

## LEAFLET: INFORMATION FOR THE USER

Imigran FTAB 50 mg, dispersible tablets  
Imigran FTAB 100 mg, dispersible tablets  
sumatriptan

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

### Contents of this leaflet

1. What is Imigran FTAB and what is it used for?
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## 1. WHAT IS IMIGRAN FTAB AND WHAT IS IT USED FOR?

Imigran FTAB contains sumatriptan, which belongs to a group of medicines called triptans (also known as 5-HT<sub>1</sub>-receptor agonists).

Imigran FTAB is used for the treatment of migraine.

Migraine symptoms can be caused by the temporary dilation of blood vessels in the head. It is believed that Imigran reduces the dilation of these blood vessels. This helps relieve the headache and other symptoms of migraine such as nausea and vomiting and a sensitivity to light and sound.

## 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR EXERCISE EXTRA CAUTION?

When should you not use this medicine?

You are allergic (hypersensitive) to any of the ingredients in this medicine. You can find these ingredients in section 6.

You have heart problems such as ischemic heart disease (heart disease caused by a local shortage of blood due to narrowing of the blood vessels near the heart), a previous heart attack, or angina pectoris (chest pain).

You have blood circulation disorders in your legs that cause cramps when you walk (called peripheral vascular disease).

You have had a stroke or mini-stroke (also called a "transient ischemic attack" or TIA).

You have high blood pressure. You can use Imigran if your high blood pressure is mild and treated.

You have a severe liver disease.

Together with other migraine medications, including medications that contain ergotamine or similar medications such as methysergide or any other triptan/5-HT<sub>1</sub>-receptor agonist (medications also used to treat migraine).

Together with a certain type of antidepressant medication, the so-called monoamine oxidase inhibitors (MAOIs) or if you have used these medications in the last two weeks.

If one or more of the above situations apply to you:

⇒ Then consult your doctor for advice and do not use Imigran FTAB.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

If you have additional risk factors:

If you are a heavy smoker, or if you are using nicotine replacement therapy, and in particular:

if you are a man over 40, or

if you are a woman post-menopause

In very rare cases, people have developed serious heart problems after using Imigran, even if they had no previous signs of heart disease. If any of the above conditions apply to you, it may mean you are at greater risk of developing heart disease, so:

⇒ Tell your doctor so that your heart function can be checked before Imigran is prescribed.

If you have a history of seizures (fits) or if you have another condition that makes you more likely to have a fit – for example, after head injury or with alcoholism:

⇒ Tell your doctor so you can be monitored closely.

If you suffer from liver or kidney disease

⇒ Tell your doctor so you can be monitored carefully.

If you are hypersensitive to certain antibiotics called sulfonamides, you may also be hypersensitive to Imigran. If you know you are hypersensitive to an antibiotic but are not sure if it is a sulfonamide, consult your doctor or pharmacist.

⇒ Tell your doctor or pharmacist before using Imigran.

If you are using certain antidepressants, the so-called SSRIs (selective serotonin reuptake inhibitors), or SNRIs (serotonin-norepinephrine reuptake inhibitors)

⇒ Consult your doctor or pharmacist before using Imigran. See also the section Are you using any other medicines? below.

If you use Imigran regularly

If you use Imigran too often, your headache may worsen.

⇒ Tell your doctor or pharmacist if this applies to you. Your doctor may advise you to stop using Imigran.

If you experience pain or a feeling of tightness in the chest after using Imigran

These effects can be intense, but they pass quickly. If they do not pass quickly, or if they worsen:

⇒ Seek medical help immediately. Section 4 of this leaflet contains more information about these possible side effects.

Are you using any other medicines?

Are you using any other medicines besides Imigran FTAB, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to herbal medicines or medicines you have bought without a prescription.

Some medicines should not be taken with Imigran, and others may cause side effects when used at the same time.

You must tell your doctor if you are using any of these medicines:

ergotamine, which is also used to treat migraine, or ergotamine-like substances, such as methysergide (see section 2: 'When should you not use this medicine?'). Do not use Imigran simultaneously with these medicines. You must stop treatment with these medicines at least 24 hours before using Imigran. Also, do not use medicines containing ergotamine or substances similar to ergotamine for at least 6 hours after using Imigran.

other triptans/5-HT<sub>1</sub>-receptor agonists (such as naratriptan, rizatriptan, zolmitriptan), which are also used for the treatment of migraine (see section 2 'When should you not use this medicine?'). Do not use Imigran simultaneously with these medicines. You must stop treatment with these medicines at least 24 hours before using Imigran. Do not use any other triptan/5-HT<sub>1</sub>-receptor agonist for at least 24 hours after using Imigran.

SSRIs (selective serotonin reuptake inhibitors) or SNRIs (serotonin-norepinephrine reuptake inhibitors) used for the treatment of depression. Using Imigran with this group of medications can cause serotonin syndrome (a collection of symptoms that may include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heart rate, and tremors). If you experience these symptoms, contact your doctor for advice.

MAO inhibitors (monoamine oxidase inhibitors): used to treat depression. Do not use Imigran if you have taken these medications in the last 2 weeks.

St. John's wort (*Hypericum perforatum*): using herbal therapies containing St. John's wort while taking Imigran may increase the likelihood of side effects.

### Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Contact your doctor before using this medication. There is only limited data on the safety of Imigran in pregnant women. So far, this data does not indicate an increased risk of malformations. Your doctor will decide in consultation with you whether you can use Imigran during your pregnancy.

You should not breastfeed within 12 hours after using Imigran. If you express milk during this period, you should discard it and not give it to your baby. Some breastfeeding women report pain in the breast and/or nipple after using sumatriptan. The pain is usually temporary and disappears within 3 to 12 hours.

### Driving and using machines

Both the migraine itself and your medication can make you drowsy. If this is the case for you, do not drive or operate machines.

### Imigran FTAB contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Do not use Imigran to try to prevent an attack.

It is best to swallow the tablet whole with some water. If you have difficulty swallowing, you can also dissolve the tablet in some water. The resulting solution has a bitter taste.

Imigran is not recommended for use in children under 18 years or in the elderly (> 65 years).

Use Imigran as soon as you feel a migraine attack coming on, although you can also administer it later during the attack.

The recommended dosage for an attack is one tablet of Imigran FTAB 50 mg. However, since the severity of migraine attacks can vary, both from patient to patient and from attack to attack, in individual cases a tablet of Imigran FTAB 100 mg may be needed.

If your liver is not functioning well, this may be a reason for your doctor to prescribe you Imigran FTAB 50 mg.

If you notice that the symptoms return, you can take another tablet. However, you must wait 2 hours or longer after the first dose before taking the second one.

Within a 24-hour period, you must not use more than 3 tablets of Imigran FTAB 100 mg.

If the first tablet of Imigran FTAB does not help, it is pointless to take Imigran FTAB again during the same attack. Imigran FTAB can be taken again during a subsequent attack. Imigran FTAB does not help to prevent a migraine attack, so it is USELESS to use Imigran FTAB if you do not have a migraine attack.

Have you used too much of this medicine?

Using too much Imigran can make you sick. If you have taken too much FTAB, contact your doctor for advice.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

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

Allergic reaction: seek medical help immediately

The following side effects occur, but it is not known how often they occur.

Signs of hypersensitivity include rash, hives (severely itchy rash), wheezing, swollen eyelids, face or lips; fainting

If you experience any of these symptoms shortly after administering Imigran:

⇒ Do not use it anymore. Contact your doctor immediately.

Common side effects (occur in less than 1 in 10 patients):

pain, heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feelings of unusual sensations including tingling, numbness or feeling warm or cold (these can be intense but generally pass quickly)

If these effects persist or become severe (especially chest pain):

⇒ Seek immediate medical help. In a very small number of patients, these symptoms can be caused by a heart attack.

Other common side effects include:

nausea or vomiting, although these effects may also be due to the migraine itself  
feeling of tiredness or drowsiness  
dizziness, feeling of weakness or hot flashes  
temporarily increased blood pressure  
shortness of breath  
muscle pain.

Rare side effects (occur in less than 1 in 1,000 patients):

chest pain

Very rare side effects (occur in less than 1 in 10,000 patients):

abnormal liver function test results. If you have blood taken for liver function tests, tell your doctor or nurse that you are using Imigran.

Unknown: based on available data, the frequency cannot be determined

seizures/convulsions, tremors, muscle spasms, stiff neck  
vision problems such as flickering, reduced vision, double vision, loss of vision, in some cases even permanent damage (although these may also be due to the migraine attack itself)  
heart problems, where your heart rate speeds up, slows down or changes rhythm, chest pain (angina) or a heart attack  
pale, blue-colored skin and/or pain in your fingers, toes, ears, nose or jaw in cold and stress (Raynaud's phenomenon)  
feeling faint (blood pressure may drop)  
pain in the lower left side of the stomach and bloody diarrhea (ischemic colitis)  
diarrhea  
joint pain  
anxiety  
excessive sweating  
if you have recently suffered an injury or have an inflammation (such as rheumatism or an intestinal inflammation), you may experience pain or worsening pain at the site of the injury or inflammation  
difficulty swallowing.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date. You can find it on the label on the packaging after 'EXP:'. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is sumatriptan (50 mg or 100 mg).
- The other substances in this medicine are:

Tablet core (Imigran FTAB 50 mg and 100 mg) calcium hydrogen phosphate (E341), sodium bicarbonate (E500), microcrystalline cellulose (E460), sodium croscarmellose (E468), and magnesium stearate (E470b). Coating

Imigran FTAB 50: hypromellose (E464), triacetin (E1518), titanium dioxide (E171), red iron oxide (E172) Imigran FTAB 100: hypromellose (E464), triacetin (E1518), titanium dioxide (E171).

What does Imigran FTAB look like and how many are in a package?

Imigran FTAB 50 mg: pink, triangular tablet, marked on one side with 'GS 1YM', on the other side marked with '50'.

Imigran FTAB 100 mg: white, triangular tablet, marked on one side with 'GS YE7', on the other side marked with '100'.

Imigran FTAB 50 mg: package contains 2 blister packs with push-through strips. 4 tablets per package. Each blister contains 2 tablets. Imigran FTAB 100 mg: package contains 2 blister packs with push-through strips. 4 tablets per package. Each blister contains 2 tablets.

Marketing authorization holder and manufacturers

Registration holder:

Euro Registratie Collectief b.v.

Kempkens 2200

5465 PR Veghel

Repacker (see label on the outer packaging):

Brocef B.V., Maroestraat 43, 1060 LG Amsterdam

or

Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer:

Delpharm Poznań Spółka Akcyjna

Ul. Grunwaldzka 189

60-322 Poznan

Poland

Registered under

RVG 112032//29413 Imigran FTAB 50 mg, dispersible tablets (Italy)

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The product from this leaflet is marketed in the country of origin under the name

Italy: IMIGRAN 50mg, film-coated tablets

IMIGRAN 100mg, film-coated tablets

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