

PACKAGE LEAFLET: INFORMATION FOR THE USER

MIGRAITAN® 50mg FILM-COATED TABLETS

(Sumatriptan succinate)

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 MIGRAITAN® is and what it is 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 MIGRAITAN® is and what it is used for

- **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 natural 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. They start to relieve migraine headache about 30 minutes after you take them.

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) or to sulfonamide antibiotics
- unless you suffer from migraines (a doctor or pharmacist needs to confirm this)
- if you are trying to prevent a migraine attack – only take it when your migraine headache begins
- until you are sure this is a migraine and not just a headache
- if you are under 18 or over 65
- if you have heart problems including heart failure, a previous heart attack, angina (chest pain), or an irregular heartbeat.

- if you have had a stroke or a mini-stroke (also called a transient ischaemic attack or TIA)
- if you have high blood pressure or are being treated for it
- if you have kidney or liver disease
- if you have epilepsy or are prone to seizures (fits)
- if you have circulation problems in your legs and have cramp-like pains in your legs when you walk, or if your doctor has told you that you suffer from peripheral vascular disease
- if your doctor diagnosed one of the rare forms of migraine (hemiplegic; basilar or ophthalmoplegic migraine)

Do not take Migraitan® with these medicines:

- **antidepressants called monoamine oxidase inhibitors (MAOIs)**, for example, phenelzine, isocarboxazid, tranylcypromine. If you take these or if you have taken them in the last two weeks, don't take Migraitan®. (If you are taking antidepressants and are not sure what they are, talk to your doctor or pharmacist.)
- **certain other migraine treatments.** Do not take Migraitan® if you have taken a medicine containing a triptan (including other sumatriptan-containing products, zolmitriptan, rizatriptan, naratriptan) or medicines containing ergotamine or methysergide within the last 24 hours. After taking Migraitan® you should wait at least 24 hours before taking a medicine containing a triptan (including other sumatriptan-containing products, zolmitriptan, rizatriptan, naratriptan) or at least 6 hours before taking a medicine containing ergotamine or methysergide.

Warnings and Precautions

Your pharmacist will have checked the points listed below to make sure this medicine is right for you.

- if you have three or more risk factors:
 - you are a man over 40, or a woman who has had the menopause
 - you are very overweight
 - you are a regular smoker (more than 10 cigarettes a day)
 - you have diabetes
 - you have high cholesterol
 - you have a close relative who developed early heart disease – either your father or brother developed heart disease before the age of 55, or your mother or sister developed heart disease before the age of 65.

If three or more of the points above apply to you, you may be at higher risk of heart disease – see your doctor without taking Migraitan®. If you are not sure, your pharmacist or doctor can help.

- if your headaches usually last longer than 24 hours, or become more frequent
- if you generally have four or more migraine attacks each month
- if you do not recover completely in between your migraine attacks
- if you are over 50 and this is your first headache of this type

- if your migraine attacks get worse or become more frequent, or your symptoms change
- if your migraine includes symptoms such as
 - weakness on one side of your body
 - clumsy and un-coordinated movements
 - reduced level of consciousness
 - a recent rash with a headache
 - double vision
 - tinnitus (ringing in the ears)
 - seizure (fit)-like movements

If any of the points in this list apply to you, and you haven't already talked to a pharmacist or doctor about these, get their advice before taking Migraitan®.

Other medicines and MIGRAITAN®

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

Some antidepressants and some migraine medicines mean you can't take Migraitan®.

See above under "*Do not take Migraitan® with these medicines.*"

- **Antidepressants called SSRIs or SNRIs** (Selective Serotonin Reuptake Inhibitors or Serotonin Noradrenaline Reuptake Inhibitors) – for example citalopram, fluoxetine, paroxetine, fluvoxamine, sertraline, duloxetine and venlafaxine. Using Migraitan® with this group of medicines can make some side effects more likely. If you experience uncontrolled twitching or jerking of the muscles, sweating, and/or changes in mental status such as confusion or agitation after using Migraitan®, tell a doctor straight away. If you are not sure if you are taking an SSRI or SNRI, check with your doctor or pharmacist.
- **Tricyclic antidepressants** – for example doxepin and amitriptyline. Using Migraitan® with this group of medicines may make some side effects more likely. If you are worried, talk to your pharmacist or doctor.
- **Certain types of contraceptive pill** – women with migraine who are taking a combined oral contraceptive pill have a higher risk of stroke. If you are taking these contraceptive pills and you only recently started to have migraines (in the last 3 months), or your migraine symptoms have got worse, or you have migraine with aura (attacks that start with disturbed vision or a change in sensation such as 'pins and needles'), **talk to your doctor.**
- **St John's wort** (a herbal remedy – *Hypericum perforatum*) – using St. John's Wort with Migraitan® may increase the likelihood of you suffering side effects. If you are worried, talk to your pharmacist or doctor.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take Migraitan® unless you've agreed it with your doctor.

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Driving and using machines

Either the symptoms of migraine or your medicine may make you drowsy. If you are affected, do not drive or 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.

Adults aged 18 to 65

- Take one tablet as soon as possible at the first signs of a migraine headache.
- If your symptoms start to come back, you can take a second tablet after 2 hours. You must leave at least 2 hours after the first tablet.

Swallow each tablet whole with water.

Don't take more than two tablets in 24 hours.

Don't take more than two tablets for the same attack.

If the first tablet does not provide any relief:

Don't take a second tablet.

If you use Migraitan® too often, it may make your headaches worse. If this happens you should consult your doctor or pharmacist, who may tell you to stop taking Migraitan®.

You should wait at least 24 hours before taking a medicine containing a triptan (including other sumatriptan-containing products, zolmitriptan, rizatriptan, naratriptan) or at least 6 hours before taking a medicine containing ergotamine or methysergide.

Talk to your doctor before you take any more Migraitan® tablets. Getting no relief at all from Migraitan® may mean that you do not have migraine.

Migraitan® is only to relieve migraine symptoms.

Don't take it to try to prevent an attack. Don't take it until you are sure it's a migraine and not just a headache.

If you take more Migraitan® than you should

Taking too much could make you ill. Keep to the dose and follow the instructions. If you take too many tablets, tell a doctor straight away. Take the box and this leaflet with you.

If you forget to take Migraitan®

Do not take a double dose to make up for a forgotten dose.

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.

Some people may be allergic to these tablets.

Signs of allergy include rash; wheezing; breathlessness; swollen eyelids, face or lips; complete collapse.

If you get any of these symptoms soon after taking Migraitan®, don't take any more. Tell a doctor straight away; Take the packaging and this leaflet with you.

Very rare side effects: tell doctor as soon as possible

(affect less than 1 in 10,000 people)

- Pain in the lower left side of the stomach and bloody diarrhoea.
- Pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress (Raynaud's phenomenon).
- Seizures/fits.

Common side effects: tell doctor if long or severe

(affect less than 1 in 10 people)

These effects usually develop within 30 minutes of treatment, and are not usually troublesome. They may be intense, but they do not last long.

- Heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feelings of tingling or warmth.
- Unusual sensations including reduced sensation or numbness and feeling hot/cold.

If these effects continue for more than two hours, or are particularly severe (especially the chest pain), tell your doctor straight away. In a very small number of people, these symptoms can be caused by a heart attack.

Other side effects: speak to a pharmacist if you are worried

Very rare (affect less than 1 in 10,000 people)

- Visual disturbances – although this is often part of the migraine attack itself.
- Uncontrolled movements, shaking or tremors.
- Heart beat may go faster, slower or change rhythm.
- Angina or heart attack.
- Liver function changes. If you have a blood test to check your liver function tell your doctor or nurse that you are taking Migraitan®.

Common (affect less than 1 in 10 people)

- Feeling sick (nauseous) or being sick (vomiting) – although this is often part of the migraine attack itself.
- Tiredness or drowsiness.
- Dizziness, feeling weak, or getting hot flushes.
- Feeling faint (blood pressure may go up or down).
- Shortness of breath.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.

This medicine is available in packs of 2,6 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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MIGRAITAN® 50mg Film-coated Tablets; PL 17907/0240

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To request a copy of this leaflet in braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.