Package leaflet: Information for the user

Frovatriptan DOC Generici 2,5 mg, filmomhulde tabletten [Frovatriptan (as frovatriptan succinate monohydrate)]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this 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 <*Invented name*> *2.5 mg film-coated tablets* is and what it is used for

<*Invented name*> 2.5 mg film-coated tablets contain frovatriptan (as frovatriptan succinate monohydrate), which belongs to a group of medicines called triptans (also known as 5-HT_1 receptor agonists).

<*Invented name*> 2.5 mg film-coated tablets are used to treat migraine with or without aura (a temporary subjective feeling before a migraine attack, which varies greatly from person to person and which can affect vision, sense of smell, or hearing).

<Invented name> 2.5 mg film-coated tablets should not be used to prevent migraines.

2. What you need to know before you take <*Invented name*> *2.5 mg film-coated tablets*

The diagnosis of a migraine episode must have been clearly established by your doctor.

Do not take <*Invented name*> 2.5 mg film-coated tablets:
- If you are allergic to frovatriptan, or any of the other ingredients of this medicine (listed in section 6)
- If you have a heart problem such as heart failure 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 moderate to severe high blood pressure. You may be able to take <*Invented name*> 2.5 mg film-coated tablets if your high blood pressure is mild and is being treated
- If you have severe liver disease
- With other migraine medicines, including those which contain ergotamine, or with similar medicines such as methysergide, or with other 5-HT_1 receptor agonists, such as sumatriptan.

If any of these apply to you, tell your doctor, and do **not** take <*Invented name*> 2.5 mg film-coated tablets.

Warnings and precautions
Talk to your doctor or pharmacist before taking<*Invented name*> 2.5 mg film-coated tablets

Take special care with <*Invented name*> 2.5 mg film-coated tablets if you are a patient with cardiovascular risk factors, including if:

- You are a heavy smoker or taking smoking-cessation medicines
- If you are a woman in post-menopause or a man over 40 years of age.

In these cases, ask your doctor for advice before taking <*Invented name*> 2.5 mg film-coated tablets.

In some rare cases, symptoms such as chest pain and feeling of heaviness may appear in patients on triptans, even in cases with no history of cardiovascular diseases.
If you notice any of these symptoms, contact your doctor and do not take any further doses of this medicine.

Other medicines and <*Invented name*> 2.5 mg film-coated tablets
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take this medicine at the same time as certain other medicines used to treat migraines:
- Especially ergotamine and ergotamine derivatives (including methysergide), sumatriptan or other 5-HT_1 receptor agonists; a period of at least 24 hours must be observed between stopping these medicines and administering <*Invented name*> 2.5 mg film-coated tablets. Similarly, these medicines must not be administered within 24 hours of administering frovatriptan.
- Particularly other triptans (5-HT_1 agonists, such as sumatriptan, almotriptan, eletriptan, naratriptan, rizatriptan or zolmitriptan).

Do not take this medicine, unless otherwise advised by your doctor, at the same time as monoamine oxidase inhibitors (MAOI) type medicines used to treat depression (iproniazid, isocarboxazid, tranylcypromine, moclobemide).

Inform your doctor or pharmacist if you are taking oral contraceptives (the pill) or selective serotonin re-uptake inhibitors (citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline).

Taking <*Invented name*> 2.5 mg film-coated tablets together with St John's Wort (Hypericum perforatum) is not recommended.

The combination of <*Invented name*> 2.5 mg film-coated tablets with the above medicines (particularly monoamine oxidase inhibitors, selective serotonin reuptake inhibitors and St John's Wort) may increase the risk of serotonin syndrome (the symptoms of this syndrome include: chills, sweating, agitation, muscle tremor and spasm, nausea, fever and confusion).

If you have any doubts about the use of other medicines and <*Invented name*> 2.5 mg film-coated tablets, ask your doctor or pharmacist.

***<Invented name>* 2.5 mg film-coated tablets with food and drink**
<*Invented name*> 2.5 mg film-coated tablets may be taken with food or fasting, and always with plenty of water.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Unless otherwise advised by your doctor, the use of <*Invented name*> 2.5 mg film-coated tablets is **not** recommended while pregnant or breast-feeding.
In any case, you should not breast-feed for 24 hours after taking the medicine. The milk expressed during this period should be discarded.

Driving and using machines
- Either the symptoms of migraine or your medicine may make you drowsy. If you are affected, do not drive or use any tools or machines.

<Invented name> 2.5 mg film-coated tablets contains lactose
<Invented name> 2.5 mg film-coated tablets contain a small amount of a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking <*Invented name*> 2.5 mg film-coated tablets.

3. How to take <*Invented name*> 2.5 mg film-coated tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take <*Invented name*> 2.5 mg film-coated tablets as soon as possible after the onset of the migraine.

Do not use this medicine to prevent migraines.

The tablet must be swallowed whole with a large glass of water.

If you feel no relief after the first dose, a second dose must not be taken during the same episode. <*Invented name*> 2.5 mg film-coated tablets may be used for the next attack.

If you obtain relief after the first dose but pain re-appears within 24 hours, a second tablet may be taken, provided that you observe an interval of at least 2 hours between the two doses.
Do not exceed the maximum dose of 5 mg in 24 hours (i.e. two tablets).

Prolonged use (repeated use over several days) of <*Invented name*> 2.5 mg film-coated tablets is not recommended, and may cause an increase in side effects and lead to daily headaches requiring discontinuation of treatment. Consult your doctor if you experience frequent or daily headaches, as a diagnosis of headache due to medication misuse should be considered.

Use in children and adolescents

<*Invented name*> 2.5 mg film-coated tablets should **not** be used in children under 18 years.

There are limited data on the safety and efficacy in patients over 65 years, so <*Invented name*> 2.5 mg film-coated tablets is not recommended in these patients.

If you take more <*Invented name*> 2.5 mg film-coated tablets than you should
If you accidentally take more <*Invented name*> 2.5 mg film-coated tablets than you should, consult your doctor or pharmacist immediately, or go to your nearest hospital emergency department. Take any remaining tablets or this leaflet with you.

The symptoms of overdose are: dizziness, drowsiness, vomiting, feeling unwell and decreased heart rate.

If you stop taking <*Invented name*> 2.5 mg film-coated tablets

No special precautions are necessary when stopping this treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Description of the side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
A feeling of pressure or pain in the chest, at times intense and which could extend to the throat, may appear some minutes after taking the medicine. If you notice these symptoms, contact your doctor and do not take any further doses of this medicine.
The side effects reported during the clinical studies with Frovatriptan were temporary, mild to moderate and spontaneously disappeared. Certain symptoms reported as side effects could be attributed to the migraine episode.

The following effects were **common (affecting more than 1 in 100 people and fewer than 1 in 10 people):**
- nausea, dry mouth, indigestion, stomach pain,
- fatigue, chest discomfort (feeling of heaviness, pressure or tightness in the chest),
- headache, dizziness, pins and needles in arms and legs, reduced or increased sensations of touch, extreme desire to sleep,
- hot flushes,
- tightness in throat,
- visual disorders,
- increased sweating.

The following effects were **uncommon (affecting more than 1 in 1,000 people and fewer than 1 in 100 people):**
- taste alteration, tremor, poor concentration, lethargy, skin hypersensitivity, drowsiness, involuntary muscle contractions,
- diarrhoea, difficulty swallowing, bloatedness, stomach discomfort, flatulence,
- increased heart rate, palpitations, high blood pressure, chest pain (intense feeling of tightness or pressure in the chest),
- feeling hot, decreased tolerance to hot and cold, pain, weakness, fever, thirst, lack of energy, hyperactivity, feeling unwell, a feeling of intoxication, dizziness,
- anxiety, insomnia, confusion, agitation, nervousness, depression, personality disorders, cold extremities,
- rhinitis, sinusitis, sore throat,
- muscle stiffness, bone and muscle pain, pain in hands and feet, joint pain, back pain, eye pain, eye irritation, discomfort looking at light,
- pruritus,
- ringing in the ears, earache,
- dehydration,
- urinary urgency, increased urination,
- high blood pressure.

The following effects are **rare (affecting more than 1 in 10,000 people and less than 1 in 1,000 people):**
- muscle spasms, decreased muscle tone, reduced muscle reflexes (hyporeflexia), movement disorders,
- constipation, belching, heartburn, intestinal irritation, mouth ulcers, lip pain, oesophageal spasm, gastro-duodenal ulcer, pain in salivary gland, inflammation of the mouth, toothache,
- fever,
- memory loss, nightmares, personality disorders,
- nosebleeds, increased respiratory rate, hiccups, throat irritation,
- night blindness,

- purple marks on skin or mucous membranes, skin redness, hives, goose bumps,
- bradycardia
- hearing disorders, ear discomfort, itchy ears, sensitive hearing,
- increased blood bilirubin, decreased blood calcium, abnormal urinalysis,
- hypoglycaemia,
- night-time urinary urgency, kidney pain,
- self-mutilation (such as biting, bruising),
- enlarged lymph nodes,
- breast pain.

Some cases of allergic reactions to <*Invented name*> 2.5 mg film-coated tablets have been reported, manifesting as a rash, as well as a generalised severe allergic reaction (anaphylaxis) which can cause breathing difficulties, increased heart rate and palpitations. In this case, contact your doctor immediately.
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 national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <*Invented name*> 2.5 mg film-coated tablets

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

Do not store above 30□C

Do not use this medicine after the expiry date which is stated on the blister and on the outer carton after EXP. 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. Content of the pack and other information

What <*Invented name*> 2.5 mg film-coated tablets contain
The active substance is frovatriptan.
Each film-coated tablet contains 2.5 mg of frovatriptan (as frovatriptan succinate monohydrate).

The other ingredients are:
Tablet core: silicified microcrystalline cellulose, lactose anhydrous*, silicon dioxide, sodium starch glycolate (Type A) and magnesium stearate.
Film-coating: hypromellose (E464), lactose monohydrate*, macrogol 3350 (E1521), triacetin and titanium dioxide (E171).

*Contains approximately 107 mg of lactose per tablet.

What <*Invented name*> 2.5 mg film-coated tablets look like and contents of the pack

NL/H/2757/2759/2762/001/DC
<*Invented name*> 2.5 mg film-coated tablets are white to off white round film-coated tablets, plain on both sides. They are available in blister packs of 1, 2, 3, 4, 6 or 12 tablets.

NL/H/2758/001/DC
<*Invented name*> 2.5 mg film-coated tablets are white to off white round film-coated tablets, plain on both sides. They are available in blister packs of 2 or 6 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
DOC Generici S.r.l.
Via Turati Filippo
40 20121 Milano
Italië

Fabrikant
Chanelle Medical Unlimited Company
Loughrea, Co. Galway
Ierland

In het register ingeschreven onder:
RVG 112365, Frovatriptan DOC Generici 2,5 mg, filmomhulde tabletten

This medicinal product is authorised in the Member States of the EEA under the following names:

NL:	Frovatriptan DOC Generici
IT:	FROVATRIPTAN DOC Generici

Deze bijsluiter is voor het laatst goedgekeurd in december 2023