Package Leaflet: Information for the User

Imigran

50 mg film-coated tablets
100 mg film-coated tablets
Sumatriptan

Read all of this leaflet carefully before you start taking 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 Imigran is and what it is used for
2 What you need to know before you use Imigran
3 How to use Imigran
4 Possible side effects
5 How to store Imigran
6 Contents of the pack and other information

1 What Imigran is and what it is used for

Each Imigran capsule-shaped tablet contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (also known as 5-HT_1 receptor agonists). **Imigran is used to treat migraine headache.**
Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Imigran 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 Imigran

Don't use Imigran:
- **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 Imigran 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 5HT_1 agonist (such as naratriptan or zolmitriptan)
- **With any of the following anti-depressants:**
  - **MAOIs** (*monoamine oxidase inhibitors*) or if you have taken an MAOI in the last 2 weeks
- **For children under 18 years of age.**

If any of these apply to you:
➔ **Tell your doctor, and don't use Imigran tablets.**

Take special care with Imigran
Talk to your doctor or pharmacist before using Imigran.

If you have any extra risk factors
- **If you are a heavy smoker, or 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 Imigran, 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 Imigran 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 had high blood pressure Imigran may not be suitable for you
➔ **Tell your doctor or pharmacist before using Imigran.**

If you have liver or kidney disease
If either of these apply to you:
➔ **Tell your doctor or pharmacist before using Imigran.**

If you have an intolerance to some sugars
➔ **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 Imigran. 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 Imigran.**

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 Imigran.** Also see Other medicines and Imigran, below.

If you use Imigran frequently.
Using Imigran too often may make your headaches worse.
➔ **Tell your doctor if this applies to you.** He or she may recommend you stop using Imigran.

If you feel pain or tightness in your chest after you use Imigran
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 has more information about these possible side effects.

Other medicines and Imigran
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 Imigran and others may cause adverse effects if they're taken with Imigran. **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 Imigran). Don't use Imigran at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imigran. Don't take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Imigran.
- **other triptans/5-HT_1 receptor agonists (**such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine,** (see section 2 Don't use Imigran). Don't use Imigran at the same time as these medicines. Stop taking these medicines at least 24 hours before using Imigran. Don't take another triptan/5-HT_1 receptor agonist again for at least 24 hours after using Imigran.
- **MAOIs** used to treat **depression.** Don't use Imigran if you have taken these in the last 2 weeks.
- **SSRIs and SNRIs** used to treat **depression**. Using Imigran 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 doctor immediately if you are affected in this way.
- **St John's Wort** (*Hypericum perforatum*). Taking herbal remedies that contain St John's Wort together with Imigran 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 Imigran 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 Imigran while you are pregnant
- **Don't breast-feed your baby for 12 hours after using Imigran.** 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 the symptoms of migraine or your medicine may make you drowsy. **If you are affected, don't drive or operate machinery.**

Imigran contains
- **Lactose:** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to use Imigran

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

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

How much to take

Adults aged 18 to 65
- **The usual dose for adults aged 18 to 65** is one Imigran 50 mg tablet, swallowed whole with water. Some patients may need a 100 mg dose - you should follow your doctor's advice.

Children under 18
- **Imigran** is not recommended for children under 18 years old.

Elderly (aged over 65)
- **Imigran** is not recommended for people aged over 65.

If your symptoms start to come back
- You can take a second Imigran tablet 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 Imigran preparation for the same attack. Imigran can still be used for your next attack.

If Imigran doesn't give you any relief:
➔ **Ask your doctor or pharmacist for advice.**

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

Taking too much Imigran could make you ill. If you have taken more than 300 mg in 24 hours:
➔ **Contact your doctor for advice.**
If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, but not everybody gets them. Some symptoms may be caused by the migraine itself.

Allergic reaction: get doctor's 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 Imigran:
➔ **Don't use any more. Contact a doctor straight away.**

Common side effects (affect up to **1 in 10** people)
- 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:
- 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
(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 taking Imigran.

Some patients may get 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 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 diarrhea (*ischaemic colitis*)
- Diarrhea
- 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

5 How to store Imigran

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date shown on the carton. The expiry date refers to the last day of that month.
- Store below 30°C.

Don't throw away any medicines via wastewater 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 Imigran contains
- The active substance is sumatriptan 50 mg or 100 mg
- The other ingredients in 50 mg film-coated tablets are lactose monohydrate, lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, and Opadry Pink YS-1-1441-G (hypromellose, titanium dioxide, triacetin and iron oxide red).
- The other ingredients in 100 mg film-coated tablets are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate and Opadry White OY-S-7393 (hypromellose, titanium dioxide) or Opaspray white M-1-7-120 (hypromellose, titanium dioxide, sodium benzoate, industrial methylated spirits) and hypromellose.

What Imigran looks like and contents of the pack
- Sumatriptan Tablets 50 mg are pink, film-coated, capsule shaped biconvex tablets engraved 'GX ES3' on one face and plain on the other face, or engraved '50' on one face and plain on the other face. Each tablet contains 50 mg sumatriptan base (as the succinate salt).
- Sumatriptan Tablets 100 mg are white to off-white, film-coated, capsule shaped biconvex tablets engraved 'GX ET2' on one face and plain on the other face, or engraved '100' on one face and plain on the other face. Each tablet contains 100 mg sumatriptan base (as the succinate salt).
- Imigran film-coated tablets 50 mg & 100 mg are packed in individual pockets into cold form foil / child resistant lidding foil blister packs and placed in a cardboard carton.
  Pack size: 2 or 6 tablets.
  Not all pack sizes may be marketed.

Marketing Authorisation Holder
Glaxo Wellcome UK Limited
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Manufacturer:
Delpharm Poznań Spółka Akcyjna, Poznań, Poland

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This is a Medicament
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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