release button depressed.

Do not take the pen away from the skin too soon or some of the injection may be wasted.

Then lift the pen away taking care not to touch the needle point.

- 9 Return the used syringe to the empty space in the cartridge pack straight away.



- 10 Push the pen down into the cartridge pack as far as it will go, unscrew the pen by twisting it anti-clockwise (about half a turn) until it comes away.



- 11** Withdraw the Imitrex Injection pen from the cartridge pack. Close the blue lid over the used syringe.



- 12** Put the Imitrex Injection pen back into the carrycase and push it down until it stays down. It will click into place. The Imitrex Injection pen is then ready for use next time.



- 13** Close the lid of the carrycase until you need to use the second syringe.

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