

Imigran Ftab[®] 100 mg film-coated tablets (sumatriptan)

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PACKAGE LEAFLET: INFORMATION FOR THE USER

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 Ftab is and what it is used for
- 2 What you need to know before you take Imigran Ftab film-coated tablets
- 3 How to take Imigran Ftab film-coated tablets
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- 5 How to store Imigran Ftab film-coated tablets
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1 What Imigran Ftab is and what it is used for

Each Imigran Ftab film-coated tablet contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*).

Imigran Ftab film-coated tablets are used to treat migraine headaches with or without warning signs (aura) and to treat migraine headaches associated with menstruation.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Imigran Ftab film-coated tablets are 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 take Imigran Ftab film-coated tablets

Do not take Imigran Ftab film-coated tablets:

- * **If you are allergic** to sumatriptan, or any of the other ingredients (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 severe 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 you are under 18 or over 65 years of age.**
- * For the treatment of migraines with accompanying: weakness of one side of the body (hemiplegic migraines), speaking difficulties, vertigo, ringing in ears (basilar migraines) or weakness in the eye muscles (ophthalmoplegic migraines).

If any of these apply to you:

- **Tell your doctor, and don't use Imigran Ftab film-coated tablets.**

Warnings and precautions

Talk to your doctor or pharmacist before 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 of this leaflet has more information about these possible side effects.

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

- **Tell your doctor or pharmacist before you use Imigran.** Also see *Other medicines and Imigran*, below.

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 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 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

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

Other medicines and Imigran

Tell your doctor or pharmacist if you are 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-HT₁ 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-HT₁ receptor agonist again for at least 24 hours after using Imigran.
- * **SSRIs** (Selective Serotonin Reuptake Inhibitors) or **SNRIs** (Serotonin Noradrenaline Reuptake Inhibitors) 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 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 Imigran 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 Imigran may make side effects more likely.

Pregnancy and breast-feeding

- * **If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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.**

Patient Information Leaflet (continued)

3 How to take Imigran Ftab film-coated tablets

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

When to take Imigran Ftab:

- * **It's best to use Imigran as soon as you feel a migraine coming on**, although it can be used at any time during an attack. **Don't use Imigran to try to prevent an attack. Only use Imigran after your migraine headache begins.**

How much to take:

Adults aged 18 to 65

- * **The usual dose for adults aged 18 to 65** is one Imigran Ftab 50 mg film-coated tablet swallowed whole with water. Some patients may require 100 mg.
- * Patients with swallowing difficulties may disperse the tablet in a small amount of water before taking. Imigran Ftab film-coated tablet dispersed in water has a bitter taste.

Children and Adolescents (under 18 years of age)

- * **Imigran Ftab film-coated tablets are not recommended** for children and adolescents under 18 years of age.

Older people (aged over 65)

Imigran Ftab film-coated tablets are not recommended for people aged over 65. If your symptoms start to come back

- * You can use a second Imigran Ftab film-coated tablet, but **don't use more than six 50 mg tablets or three 100 mg tablets in 24 hours, that is 300 mg in total.**
- * You should allow 2 hours between each dose

If the first tablet has no effect

- * **Don't use a second tablet**, or any other Imigran preparation for the same attack.

If Imigran doesn't give you any relief:

- **Ask your doctor or pharmacist for advice**

If you use more Imigran than you should

- * **Don't use more than 300 mg in 24 hours**

Using too much Imigran could make you ill. If you have used more than 300 mg in 24 hours:

- **Contact your doctor for advice.**

If you have any further question on the use of this product, 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: get doctor's help straight away

The following side effects have occurred in a very small number of people 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, 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:

- * 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 using Imigran Ftab.

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 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
- * Pain in the joints
- * Feeling anxious
- * 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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5 How to store Imigran Ftab film-coated Tablets

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

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton or blister foil after EXP.

The expiry date refers to the last day of that month.

Do not throw away medicines via waste water or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help to protect the environment.

6 Contents of the pack and other information.

What Imigran Ftab film-coated tablets contain:

The active substance is sumatriptan

The other ingredients are dibasic calcium phosphate, anhydrous microcrystalline cellulose, sodium bicarbonate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171), glycerol triacetate.

What Imigran Ftab film-coated tablets look like and contents of the pack
Imigran Ftab 100 mg film-coated tablets are white film-coated, triangular shaped, biconvex tablets with the text 'GS YE7' on one side and '100' on the other. They are available in packs of 2, 4, or 6 film-coated Tablets.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is: GlaxoSmithKline Pharmaceuticals S.A, Poznan, Poland, Or Glaxo Operations UK Ltd, Ware, UK.

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Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.