Package leaflet: information for the user

FROVEX 2.5 mg film-coated tablets

Frovatriptan

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 FROVEX is and what it is used for
2. What you need to know before you take FROVEX
3. How to take FROVEX
4. Possible side effects
5. How to store FROVEX
6. Contents of the pack and other information

1. What FROVEX is and what it is used for

FROVEX 2.5 mg tablets contain frovatriptan, an anti-migraine treatment belonging to the class of triptans (5-hydroxytryptamine ($5HT_1$) selective receptor agonists).
FROVEX 2.5 mg tablets is a medicine for the treatment of the headache phase of a migraine attack with or without aura (a temporary strange feeling before a migraine, which varies from person to person but can affect, for example, vision, smell, hearing).
FROVEX 2.5 mg tablets should not be used to prevent a migraine attack.

FROVEX is used to treat migraine attacks in adults.

2. What you need to know before you take FROVEX

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

Do not take FROVEX
- If you are allergic to frovatriptan or any of the other ingredients of this medicine (listed in section 6.1).
- if you have had a heart attack, or suffer or have suffered from certain cardiovascular diseases such as angina pectoris (characterised by crushing pain in the chest which can extend into the left arm), or circulation disorders of the legs or arms (especially in the fingers and toes),
- if you have had a stroke or a transient ischaemic attack (TIA),
- if you have severely or moderately high blood pressure, or if your blood pressure is not adequately controlled,
- if you have severe liver disease,
- in combination with certain other medicines also used in the treatment of migraine (ergotamine and ergotamine derivatives (including methysergide) or other triptans (5-hydroxytryptamine ($5HT_1$) agonists).

Warning and precautions
Talk to your doctor before taking **FROVEX**
if you are a patient at risk of coronary artery disease, including if:

> you are a heavy smoker or a user of nicotine substitution therapy
> you are a post-menopausal female or a male aged over 40 years

Stop taking FROVEX and talk to your doctor right away if you:
> experience a feeling of tightness or pain in the chest, shortness of breath and/or pain or discomfort in one or both arms, your back, shoulders, neck, jaw, or upper part of the stomach; these might be symptoms of a heart attack, which can occur when taking triptans, even in patients with no history of cardio-vascular disease. (see also section 4);

> have generalized skin rash and itching, rapid-onset swelling (especially around the lips, eyes, or of the tongue), with possible sudden difficulty in breathing and a fast heartbeat and thumping heart. These are all symptoms and signs of allergy and whole-body hypersensitivity reaction (see also section 4).

Children and adolescents
Do not give this medicine to children and adolescents (under 18 years of age) because the safety and efficacy of FROVEX have not been established in these groups.

Other medicines and FROVEX

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
You should not take this medicine at the same time as certain other medicines used for the treatment of migraine:
- especially ergotamine, ergotamine derivatives (including methysergide); you should allow at least 24 hours to elapse between the discontinuation of these medicines and the administration of FROVEX 2.5 mg tablets. Similarly, you should not take these medicines within 24 hours following a dose of FROVEX 2.5 mg tablets.
- especially other triptans ($5\text{-}HT_1$ agonists, such as sumatriptan, almotriptan, eletriptan, naratriptan, rizatriptan or zolmitriptan).
Unless otherwise directed by your doctor, you should not take this medicine at the same time as monoamine oxidase inhibitor (MAOI) medicines used in the treatment of depression (phenelzine, isocarboxazid, tranylcypromine, moclobemide).
- you should also tell your doctor or pharmacist if you are taking oral contraceptives or selective serotonin-reuptake inhibitors (citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline).

It is recommended that you do not take FROVEX 2.5 mg tablets at the same time as taking St. John's Wort (hypericum perforatum).

Concomitant use of FROVEX with the medicines listed above (especially monoamine oxidase inhibitors, selective serotonin-reuptake inhibitors and hypericum perforatum) may also increase the risk of serotonin syndrome (the symptoms of serotonin syndrome include: shivering, sweating, agitation, trembling and abrubt contraction of muscles, nausea, fever, confusion).

If you have any doubt about taking other medicines with FROVEX 2.5 mg tablets, consult your doctor or pharmacist.

FROVEX with food and drink
FROVEX 2.5 mg tablets can be taken with food or on an empty stomach, always with an adequate amount 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.
FROVEX 2.5 mg tablets should not be used during pregnancy or when breast feeding, unless you are told so by your doctor. In any case, you should not breastfeed for 24 hours after taking FROVEX and during this time any breast milk expressed should be discarded.

Driving and using machines
FROVEX 2.5 mg tablets and the migraine itself can cause drowsiness. If affected, driving or operating machinery can be dangerous and should be avoided.

FROVEX contains lactose
This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

FROVEX contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take FROVEX

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
Take FROVEX 2.5 mg tablets as early as possible after the onset of the migraine headache. Swallow one tablet whole with water.
If the first dose does not give you any relief, **do not take a second dose during the same attack**. You can use FROVEX 2.5 mg tablet for any following attacks.
If you obtain relief after the first dose, but later on suffer from the re-appearance of a headache within 24 hours, you can take a second dose provided that **at least 2 hours** have elapsed between the 2 doses.
Do not exceed the maximum dose of 5 mg (two tablets) in 24 hours.

Excessive use (repeated use over several consecutive days) of FROVEX 2.5 mg tablets constitutes incorrect use of this medicine and may cause an increase in side effects and lead to chronic daily headaches requiring the temporary discontinuation of treatment. Consult your doctor if you start having too frequent or daily headaches as you may be suffering from medication overuse headache.

Use in children and adolescents
FROVEX should not be used in patients under 18 years of age.

Elderly
As there is little experience in patients over 65 years, the use of FROVEX is not recommended in patients in this age group.

If you take more FROVEX than you should

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately or go to the emergency department of your nearest hospital. Please remember to take the remaining tablets or this leaflet with you.

If you stop taking FROVEX
No special precautions are necessary when stopping the drug.

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.

Stop taking FROVEX and tell your doctor right away if you experience any of the following symptoms:

> a feeling of tightness or pain in the chest, shortness of breath and/or pain or discomfort in one or both arms, your back, shoulders, neck, jaw, or upper part of the stomach; these might be symptoms of a heart

attack (myocardial infarction), which can occur when taking triptans, even in patients with no history of cardio-vascular disease;

> have generalized skin rash and itching, rapid-onset swelling (especially around the lips, eyes, or of the tongue and mucosa), with possible sudden difficulty in breathing and a fast heartbeat and thumping heart. These are all symptoms and signs of allergy and whole-body hypersensitivity reaction (hypersensitivity reactions, angioedema, anaphylaxis).

The side-effects reported with FROVEX 2.5 mg tablets were temporary, generally mild to moderate and disappeared spontaneously. Some symptoms reported may be caused by the migraine itself.

The following side-effects were *commonly* observed (estimated frequency is more than 1 person out of 100 and less than 1 person out of 10):
- nausea (feeling sick), dry mouth, digestion problems, stomach pain,
- fatigue, chest discomfort (sensation of slight heaviness, pressure or tightness in the chest),
- headache, dizziness, sensation of pins and needles, most frequently in the arms and legs, reduction or disturbance of the sensations of touch, extreme sleepiness
- hot flushes,
- tightness in the throat,
- sight disturbances,
- increased sweating.

The following were *uncommonly* observed (estimated frequency is more than 1 person out of 1000 and less than 1 person out of 100):
- altered sense of taste, trembling, poor concentration, lethargy, increased sensation of touch, drowsiness, involuntary muscle contractions,
- diarrhoea, difficulty in swallowing, gas in stomach or bowel, stomach discomfort, bloated stomach,
- awareness of heart beat (palpitations), fast heart beat, high blood pressure, chest pain (intense tightness or feeling of pressure in the chest),
- feeling hot, reduced tolerance of heat and cold, pain, weakness, thirst, sluggishness, increased energy, generally feeling unwell, sensation of spinning,
- anxiety, inability to sleep, confusion, nervousness, agitation, depression, loss of sense of personal identity,
- coldness in the hands and feet,
- irritation of the nose, inflamed sinus, sore throat and/or voice box,
- muscle stiffness, muscle and bone pain, pain in the hands and feet, back pain, painful joints,
- eye pain, eye irritation, painful oversensitivity to light,
- itchiness,
- ringing in the ears, earache,
- dehydration,
- passing urine frequently, production of large amounts of urine.

The following were *rare* (estimated frequency is more than 1 person out of 10,000 and less than 1 person out of 1000):
- muscle spasm, floppy muscles, diminution of reflexes (hyporeflexia), movement problems,
- constipation, burping, heartburn, irritable bowel syndrome, lip blisters, lip pain, spasm of the gullet, blisters in the mouth, ulcer in the stomach or upper part of the small intestine, pain in the salivary gland, inflammation of the mouth, toothache,
- fever,
- loss of memory, abnormal dreams, personality disorder,
- nosebleed, hiccups, overbreathing, breathing disorder, irritation in the throat,
- night blindness,
- skin reddening, sensation of hairs standing on end, purplish spots or patches on skin and mucous surfaces of the body, hives,
- slow heart beat,
- ear discomfort, ear disorder, ear itchiness, sensitive hearing,
- increase in bilirubin (a substance produced by the liver) in the blood, decrease of calcium in the blood, abnormal urine analysis,

- low sugar in the blood,
- passing urine frequently at night, pain in the kidneys,
- self-inflicted injury (eg bite or bruising),
- swollen lymph nodes,
- breast pain or discomfort.

Although the frequency cannot be estimated from the available data the following events were also reported:
- allergic reactions (hypersensitivity) including generalized skin rash and itching, rapid-onset swelling (especially around the lips, eyes, or of the tongue), with possible sudden difficulty in breathing, that can be associated with fast heartbeat and thumping heart (anaphylaxis),
- heart attack (myocardial infarction),
- chest discomfort or pain that is caused by a temporary spasm (constriction) in your coronary arteries (the blood vessels that bring oxygen and nutrients to your heart, i.e. coronary artery spasm).

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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FROVEX

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from moisture.
Keep this medicine out of the sight and reach of children.

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 to protect the environment.

6. Contents of the pack and other information

What FROVEX contains

The active substance is frovatriptan as succinate monohydrate.
Each tablet contains 2.5 mg of frovatriptan.
The other ingredients are:
Tablet core: anhydrous lactose, microcrystalline cellulose, magnesium stearate, sodium starch glycollate (type A), silica colloidal anhydrous.
Tablet coat: OPADRY white: titanium dioxide (E171), anhydrous lactose, hypromellose (E464), macrogol 3000, triacetin.

What FROVEX looks like and contents of the pack

FROVEX 2.5 mg film-coated tablets are available in the form of round film-coated tablets, debossed with "m" on one side and "2.5" on the other.
FROVEX is packed in:
PVC/PE/PVDC/Aluminium blister: 1, 2, 3, 4, 6 or 12 tablets per each blister
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Menarini International Operations Luxembourg S.A.
1, Avenue de la Gare
L-1611, Luxembourg

Manufacturer:
Berlin-Chemie AG
Glienicker Weg 125 – D-12489 Berlin, Germany
or
A.Menarini Manufacturing Logistics and services s.r.l.
Via Campo di Pile – L'Aquila (AQ), Italy
or
Laboratorios Menarini S.A.
Alfonso XII, 587, 08918 - Badalona (Barcelona), Spain

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

France (RMS): Tigreat
Belgium, Luxembourg: Frovatex
Germany: Allegro
Greece: Migralin
Ireland: Frovex
Italy: Auradol
Portugal: Dorlise
Slovakia: Frovamen
Slovenia: Frotan
The Netherlands: Fromirex

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