

The logo for FORMIGRAN, featuring the brand name in a bold, sans-serif font. To the right of the text is a stylized graphic of a white rectangular object, possibly a tablet, with a vertical line and a shadow effect, set against a dark blue background.

FORMIGRAN® 2.5 mg film-coated tablets

Naratriptan hydrochloride

This medicine is available without prescription. To get the best possible results, FORMIGRAN® must be used as directed. FORMIGRAN® is only suitable for people who know they have a migraine. If you are not sure that you suffer from migraine or if you require further information or advice, please speak to your doctor or pharmacist.

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1. WHAT IS FORMIGRAN® AND WHAT IS IT USED FOR?

FORMIGRAN® tablets contain naratriptan which belongs to a group of medicines called triptans (selective serotonin (5-HT₁) receptor agonists). FORMIGRAN® is used for the acute treatment of the headache phase of migraine attacks with and without aura.

2. WHAT MUST YOU CONSIDER BEFORE TAKING FORMIGRAN®?

FORMIGRAN® should be taken at the first signs of a migraine headache. The safety and efficacy of naratriptan for the treatment of aura symptoms which may occur prior to onset of the headache have not been established.

FORMIGRAN® must not be taken:

- to prevent a migraine;
- if you are under 18 or over 65;
- if you are hypersensitive (allergic) to naratriptan or any of the other constituents of FORMIGRAN®;
- if you have, or have had in the past, a heart attack or impaired blood supply to the heart (ischaemic heart disease), spasms of the coronary vessels (Prinzmetal's angina) or peripheral vascular disease;
- if you have or have had a stroke or mini-stroke (also called transient ischaemic attack);

- if you have high blood pressure or are being treated for high blood pressure;
- if you are suffering from impaired kidney or liver function;
- if you have circulatory problems in the legs (cramp-like pain in the legs when walking) or your doctor has told you that you are suffering from peripheral vascular disease;
- if you have been diagnosed with one of the rare forms of migraine (hemiplegic, basilar or ophthalmoplegic migraine);
- if you are currently taking medicines for the treatment of migraine which contain ergotamine, derivatives of ergotamine (including methysergide) or triptans (e.g. products containing sumatriptan or naratriptan).

Special precautions when taking/using FORMIGRAN®:

Consult your doctor

- if your headache usually lasts for more than 24 hours or becomes more frequent;
- if you have four or more migraine attacks each month;
- if you do not completely recover in between your migraine attacks;
- if you are over the age of 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
 - double vision
 - clumsy and uncoordinated movements
 - tinnitus (ringing in the ears)
 - reduced level of consciousness
 - seizure (fit)-like movements
 - sudden skin rash with a headache;
- if three or more of the following points apply to you you may be at higher risk of heart disease:
 - you are male and over the age of 40
 - you are postmenopausal
 - you are very overweight
 - you smoke a lot (more than 10 cigarettes a day) or are using nicotine products as an aid to stopping smoking
 - you are diabetic
 - you have high cholesterol
 - one of your immediate relatives (parent, brother, sister) had heart disease before the age of 60

a) Children and adults:

FORMIGRAN® must not be used if you are under 18 or over 65.

b) Pregnancy and breastfeeding:

If you are pregnant, could be pregnant or are breastfeeding, you must speak to your doctor before using FORMIGRAN®. There is no information on the excretion of naratriptan in human breast milk. It is therefore recommended

that nursing mothers refrain from breastfeeding for up to 24 hours after taking FORMIGRAN[®] in order to avoid the child ingesting any active ingredient.

c) Oral contraceptives:

Women with migraine who also use the combined oral contraceptive pill have a higher risk of a stroke. If you are taking these contraceptive pills and you have only recently (in the last 3 months) started to have migraines or your migraine symptoms have got worse, or if you have migraine with aura (migraine attacks which start with visual disturbances or altered sensations) you should ask your doctor for advice.

d) Ability to drive and operate machines:

Tiredness and other symptoms may be caused by migraine or use of this medicine. These may affect the ability to drive and operate machines.

e) Important information on some of the other constituents of FORMIGRAN[®]:

The active ingredient of FORMIGRAN[®], naratriptan, contains a sulphonamide component. There is a theoretical risk of an allergic reaction in people with known hypersensitivity to sulphonamides.

The tablets contain lactose. Do not take FORMIGRAN[®] until after you have talked to your doctor if you know that you suffer from sugar intolerance.

The following symptoms may occur after taking FORMIGRAN[®]:

Feelings of tingling or warmth, heaviness, pressure and tightness or pain in various parts of the body including chest and neck (see Side effects). If these symptoms continue for more than two hours or are particularly severe (especially the chest pain) tell your doctor straight away (see Side effects). Further FORMIGRAN[®] tablets may only be taken with the permission of a doctor.

Please note that migraine sufferers have an increased risk of certain vascular disorders of the brain (e.g. stroke, temporary states of impaired blood flow to the brain [ischaemic attacks]).

As with other medicines for the treatment of acute migraine, there have been reports of chronic daily headache or potentiation of headache from excessive use of naratriptan. This sometimes leads to the need to stop taking the medicine.

Taking FORMIGRAN[®] with other medicines:

Tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those available over the counter.

You must not take FORMIGRAN[®] if you have been prescribed other antimigraine drugs by your doctor (products containing ergotamine, derivatives of ergotamine (incl. methysergide) or triptans, e.g. sumatriptan).

Sulphonamide antibiotics: People who are allergic to sulphonamides may also have an allergic reaction to FORMIGRAN[®]. If you know that you have an

allergic reaction to an antibiotic but are not sure whether it is a sulphonamide, please ask your doctor or pharmacist.

St John's wort (a herbal remedy – *Hypericum perforatum*) – using St John's wort with FORMIGRAN® may increase the likelihood of you suffering side effects. If you are worried, talk to your pharmacist or doctor.

Interactions may occur with other medicines which, like naratriptan, are actively excreted by the kidneys. If you know you are taking other medicines excreted by the kidneys, you should talk to your doctor before taking FORMIGRAN® as naratriptan may have an effect on their elimination and possibly potentiate their effect.

Antidepressants called SSRIs (Selective Serotonin Reuptake Inhibitors) – for example citalopram, fluoxetine, paroxetine, fluvoxamine and sertraline. Using FORMIGRAN® with this group of medicines can make some side effects more likely. If you experience weakness and/or lack of co-ordination, talk to your doctor. If you are not sure if you are taking an SSRI, check with your doctor or pharmacist.

Taking FORMIGRAN® at the same time as drinking:
There is no evidence of interactions with alcohol.

3. HOW SHOULD FORMIGRAN® BE TAKEN?

Please follow the instructions for use as otherwise FORMIGRAN® cannot work properly. The following information applies unless your doctor has prescribed FORMIGRAN® differently. Always take FORMIGRAN® exactly as stated in this leaflet. Please ask your doctor or pharmacist if you are not quite sure.

Method of administration:

FORMIGRAN® film-coated tablets should be swallowed whole with water, without chewing.

Unless prescribed otherwise by your doctor, the usual dose for adults aged 18 to 65 years is:

One film-coated tablet, equivalent to 2.5 mg naratriptan, as soon as possible after the start of the migraine headache.

If the symptoms improve after taking the first tablet but then start to come back, you can take a second tablet after 4 hours. You leave at least 4 hours after taking the first tablet.

Do not take more than 2 film-coated tablets in 24 hours.

Do not take more than 2 film-coated tablets for the same migraine attack.

If the first tablet does not provide any relief, do not take a second tablet for the same attack. Talk to your doctor before using FORMIGRAN® again. Getting no relief from FORMIGRAN® may mean that you do not have migraine.

After taking FORMIGRAN® you should not use any product containing ergotamine or another triptan (e.g. sumatriptan or naratriptan) during the following 24 hours. Also at least 24 hours should be left between using a product containing ergotamine and taking FORMIGRAN®.

If you have taken more FORMIGRAN® than you should, inform your doctor.
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.

4. POSSIBLE SIDE EFFECTS.

In common with all medicines, FORMIGRAN® can cause side effects. The evaluation of undesirable effects is based on the following frequencies:

Very common affect more than 1 in 10 persons treated
Common affect more than 1 in 100 persons treated
Uncommon affect more than 1 in 1000 persons treated
Rare affect more than 1 in 10,000 persons treated
Very rare affect less than 1 in 10,000 persons treated, including isolated cases

Important side effects or signs you should look out for:

Disorders of the immune system:

Rare Anaphylactic reactions

Neurological disorders:

Common Tingling sensation, dizziness and drowsiness

Disorders of the eye:

Uncommon Visual disturbances

Cardiac disorders:

Uncommon Slowing down of heart rate (bradycardia), acceleration of heart rate (tachycardia), palpitations

Very rare: Spasms of the coronary vessels (coronary vasospasm), angina, myocardial infarction

Medicines in this substance class (5-HT_{1B/1D} agonists) have been associated with myocardial infarction.

Vascular disorders:

Very rare Impaired blood supply to the extremities (peripheral vascular ischaemia)

Gastrointestinal disorders:

Common Nausea, vomiting

Rare Inflammation of a section of the large intestine due impaired blood supply (ischaemic colitis)

Skin and subcutaneous tissue disorders:

Rare Skin rash, nettle rash, itching, facial swelling (facial oedema)

Musculoskeletal and connective tissue disorders:

The following symptoms are usually temporary, sometimes intense and may occur in various parts of the body, incl. the chest and neck.

Uncommon Feeling of heaviness

General disorders:

Common Malaise, tiredness

The following symptoms are usually temporary, sometimes intense and may occur in various parts of the body, incl. the chest and neck.

Common Sensation of heat

Uncommon Pain, sensation of pressure or tightness

Other possible side effects / Countermeasures:

Tell your doctor or pharmacist immediately if you are significantly affected by any of the side effects listed or if you notice any effects not mentioned in this leaflet.

5. HOW SHOULD FORMIGRAN® BE STORED?

You must not use the tablets after the expiry date shown on the pack and on the blister. Do not store above +30°C.

6. OTHER INFORMATION.

What FORMIGRAN® contains:

The active ingredient is: 1 film-coated tablet contains 2.5 mg naratriptan (equivalent to 2.78 mg naratriptan hydrochloride)

The other constituents are:

Microcrystalline cellulose, lactose, croscarmellose sodium, magnesium stearate (Ph. Eur.), hypromellose, titanium dioxide (E 171), triacetin, iron (III) hydroxide oxide (E 172), indigo carmine, aluminium salt (E 132)

What FORMIGRAN® looks like and contents of the pack:

Crescent-shaped, biconvex tablets embossed "GX CE5" on one side; light green film coating. FORMIGRAN® is available in a pack of 2 film-coated tablets.

Pharmaceutical company and manufacturer:

GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, D-77815 Bühl

Keep medicines out of the reach of children.

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