

IMIGRAN® FDT tablets

(Sumatriptan succinate)

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start taking *Imigran FDT* tablets.

This leaflet answers some common questions about *Imigran FDT*. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking *Imigran FDT* against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is Imigran FDT used for?

Imigran FDT contains the active ingredient sumatriptan succinate. This medicine belongs to a group of drugs called serotonin agonists.

Imigran FDT is used to relieve a migraine attack. It should not be used to prevent migraine attacks from occurring. *Imigran FDT* may be used for migraine headaches with or without what is known as 'aura'.

It is thought that migraine headache is due to widening of certain blood vessels in the head.

Imigran FDT works by making those vessels normal again and eases the symptoms of migraine.

Your *Imigran FDT* does not work in other types of headache which are not a migraine.

Imigran FDT is not addictive.

Before you take Imigran FDT

Do not take if:

You must not take *Imigran FDT* if:

- **you have ever had an allergic reaction to sumatriptan succinate (See "Side-Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").**
- **you have or have had:**
 - heart disease or heart attack
 - shortness of breath, pain or tightness in the chest, jaw or upper arm
 - peripheral vascular disease (pain in the back of the legs) or are prone to cold, tingling or numb hands and feet
 - Prinzmetal's angina (an uncommon form of angina where pain is experienced at rest rather than during activity)
 - angina
 - high blood pressure
 - stroke
 - severe liver disease.

- **you have taken any other medicines for migraine in the last 24 hours, such as:**
 - ergotamine (eg Cafergot)
 - dihydroergotamine (eg Dihyergot)
 - methysergide (eg Deseril)
 - naratriptan (eg Naramig)
 - zolmitriptan (eg Zomig).
- **you have taken any of these medicines in the last two weeks:**
 - Monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression.
 - SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin-Noradrenaline Reuptake Inhibitors) used to treat depression.
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines, including any that contain sulphur (eg sulphonamide antibiotics)**
- **you are taking or have taken any other medicines in the last two weeks, including medicines you buy without a prescription, particularly herbal preparations containing St John's Wort and medicines prescribed for depression**
- **you are breastfeeding, pregnant or trying to become pregnant.**

- **you have or have had medical conditions like:**
 - liver or kidney problems
 - heart problems. Risk factors including high blood pressure, even if it is under control, high blood cholesterol levels, a family history of heart problems, obesity, diabetes, you are male and over 40 years of age, you are female and have undergone menopause or you smoke
 - epilepsy seizures or fits, or been told that you are prone to this problem
 - stroke
- **you are under 18 or over 65 years of age.**
- **you think that this headache is different and worse than your usual migraine.**
- **you have difficulty moving one side of your body when you have the migraine headache.**

How do I take Imigran FDT?

Take your medicine as your doctor has told you. The label on the pack will tell you how many tablets to take and how often you should take them. If you do not understand what you should do, ask your doctor or pharmacist.

How much to take

The recommended starting dose for adults aged 18 to 65 is 50 mg, however you may need to have your dose of *Imigran FDT* increased to 100 mg. Your doctor will tell you which dose is right for you.

If the first *Imigran FDT* helps your migraine, but the migraine comes back later, you may take another *Imigran FDT*. Do not take more than 300 mg of *Imigran FDT* in any twenty-four hour period. Six pink (50 mg strength) or three white (100 mg strength) FDT contain 300 mg.

Do not take more *Imigran FDT*, or any other form of *Imigran* if the first dose has not provided any relief from your symptoms. You may take your usual headache relief medication provided it does not contain ergotamine or methysergide. If you are not sure what to do, ask your doctor or pharmacist.

If your migraine is not relieved by *Imigran*, you may use *Imigran FDT* on another occasion to treat another migraine attack. Provided there are no side effects, you can use *Imigran FDT* to treat at least three separate migraine attacks before you and your doctor decide this medicine is ineffective for you.

How to take it

Imigran FDT should be swallowed with a drink of water. Do not crush or chew the tablet as it has a bitter taste.

When to take it

It is best to take your *Imigran FDT* -

- a) when the migraine headache begins; or
- b) when other symptoms of the migraine begin, such as nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you take your tablet later during the migraine attack it will still work for you. Do not take your *Imigran FDT* before the above symptoms occur.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too many *Imigran FDT*, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Imigran FDT

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Tell your doctor or pharmacist that you are taking *Imigran FDT* if you are about to be started on any new medicines.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

As with many other medicines, *Imigran FDT* may cause drowsiness in some people.

Be careful driving or operating machinery until you know how *Imigran FDT* affect you.

If you use *Imigran FDT* too often, it may make your headache worse. If this happens, your doctor may tell you to stop taking *Imigran FDT*.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking *Imigran FDT*, even if the problem is not listed below.

Like other medicines, *Imigran FDT* can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor if you experience any of the following after taking *Imigran FDT*:

- pain, tingling, heat or flushing in any part of the body
- feeling of sleepiness, dizziness or tiredness
- nausea (feeling sick) or vomiting.
- a change in blood pressure.
- feeling of faintness.
- problems with your eyesight.
- pain in the lower tummy and bloody diarrhoea (ischaemic colitis).
- shaking or tremors,
- uncontrolled movements,
- shortness of breath.

Tell your doctor immediately, or seek urgent medical attention, and do not take any more *Imigran FDT* if you:

- feel heaviness, pressure or tightness in any part of the body including the chest or throat.
- feel irregular heart beats.
- have a fit or convulsion.
- have wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting. These could be a symptom of an allergic reaction.
- have persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold.

These side effects are likely to be serious. Stop taking *Imigran FDT* and seek medical attention straight away.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store *Imigran FDT*?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep *Imigran FDT* in the blister pack in a cool, dry place where it stays below 30°C.

Do not leave them in a car, on a window sill or in a bathroom.

Keep *Imigran FDT* in their pack until time to take.

Return any unused or expired medicine to your pharmacist.

Product description

What Imigran FDT look like

Imigran FDT comes in two strengths:

- *Imigran FDT* 100 mg are white, triangular shaped, biconvex tablets debossed with 'GS YE7' on one face and '100' on the other. A box contains 2 tablets.
- *Imigran FDT* 50 mg are pink, triangular shaped, biconvex tablets debossed with 'GS 1YM' on one face and '50' on the other. A box contains either 2 or 4 tablets.

Imigran FDT have a film coating to protect the tablet and this gives the colour.

Ingredients

Each *Imigran FDT* tablet contains the active ingredient sumatriptan (present as sumatriptan succinate) 50mg or 100mg.

Imigran FDT also contains: calcium hydrogen phosphate anhydrous, cellulose - microcrystalline, sodium bicarbonate, croscarmellose sodium and magnesium stearate.

- *Imigran FDT* 100 mg are coated with Opadry white OY-S-7322.
- *Imigran FDT* 50 mg are coated with Opadry YS-1-1441-G.

Supplier

Your *Imigran FDT* are supplied by:
Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards, NSW 2065
Australia

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

This leaflet was prepared on 20 October 2009.

The information provided applies only to: *Imigran FDT* tablets.

Imigran FDT is a registered trade mark of Aspen Global Incorporated.

- *Imigran FDT* tablets, Sumatriptan (as succinate) 100 mg: AUST R 106715
- *Imigran FDT* tablets, Sumatriptan (as succinate) 50 mg: AUST R 106714

©2003 Aspen Global Incorporated.

Version 2.0