

# IMIGRAN<sup>®</sup> FD TABLET 50 MG

Sumatriptan (50 mg)

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## What IMIGRAN FD is used for

Imigran FD tablets are used to relieve migraine attacks, including the acute treatment of migraine attacks associated with the menstrual period in women. Imigran FD tablets should only be used when you first experience signs and symptoms of a migraine attack, not to try and prevent an attack from occurring.

## How IMIGRAN FD works

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<sub>1</sub> receptor agonists*). 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.

## Before you use IMIGRAN FD

- When you must not use it

Do not use your medicine: If you are hypersensitive (allergic) to sumatriptan or to any of the ingredients of Imigran FD.

- Before you start to use it

If you answer 'Yes' to any of the following questions tell your doctor about this before using your medicine as it may not be suitable for you.

- Are you pregnant or trying to become pregnant?
- Are you breast-feeding? – to minimise infant exposure, mothers should not breastfeed for 12 hours after using Imigran FD.
- Is this headache any different from your usual migraine attacks?
- Have you been told that you are allergic to Imigran FD, sumatriptan, or any of the other ingredients in Imigran FD?
- Are you taking any medicines for your migraine, which contain ergotamine or dihydroergotamine? – if so, you must not use Imigran FD preparations at the same time.
- Are you taking, or have you taken any antidepressants within the past 2 weeks, particularly those that contain monoamine oxidase inhibitors? – if so, you must not use Imigran FD preparations.
- Are you taking any antidepressants classed as selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs)?

- Are you allergic to sulphonamide antibiotics? If you are allergic to an antibiotic but you are not sure if it belongs to this group, check with your doctor or pharmacist.
- Are you taking any other medication for your migraine?
- Do you have ischaemic colitis?
- Do you suffer from unexpected shortness of breath or from pain or tightness in the chest (which may or may not spread to your jaw or upper arms)?
- Have you ever had a heart attack?
- Do you have high blood pressure?
- Do you have any heart disease or suffer with angina?
- Have you had, or been told that you may have had a stroke?
- Do you suffer from Raynaud's disease, peripheral vascular disease (pain in the back of the legs) or are prone to cold, tingling or numb hands and feet?
- Have you been told that you may have an increased risk of heart disease? You may be considered to have an increased risk of heart disease if you are:
  - A man over 40
  - A woman who has been through the menopause (change of life)
  - Overweight.
  - If you have diabetes or high blood cholesterol
  - If you smoke
  - You may also have an increased risk of heart disease if blood relatives have suffered from heart disease.
- Do you have liver disease?

- Do you have kidney disease?
- Have you had seizures or fits in the past or been told that you are prone to this problem?
- If you use Imigran FD too often, it may make your headaches worse. If this happens, your doctor may tell you to stop taking Imigran FD.
- Are you under 18 or over 65 years of age?

- Taking other medicines

Make sure your doctor knows what other medicines you are taking, or have recently taken, even those you have bought yourself. Remember to include all medicines, herbal remedies or dietary supplements, such as vitamins, iron or calcium.

**How to use IMIGRAN FD**

- How much to use

The recommended adult dose of Imigran FD is one 50 mg tablet. To be swallowed whole with water as soon as the symptoms of your migraine headache appear, although they may be taken at any time during a migraine headache attack. Your doctor will tell you which dose to take.

Do not take more Imigran FD tablets, or any other form of Imigran FD, if the first dose has not provided relief from your symptoms. You may take your usual headache relief medication provided it does not contain ergotamine or dihydroergotamine.

A second dose may be used if the first dose has relieved the symptoms of your migraine but the symptoms have come back, provided that there is a minimum interval of two hours between doses.

Do not take more than a total dose of 300 mg (six 50 mg tablets) in a 24 hour period. Any leftover tablets should be returned to the doctor or pharmacist.

- When to use it

To be swallowed whole with water as soon as the symptoms of your migraine headache appear, although they may be taken at any time during a migraine headache attack.

- How long to use it

Continue taking Imigran FD for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

It is important to keep to the recommended dose. If you accidentally exceed the maximum daily dose contact your doctor or pharmacist immediately. Take the packaging with you so as they can identify what has been taken.

**While you are using it**

- Things you must do

Use your medicine as your doctor has told you. The label on it will usually tell you how much to use and how often. If you are not sure, ask your doctor or pharmacist.

Imigran FD should only be used after the onset of a migraine attack. Do not use Imigran FD to

try and prevent the onset of a migraine.

This leaflet does not tell you everything about your medicine. If you have any questions or are not sure about anything then ask your doctor or pharmacist.

- Things you must not do

Do not use any medicines that contain ergotamine or dihydroergotamine for 6 hours after using Imigran FD. If you are unsure about any medicines you are taking, ask your doctor or pharmacist.

Do not use Imigran FD for at least 24 hours after you have taken any medicines that contain ergotamine or dihydroergotamine.

If you have any difficulties or do not understand the instructions ask your doctor or pharmacist.

This medicine is for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

- Things to be careful of

This medicine is not suitable for children or elderly patients (over 65 years).

Imigran FD or your migraine itself may make you drowsy so you should not drive or operate machinery if you are affected.

A small number of people find their migraine begins to get better starting 30 minutes after dosing using Imigran FD Fast Disintegrating Tablet (FD) 50 mg and starting 20 minutes after dosing using Imigran FD (FD) 100 mg. By 2 hours most people will experience relief using either dosage.

Patients with swallowing difficulties may choose to disperse a tablet in a small amount of water before administration. Sumatriptan fast disintegrating tablets dispersed in water have a bitter taste.

### Side Effects

Like all medicines, Imigran FD can have side effects.

Some people can be allergic to medicines. If you have any of the following symptoms soon after using Imigran FD stop taking this medicine and tell your doctor immediately.

- Sudden wheeziness or chest tightness.
- Swelling of eyelids, face or lips.
- Seizures/fits.
- Lumpy skin rash or "hives" anywhere on the body.
- Lower abdominal pain and/or severe rectal bleeding.

If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

Other symptoms you may experience include:

- Unusual sensations including numbness, tingling and feeling hot/cold.
- Pain, heaviness or pressure in any part of the body including the chest and throat.

These symptoms may be intense but generally pass off quickly. If the symptoms continue and become severe, tell your doctor immediately, this may be a sign of a heart attack. Do not use any more Imigran FD until you have spoken to your doctor about your symptoms.

You may also experience the following:

- Tiredness or sleepiness.

- Dizziness or feeling light-headed.
- Unusually slow or fast heartbeats, or a feeling of irregular and/or forceful heartbeats.
- Shortness of breath.
- Feelings of weakness.
- Feeling sick or vomiting.
- Flushing (redness of the face lasting for a short time).
- Visual disturbances.
- Loss of normal colouration in the fingers and toes.
- Shaking or tremors.
- Uncontrolled movements.

If any of these symptoms occur you do not have to stop using your medicine but tell your doctor when you next visit them. However, if you have persistent purple discoloration of hands or feet, you should stop your medicine and consult your doctor immediately.

If you have a blood test to check how your liver is functioning and have used Imigran FD, tell your doctor as it may affect the results.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

### Storage and Disposal of IMIGRAN FD

#### - Storage

Keep out of the reach and sight of children.

Do not use after the expiry date written on the pack.

Store below 30°C

#### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

#### - What it looks like

Imigran FD tablets 50 mg are pink film coated and debossed with 'GS 1YM' on one face and '50' on the other.

Imigran FD Tablets 50mg is available in packs of 2 tablets.

#### - Ingredients

- Active ingredient(s)

The active substance is sumatriptan succinate.

- Inactive ingredient(s)

Calcium hydrogen phosphate, Microcrystalline cellulose, Sodium hydrogen carbonate, Croscarmellose sodium, Magnesium Stearate, Purified Water, Hypromellose, Titanium dioxide, Triacetin, Iron oxide red.

#### - MAL number

Imigran FD Tablet 50mg

- MAL06051329AZ

### Manufacturer

GlaxoSmithKline  
Pharmaceuticals S.A,  
189, Grunwaldzka Street 60-322  
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### Product Registration Holder

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