

Package leaflet:  
Information for the patient

## Numark Migraine Relief 50mg Tablets

(Sumatriptan)

This medicine is used to relieve migraine attacks (with or without an aura), in people who have been diagnosed with migraine.

- This medicine is for use by adults aged between 18 and 65 years.
- Do not take this medicine:**
  - There are some people who should not use this medicine. To find out if you are one of them see section 2.
- Speak to your doctor or pharmacist:**
  - If you suffer from any of the conditions mentioned in section 2. See section 2.
  - If you are taking any other medicines. See section 2.
- Follow the dosage instructions carefully.**
  - These are shown in the dosage table. See section 3.

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

### What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side-effects
5. How to store this medicine
6. Contents of the pack and other information
7. Information on migraine

### 1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

This is a medicine which is used to relieve migraine attacks (with or without an aura), in those people who have been diagnosed with migraine. The tablets contain sumatriptan, which belongs to a group of medicines called *triptans* (5-HT<sub>1</sub> receptor agonists). The tablets are believed to work on the imbalance of the body's natural chemicals which have caused the blood vessels in the head to temporarily swell. The tablets help to relieve the headache and other symptoms of a migraine, such as feeling sick and sensitivity to light and sound. They start to relieve the headache within about 30 minutes of taking them.

This medicine is for use in adults between the age of 18 and 65 years.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE THIS MEDICINE

This medicine is suitable for most adults, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

#### Do not take this medicine:

- If you have **not been diagnosed with migraine** by a doctor or pharmacist.
- To try and prevent a migraine attack** – only take it when your headache begins.
- If you have ever had a **bad reaction to triptans, sulphonamide antibiotics or any of the ingredients** in this medicine (see section 6).
- If you have **heart problems** including **heart failure, a previous heart attack, angina (chest pains) or irregular heart beat**.
- 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 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 you have been told by your doctor that you have one of the **rare types of migraine** known as **hemiplegic, basilar or ophthalmoplegic migraine**.

- If you are taking any of the following medicines:
  - Ergotamine or derivatives of ergotamine** (drugs which are also used to treat migraines such as *methysergide*).
  - Triptans (5-HT<sub>1</sub> receptor agonists)** (drugs which are also used to treat migraines such as *zolmitriptan, rizatriptan and naratriptan* or any other *sumatriptan* containing products).
  - Monoamine Oxidase Inhibitors (MAOIs)** (drugs used to treat mood disorders) either now or within the past two weeks.

If any of these apply to you, **get advice from a doctor or pharmacist without using this medicine.**

### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If your **headache normally lasts for longer than 24 hours**.
- If your **pattern of symptoms has changed**, or if your migraine attacks have become **more frequent, are worse than usual and last longer**.
- If you do not recover completely between attacks.
- If you have **four or more migraine attacks each month**.
- If you are **over 50 and this is your first headache of this type**.
- If your **migraine includes symptoms** such as:
  - Weakness on one side of your body.
  - Double vision.
  - Clumsy and uncoordinated movements.
  - Tinnitus (ringing in the ears).
  - Reduced level of consciousness.
  - Seizure (fit) - like movements.
  - A recent rash with a headache.

If any of these bullet points apply to you now, or in the past, talk to a doctor or pharmacist before taking this medicine.

### Other medicines and Numark Migraine Relief 50mg Tablets

Talk to your doctor before taking this medicine if you are taking any of these medicines:

- Antidepressants:
  - Monoamine Oxidase Inhibitors (drugs used to treat mood disorders) - see Do not take this medicine section.
  - Tricyclic Antidepressants (drugs used to treat mood disorders including doxepin and amitriptyline).
  - SSRIs and SNRIs
    - Selective Serotonin Reuptake Inhibitors (SSRIs) (drugs used to treat mood disorders including citalopram, fluoxetine, fluvoxamine, paroxetine and sertraline).
    - Serotonin Noradrenaline Reuptake Inhibitors (SNRIs) (drugs used to treat mood disorders including venlafaxine and duloxetine).
- Combined oral contraceptives ("the pill").
- St John's Wort (*hypericum perforatum*) (a herbal medicine).

### Pregnancy and breast-feeding

If you are pregnant, think you are pregnant or you are breast-feeding, do not take this medicine unless your doctor has told you that it is safe to do so.

### 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.

### Numark Migraine Relief 50mg Tablets contains lactose

The tablets contain lactose. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor or pharmacist before taking the tablets.

### Special warnings about this medicine

- Your pharmacist will have checked the points listed below to make sure this medicine is right for you.
- If you are a **man over 40, or a woman who has had the menopause**.
- If you are **very overweight**.
- If you are a **regular smoker** (more than 10 cigarettes a day) or use Nicotine Replacement Therapy (NRT).
- If you have **diabetes**.
- If you have **high cholesterol**.
- If 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 apply to you, you may be at higher risk of heart disease** – see your doctor without taking this medicine. If you are not sure, your doctor or pharmacist can help.

- Prolonged use of any type of painkiller for headaches can make them worse. If your headaches are daily or very frequent or getting worse you should contact your doctor.

### 3 HOW TO TAKE THIS MEDICINE

Check the table overleaf to see how much medicine to take.

- For oral use only.
- Do not use more than the stated dose shown in the table.
- Swallow the tablet whole with a drink of water.

Please turn over >

### Children and adolescents under the age of 18 years

This medicine should not be taken by children and adolescents under the age of 18 years. Contact your doctor.

### Adults aged 18 to 65 years

Age	Dose
<b>Adults aged 18 to 65 years</b>	<ul style="list-style-type: none"> <li>Take one tablet as soon as possible at the first signs of a migraine headache.</li> <li>If your symptoms start to come back you can take a second tablet after 2 hours. <b>You must leave at least 2 hours after the first tablet.</b></li> </ul>
	<ul style="list-style-type: none"> <li>Don't take more than two tablets in 24 hours.</li> <li>Don't take more than two tablets in the same attack.</li> <li>If the first tablet does not provide any relief don't take a second tablet.</li> </ul>

### Adults over the age of 65 years

This medicine should not be taken by adults over the age of 65 years. Contact your doctor.

### Special Warnings whilst taking this medicine

- This medicine is only to relieve migraine symptoms. Don't take it to try to prevent an attack. Don't take them until you are sure it is a migraine and not just a headache.
- If you do not get relief from the pain whilst taking these tablets it may mean that you do not have a migraine and you should talk to your doctor or pharmacist.
- If you are taking antidepressants called SSRIs or SNRIs whilst taking this medicine it can make some side-effects more likely. If you experience weakness and/or lack of coordination, talk to your doctor. If you are not sure if you are taking an SSRI or SNRI, talk to your doctor or pharmacist.
- If you are on the combined pill whilst taking this medicine there is an increased risk of stroke. If your migraines have only begun within the last 3 months or your symptoms have worsened or you have a migraine with an aura (attacks that start with disturbed vision or a change in sensation such as 'pins and needles'), you should contact your doctor.
- Sometimes you can develop chest pain or tightness that may involve the throat. These effects usually occur within 30 minutes, are not usually troublesome and do not last too long, they can however be intense. If they last for more than 2 hours or are very severe you should contact your doctor straight away. You should not take any more of this medicine.

### If you take more Numark Migraine Relief 50mg Tablets than you should

If anyone takes too many tablets, contact your doctor or nearest Accident and Emergency department (Casualty) taking this leaflet with you.

### If you forget to take Numark Migraine Relief 50mg Tablets

You should only take this medicine as required following the dosage instructions above carefully. Do not take a double dose.

### 4 POSSIBLE SIDE-EFFECTS

This product can cause side-effects, like all medicines, although these don't affect everyone and are usually mild.

### If you experience any of the following, stop using the medicine and seek immediate medical help:

- Very rare: (affects less than 1 in 10,000 people)**
  - Allergic reactions: signs of allergy include rash (such as hives); wheezing; breathlessness; swollen eyelids, face or lips; complete collapse
  - Seizures/fits.
  - Pain in the lower left side of your stomach and bloody diarrhoea.
  - Heart problems, including heart attack and heart or chest pains.

### If you experience any of these effects stop using the medicine and talk to your doctor:

- Very rare: (affects less than 1 in 10,000 people)**
  - Bad circulation which is shown by pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress.

### Common: (affects less than 1 in 10 people)

- Heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, breathlessness or feelings of tingling, cold or warmth. These effects usually develop within 30 minutes of treatment, and are not usually troublesome. They may be intense, but they do not last long. If these effects continue for more than two hours, or are particularly severe (especially the chest pain), tell your doctor straight away.

### Other effects which may occur include: Very rare: (affects less than 1 in 10,000 people)

- Visual disturbances - although this is often part of the migraine attack itself.
- Heart beat may go faster, slower or change rhythm.
- Neck stiffness.
- Liver function changes. If you have a blood test to check your liver function, tell your doctor or nurse that you are taking this medicine.
- Heart function changes. If you have an ECG to check your heart function tell your doctor or nurse that you are taking this medicine.

### Common: (affects less than 1 in 10 people)

- Tingling, dizziness, drowsiness, flushing, decreased sensitivity (particularly to touch).
- Feeling sick, sickness.
- Feeling faint as your blood pressure may go up and down.
- Feeling weak or heavy.
- Muscle pain.
- Shortness of breath.

### Side-effects which occur but it is unknown how often:

- Diarhoea.
- Pain in your joints.
- Anxiety.
- Excessive sweating.
- Shaking.
- Abnormal muscle rigidity.

### 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](http://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 THIS MEDICINE

#### Keep this medicine out of the sight and reach of children.

There are no special storage precautions for these tablets.

Do not use your medicine if the pack is damaged, or after the expiry date on the packaging.

### 6 CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Numark Migraine Relief 50mg Tablets contains

The active ingredient in this medicine is: Sumatriptan 50mg base (as sumatriptan succinate).

**Other ingredients are:** Lactose monohydrate, croscarmellose sodium, microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate, hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol, glycerol triacetate, iron oxide red (E172), iron oxide yellow (E172) and iron oxide black (E172).

#### What Numark Migraine Relief 50mg Tablets looks like and contents of the pack

This medicine is available in packs of 2 tablets which are peach coloured, scored oblong shaped film coated tablets marked with "5" and "0".

**Marketing Authorisation holder and manufacturer:** TEVA UK Limited, Eastbourne, BN22 9AG, England.

Text revised: June 2016.

### 7 INFORMATION ON MIGRAINE

Most migraine attacks occur for no apparent reason. However, something may trigger migraine attacks in some people. Triggers can be all sorts of things. For example:

**Diet.** Dieting too fast, irregular meals, cheese, chocolate, red wines, citrus fruits.

**Environmental.** Smoking and smoky rooms, glaring light, VDU screens or flickering TV sets, loud noises, strong smells.

**Psychological.** Stress, anxiety, anger, tiredness, etc.

**Other.** Periods (menstruation), shift work, different sleep patterns, the menopause, some medicines e.g. the Pill.

It may help if you keep a migraine diary. Note down when and where each migraine attack started, what you were doing, and what you had eaten that day. A pattern may emerge, and it may be possible to avoid one or more things that may trigger your migraine attacks.

4005802  
87091-01

THIS IS A REPRESENTATION OF AN ELECTRONIC RECORD THAT WAS SIGNED ELECTRONICALLY AND THIS PAGE IS THE MANIFESTATION OF THE ELECTRONIC SIGNATURE

**Teva Pharmaceuticals Europe B.V**

**1.3.2 mockup-pil-uk-pl-00289-0586-sumatriptan-50mg-tablets-numark**

**APPROVALS**

<b>Signed by</b>	<b>Meaning of Signature</b>	<b>Server Date</b>
Annette Huggett	Regulatory Affairs Approval	23-Jun-2016 12:58:19 PM