

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

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

Imitrex Tablets 50 mg

Film-coated tablets

Each tablet contains:

Sumatriptan (as succinate) 50 mg

Imitrex Tablets 100 mg

Film-coated tablets

Each tablet contains:

Sumatriptan (as succinate) 100 mg

For the list of inactive and allergenic ingredients in the preparation, see section 2 – “Important information about some of the ingredients of the medicine” and 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 Tablets is indicated for the acute relief of migraine attacks, with or without aura.

Imitrex Tablets should only be used where there is a clear diagnosis of migraine.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Imitrex Tablets 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.

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 Tablets 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 your physician, and don't use Imitrex Tablets.**

Special warnings regarding the use of the medicine

Before the treatment with Imitrex Tablets, 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 Tablets, 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 Tablets 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 had high blood pressure, Imitrex Tablets may not be suitable for you

- **Tell your physician or pharmacist before using Imitrex Tablets.**

If you have liver or kidney disease

If any of these apply to you:

- **Tell your physician or pharmacist before using Imitrex Tablets.**

If you have an intolerance to some sugars

- **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 Tablets. 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 Tablets.**

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 your physician or pharmacist before using Imitrex Tablets.** Also see "Drug interactions", below.

If you use Imitrex Tablets frequently

Using Imitrex Tablets too often may make your headaches worse.

→ **Tell your physician if this applies to you.** Your physician may recommend you stop using Imitrex Tablets.

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

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 (below) has more information about these possible side effects.

Drug interactions:

Some medicines must not be taken with Imitrex Tablets and others may cause adverse effects if they're taken with Imitrex Tablets.

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 Tablets at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imitrex Tablets. Don't take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Imitrex Tablets.
- **other triptans/5-HT₁ receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine** (see section 2 "Do not use the medicine"). Don't use Imitrex Tablets at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imitrex Tablets. Don't take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using Imitrex Tablets.
- **MAOIs** used to treat **depression**. If you have taken these in the last 2 weeks, don't use Imitrex Tablets.
- **SSRIs, SNRIs and TCAs (tricyclic anti-depressants)** used to treat **depression**. Using Imitrex Tablets 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.
- ***Hypericum perforatum*** (St. John's Wort). Taking herbal remedies that contain *Hypericum* together with Imitrex Tablets 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 Tablets 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 Tablets while you are pregnant.
- **Don't breast-feed your baby for 12 hours after using Imitrex Tablets.** 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.**

Important information about some of the ingredients of the medicine

Lactose: If you have been told by your physician that you have an intolerance to certain sugars, refer to your physician before taking this medicine.

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

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.

When to take Imitrex Tablets

- It's best to take Imitrex Tablets **as soon as you feel a migraine coming on**, although you can take it at any time during an attack.
- **Don't use Imitrex Tablets** to try to prevent an attack - only use it after your migraine symptoms start.

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 tablet of Imitrex Tablets 50 mg, swallowed whole with water. Some patients may need a 100 mg dose - you should follow your physician's advice.

Children under the age of 18

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

Older people (aged over 65)

- **Imitrex Tablets** is not intended for use in people over the age of 65.

Do not exceed the recommended dose.

If your symptoms start to come back

- You can take a second tablet of Imitrex Tablets if at least 2 hours have

passed since the first tablet. **Don't take more than 300 mg in total in 24 hours.**

If the first tablet has no effect

- **Don't take a second tablet** or any other Imitrex preparation for the same attack. Imitrex Tablets can still be used for your next attack.

If Imitrex Tablets doesn't give you any relief:

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

Crushing/halving/chewing

The tablets are film-coated and therefore should not be crushed/halved/divided. Swallow the tablet whole with water.

If you accidentally take too high a dosage of Imitrex Tablets

- **Don't take more than six 50 mg tablets or three 100 mg tablets** (300 mg in total) in 24 hours.

Taking too much Imitrex Tablets could make you ill. If you have taken more than 300 mg 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 further questions about the use of this medicine, ask your physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Imitrex Tablets 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 medical help 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 Tablets:

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

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)

- Liver function changes. If you have a blood test to check your liver function, tell the physician that you are taking Imitrex Tablets.

Some patients may get 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 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 recently had an injury or if you have an inflammation (like rheumatism or inflammation of the colon) you may experience pain or worsening of pain at the site of the 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.

Reporting side effects

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.it) that directs you to the online form for reporting side effects, or by entering the link:

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

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.
- Store below 30°C.
- Do not throw away any medicines via waste water or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient the medicine also contains -
Imitrex Tablets 50 mg:
Lactose, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171), triacetin, iron oxide red (E172).
Imitrex Tablets 100 mg:
Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171).
- What the medicine looks like and contents of the pack:
Imitrex 50 mg tablets are pink and capsule-shaped. They are available in a blister pack containing 2 or 6 tablets.
Imitrex 100 mg tablets are white and capsule-shaped. They are available in a blister pack containing 2 or 6 tablets.
Not all packs sizes may be marketed.
- License Holder and Importer: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Imitrex Tablets 50 mg: 102-91-28531
Imitrex Tablets 100 mg: 055-93-26919

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