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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)
- **If you have a heart problem** such as narrowing of the arteries (*Ischaemic heart disease*) or chest pains (*angina*), or have already had a heart attack
- **If you have circulation problems in your legs** that cause cramp-like pains when you walk (*peripheral vascular disease*)
- **If you have had a stroke or a mini-stroke** (*also called a transient ischaemic attack or TIA*)
- **If you have high blood pressure.** You may be able to use **Migraitan®** if your high blood pressure is mild and is being treated
- **If you have serious liver disease**
- **With other migraine medicines**, including those which contain ergotamine, or similar medicine such as methysergide maleate; or any triptan or 5HT₁ agonist (such as naratriptan or zolmitriptan)

- **With any of the following anti-depressants:**
MAOIs (*monoamine oxidase inhibitors*) or if you have taken an MAOI in the last 2 weeks

For children under 18 years of age.

If any of these apply to you: **Tell your doctor, and don’t use Migraitan® tablets.**

Warnings and precautions

Talk to your doctor or pharmacist before using **Migraitan®**.

If you have any extra risk factors

- **If you are a heavy smoker, or using nicotine replacement therapy**, and especially
- **If you are a man aged over 40**, or
- you are very overweight
- 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 you are a woman who has been through the menopause.**

In very rare cases, people have developed serious heart conditions after using **Migraitan®** tablets, even though they had no signs of heart disease before. If any of the points above applies to you it could mean you have a greater risk of developing heart disease – so: tell your doctor so that your heart function can be checked before **Migraitan®** is prescribed for you.

- If you have a history of fits (seizures) or if you have other conditions which might make it more likely that you’ll have a fit – for example, a head injury or alcoholism: tell your doctor so that you can be supervised more closely.
- If you have had high blood pressure **Migraitan®** may not be suitable for you: tell your doctor or pharmacist before using **Migraitan®**.
- If you have liver or kidney disease: If either of these apply to you: tell your doctor or pharmacist before using **Migraitan®**.
- If you have an intolerance to some sugars: tell your doctor so that you can be supervised more closely.
- If you are allergic to antibiotics called sulphonamides. If so, you may also be allergic to **Migraitan®**. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide: tell your doctor or pharmacist before using **Migraitan®**.
- If you are taking anti-depressants called SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors). Tell your doctor or pharmacist before taking **Migraitan®**. Also see Other medicines and **Migraitan®**, below.
- If you use **Migraitan®** frequently: Using **Migraitan®** too often may make your headaches worse. Tell your doctor if this applies to you. He or she may recommend you to stop using **Migraitan®**.
- If you feel pain or tightness in your chest after you use **Migraitan®**. These effects may be intense but they usually pass quickly. If they don’t pass quickly, or they become severe: get medical help immediately. Section 4 (overleaf) has more information about these possible side effects.

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

The use of buprenorphine together with **Migraitan®** can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and **Migraitan®**”).

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. This includes any herbal products or medicines you’ve bought without a prescription.

Some medicines must not be taken with **Migraitan®** and others may cause adverse effects if they are taken with **Migraitan®**. **You must tell your doctor if you are taking:**

- ergotamine also used to treat **migraine**, or similar medicines such as methysergide (see section 2 Don’t use **Migraitan®**). Don’t use **Migraitan®** at the same time as these medicines. Stop taking these medicines at least 24 hours before using **Migraitan®**. Don’t take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using **Migraitan®**.
- **other triptans/5-HT₁ receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine**, (see section 2 Don’t use **Migraitan®**). Don’t use **Migraitan®** at the same time as these medicines. Stop taking these medicines at least 24 hours before using **Migraitan®**. Don’t take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using **Migraitan®**.
- **MAOIs** used to treat depression. Don’t use **Migraitan®** if you have taken these in the last 2 weeks.
- **SSRIs and SNRIs** used to treat **depression**. Using **Migraitan®** with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heartbeat and shaking). Tell your doctor immediately if you are affected in this way.
- **St John’s Wort (Hypericum perforatum)**. Taking herbal remedies that contain St John’s Wort together with **Migraitan®** may make side effects more likely.
- Buprenorphine, naloxone: These medicines may interact with **Migraitan®** and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

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 for advice before taking this medicine. There is only limited information about the safety of this medicine for pregnant women, though up till now there is no evidence of any increased risk of birth defects. Your doctor will discuss with you whether or not you should use this medicine while you are pregnant

SAME SIZE ARTWORK
430 x 210 mm
Front

FLAT DIMENSION = 210 x 430mm
FOLDED DIMENSION = 210 x 27mm

210 mm

- Don’t breast-feed your baby for 12 hours after using this medicine. If you express any breast milk during this time, discard the milk and don’t give it to your baby.
Some breastfeeding women report breast and/or nipple pain after use of sumatriptan. The pain is usually temporary and disappears in 3 to 12 hours.

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.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

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 symptoms may be caused by the migraine itself.

Allergic reaction: 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 use any more. Contact a doctor straight away.**

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

- 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)

- Pain, heaviness, pressure or tightness in the chest, throat or other parts of the body, or unusual sensations, including numbness, tingling and warmth or cold. These effects may be intense but generally pass quickly.

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

- Get medical help urgently. In a very small number of people these symptoms can be caused by a heart attack.

Other common side effects include:

- 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.
- Temporary increase in blood pressure
- Aching muscles.

Other rare side effects include:

- Breast pain

Some patients may get the following side effects but it is not known how often they occur:

- Seizures/fits, tremors, muscle spasm, neck stiffness
- Visual disturbances such as flickering, reduced vision, double vision, loss of vision, and in some cases even permanent defects (although these may be due to the migraine attack itself)
- Heart problems, where your heartbeat may go faster, slower or change rhythm, chest pains (angina) or heart attack
- Pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress (Raynaud’s phenomenon)
- Feeling faint (blood pressure may go down)
- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis)
- Diarrhoea
- If you had a recent injury or if you have inflammation (like rheumatism or inflammation of the colon) you may experience pain or pain worsening at the site of injury or inflammation.
- Pain in the joints
- Feeling anxious
- Difficulty swallowing
- Excessive sweating

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 Website: 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, capsule shaped, biconvex film-coated tablets with “BL” debossed 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

Name and address: Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road, Berkhamsted,
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Manufacturer

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

This leaflet was last revised in August 2025

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, email) above.

V29 18-08-25 D0

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