

Pregnancy, breast-feeding and fertility

- If you are pregnant, 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
- 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.

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.

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 (Raynaudâ•™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 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, 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

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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.