

PACKAGE LEAFLET: INFORMATION FOR THE USER

MIGRAITAN® 50mg FILM-COATED TABLETS
(Sumatriptan)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep the 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 is MIGRAITAN® and what is it used for
2. What you need to know before you take MIGRAITAN®
3. How to take MIGRAITAN®
4. Possible Side Effects
5. How to store MIGRAITAN®
6. Contents of the pack and other information

1. What is MIGRAITAN® and what is it used for

The name of your medicine is MIGRAITAN® 50mg Film-Coated Tablets. The name is referred to as MIGRAITAN® in the entire leaflet.

- **MIGRAITAN® is used to treat migraine.** These tablets contain Sumatriptan succinate as active substance, which belong to a group of medicines called 'triptans' (5HT₁-receptor agonists).
- **Migraine symptoms** may be caused by the temporary swelling of blood vessels in the head due to a temporary imbalance in the body's chemicals. The tablets are believed to work on this imbalance and reduce the swelling of these blood vessels. The tablets help to take away the headache and other symptoms of a migraine attack such as feeling sick (nausea) and sensitivity to light and sound.

2. What you need to know before you take MIGRAITAN®**Do not take MIGRAITAN®:**

- if you are allergic to Sumatriptan or any of the other ingredients of this medicine (listed in section 6).
- if you have or have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart related symptoms such as shortness of breath or pressure over the chest.
- if you have problems with the blood circulation to your hands and feet (peripheral vascular disease).

- if you have had a stroke/cerebral infarction, also described as an "attack" or cerebral haemorrhage (CVA; cerebrovascular accident).
- if you have had a temporary disturbance of the blood supply to the brain that left little or no residual symptoms (TIA).
- if you have severe liver function impairment.
- if you have high blood pressure.
- if you are taking drugs containing ergotamine or ergotamine derivatives (migraine drugs such as methysergide) or other triptans (5 hydroxytryptamine (5HT₁) receptor agonists, such as almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan or zolmitriptan etc.). These must not be taken at the same time as Sumatriptan (see also "Other medicines and MIGRAITAN®").
- if you are currently taking MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease). Sumatriptan must not be used within two weeks of discontinuation of therapy with MAO inhibitors. See also "Other medicines and MIGRAITAN®" below.

Warnings and Precautions**Talk to your doctor or pharmacist before taking MIGRAITAN® if:**

- you are diabetic, especially if you are a woman past the menopause or a man over 40 years. The doctor should examine you first.
- you are a heavy user of tobacco or products containing nicotine (patches or chewing gum), especially if you are a woman past the menopause or a man over 40 years. The doctor should examine you first.
- you have liver or kidney impairment. The doctor might adjust the dose
- you have ever suffered seizures/fits (convulsions) or have a predisposition to seizures/fits (convulsions); MIGRAITAN® can cause seizures/fits. MIGRAITAN® might increase the risk of seizures.
- you are hypersensitive to certain antibiotics (sulphonamides). You may experience an allergic reaction after taking MIGRAITAN®. Caution is advisable.
- you use herbal products containing St John's Wort (*Hypericum perforatum*). Side effects may occur with greater frequency.

MIGRAITAN® must only be used if a diagnosis of "migraine" has been clearly established in your case and other factors have been excluded. Certain forms of migraine cannot be treated with MIGRAITAN®.

After taking MIGRAITAN® you may feel pain in your chest and a feeling of pressure for a short time. This can be quite intensive and may radiate up towards your throat. In very rare cases this may be caused by effects on your heart. Therefore, if the symptoms do not disappear, contact your doctor. Overuse of MIGRAITAN® may cause chronic, daily headache or worsened headache. Ask your doctor if you think that this is the case for you. It may be necessary to discontinue the treatment with MIGRAITAN® in order to correct the problem.

Other Medicines and MIGRAITAN®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

An interaction means that medicines used at the same time can influence the effect(s) and/or side effect(s) of each other. The following comments may also apply to medicines that you have used any time in the past or are to use in the near future.

- medicines containing ergotamine (migraine drugs) or other triptans. These must not be taken at the same time as MIGRAITAN® (see "Do not take MIGRAITAN®"). After taking medicines containing ergotamine, you are advised to wait at least 24 hours before taking Sumatriptan. After taking Sumatriptan you are advised to wait at least 6 hours before taking medicines containing ergotamine and atleast 24 hours before taking medicines containing other triptans.
- MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease). MIGRAITAN® must not be taken within two weeks after stopping use of MAO inhibitors.
- Use of triptans with antidepressant drugs like Selective serotonin reuptake inhibitors (SSRI) and Serotonin - nor epinephrine reuptake inhibitors (SNRI) may cause serotonin syndrome (a combination of symptoms that may include confusion, hallucination, restlessness, sweating, muscle spasms, and tremors). If you experience these symptoms please tell your doctor.
- There is a risk that concomitant use of MIGRAITAN® and lithium (for manic depressive (bipolar) disorders) may cause serotonin syndrome.

Please note that the above medicines may be known to you by other names, often the brand names. In this section only the active ingredient or therapeutic group of the medicine is given, and not the brand name. Always thoroughly check the pack and information leaflet of the medicines you are already using for the active ingredient or therapeutic group of that medicine.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

MIGRAITAN® should be used during the pregnancy only if the potential benefit to the mother outweighs the potential risk to the unborn child and no other appropriate treatment option is available.

Breast-feeding

MIGRAITAN® passes in to breast milk. You are advised not to breast-feed within 12 hours after taking Sumatriptan. Do not feed your child with milk expressed during this period.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been

performed. Drowsiness may occur as a result of migraine or its treatment with sumatriptan and this may influence the ability to drive and to operate machinery.

MIGRAITAN® contains Lactose

- If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take MIGRAITAN®

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

Dosage:

Adults:

The recommended dose is 50mg Sumatriptan. Some patients may need to take a dose 100mg Sumatriptan.

Children under 18 and adults over 65

Do not take this medicine if you are under 18 or over 65 and have migraine symptoms. Talk to your doctor.

Method of administration:

Swallow each tablet whole with a glass of water, preferably as soon as possible after onset of the migraine attack.

Duration of treatment:

If symptoms are not reduced after the first dose, you may not take a second dose for the same attack. In the event of a subsequent attack, sumatriptan can be taken again.

If, after the first dose, your symptoms are reduced, but then return, you may take a second dose within 24 hours, provided you wait at least 2 hours between doses.

You must not take more than 300mg of Sumatriptan in any 24-hour period.

The recommended dose must not be exceeded.

If you take more MIGRAITAN® Tablets than you should

Contact your doctor or nearest (A&E) immediately. Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions: 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 MIGRAITAN®, don't take anymore. Contact your doctor straight away.

Common (may affect up to 1 in 10 people)

- Feeling dizzy, drowsy or warm, sensory disturbance
- Transient increase in blood pressure soon after treatment. Flushing
- Breathlessness
- Feeling sick, Vomiting
- Feeling of heaviness, tightness, pain or pressure in any part of the body including throat or chest. Myalgia.
- Feeling pain, sensation of heat or cold.
- Feeling of weak and fatigue

Uncommon (may affect up to 1 in 100 people)

- Somnolence

Very rare (may affect up to 1 in 10,000 people)

- Disturbances in liver function tests

Not known (frequency cannot be estimated from the available data)

- Allergic/hypersensitivity reactions, varying from skin reactions to rare cases of anaphylaxis (sharp fall in blood pressure, pallor, agitation, weak and rapid pulse, clammy skin, impaired consciousness). If you think that Sumatriptan is causing an allergic reaction, **stop taking it and contact your doctor straight away.**
- Fits/seizures
- Tremor
- Dystonia
- Impaired vision, e.g. double vision, flickering and sometimes loss of vision with permanent impairment. Visual disturbances can also occur as a result of the migraine attack itself.
- Slow heart beat, fast heart beat, irregular heart beat, palpitations.
- Reduced blood flow to the arms and legs and consequent pallor or blurring to the fingers and toes.
- Angina (pain in the chest, often brought on by exercise), heart attack or spasm of the blood vessels of the heart, transient ischaemic ECG changes. If you notice chest pain or shortness of breath after taking Sumatriptan, **contact your doctor and do not take any more.**
- Spasm of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhoea. If this happens, **contact your doctor and do not take any more MIGRAITAN®.**
- Diarrhoea
- Fall in blood pressure
- Stiff neck
- Joint pain
- Anxiety
- Increased perspiration

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MIGRAITAN®

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use this medicine after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not 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 MIGRAITAN® Film-coated Tablets contain:

- Each film-coated tablet contains 50mg of the active ingredient Sumatriptan (as succinate)
- The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171), purified talc, Macrogol, iron oxide yellow E172 and iron oxide red E172.

What MIGRAITAN® Film-coated Tablets look like and contents of pack

MIGRAITAN® 50mg Film-coated Tablets are peach coloured and capsule shaped, biconvex film-coated tablets with "BL" embossing on one side and plain on the other side.

Each pack of 50mg strength contains 2 tablets in blister strips.

Marketing Authorisation Holder and Manufacturer

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