

PACKAGE LEAFLET: INFORMATION FOR THE USER

NOMIGREN

(200 mg + 80 mg + 25 mg + 20 mg + 0.75 mg) film-coated tablet

PROPYPHENAZONE, CAFFEINE, KAMILOFIN, MEKLOXAMINE, ERGOTAMINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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2. Before you take Nomigren
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1. WHAT NOMIGREN IS AND WHAT IT IS USED FOR

Nomigren film-coated tablets belong to a group of medicines with anti-migraine effect. It relieves the symptoms of migraine and prevents further progression of the migraine attacks.

Nomigren film-coated tablets are applicable:

- in the treatment of migraine, vascular headaches and cluster headaches.

2. BEFORE YOU TAKE NOMIGREN

Inform the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, hypersensitivity to medicine or have had an allergic reaction to some of them.

Do not use Nomigren film-coated tablets

- If you are allergic to any ingredient of the medicinal product (see section 6);
- If you have reduced number of leukocytes in the blood (Leucopenia)
- If you have increased eye pressure (narrow angle glaucoma)
- If you have benign prostate enlargement (Adenoma of the prostate)
- If you have mechanical narrowing in the digestive system

- If you have expanded colon (Megacolon)
- If you have rapid and irregular heartbeat
- If you have cerebral circulation disorder (severe cerebral sclerosis)
- If you have narrowed blood vessels (Vascular Stenosis)
- If you have diseases of the liver and kidney
- If you have a weak supply of the heart with oxygen or high blood pressure (Angina Pectoris or hypertension)
- If you have a hereditary metabolic disease (acute hepatic Porphyria)
- If you have genetically conditioned glukozo-6-phosphate dehydrogenase deficiency (manifested as a hemolytic anemia)
- If you are pregnant and breast-feeding

Do not use this medicine if any of the above applies to you. If you are not sure, ask your doctor or pharmacist before you take this medicine.

Be careful with Nomigren film-coated tablets

If you suffer from asthma, chronic respiratory disease, or hay fever and if you have other hypersensitivity reactions to medicines, painkillers or medicines used for the treatment of rheumatic diseases, you should consult your doctor prior to use of the medicine.

This medicine is used as needed, and can affect the ability to drive and use machines, especially if a medicine is consumed with alcohol.

The medicine is not intended for preventing attacks of migraine.

There are no data about the possibility of occurrence of dependence on the medicine.

If any of the above applies to you or if you are not sure, consult with your doctor before using this medicine.

Taking other medicines with Nomigren film-coated tablets

Keep in mind that this information can apply to medicines that you no longer taking, as well as to the medicine that you are planning to take in the future. Tell your doctor if you are taking, or have recently taken any other medicine, including the medicine being purchased without a prescription.

Inform your doctor if you are taking any of the following medicines:

- Amantadine (used in the treatment of Parkinson's disease and viral infections);
- Quinidine (used to treat heart rhythm disorders)
- Tricyclic antidepressants (used in the treatment of depression).

Avoid consuming alcohol during the use of the medicine, since alcohol potentiates the action of Nomigren tablets.

If any of the above applies to you or if you are not sure, consult with your doctor before using this medicine.

Food and drinks

The food has no effect on the action of the medicine.

Do not consume alcohol during treatment with Nomigren film-coated tablets. This can reinforce the action of Nomigren tablets.

Pregnancy and breastfeeding

Before you begin to take any medicine, consult your doctor or pharmacist.

Administration of medicine during pregnancy is risky for the fetus, so that the risk of administration in pregnant women clearly exceeds any possible benefit. It is not recommended for use in pregnant women and the potentially pregnant women.

Ergotamine and caffeine are excreted into breast milk. Breastfeeding mothers should stop breastfeeding and switch to an alternative method of feeding infants.

Driving and using machines

Δ Trigonin, a medicine with the possible influence of the psychophysical abilities (a warning when driving and using machines).

The medicine has a small or moderate effect on this ability.

If in the course of application of Nomigren film-coated tablets you experience dizziness or feel drowsy, do not operate the motor vehicles and/or use machines.

Other warnings

Nomigren film-coated tablets contain lactose (a type of sugar). If your doctor earlier said you have an intolerance to some sugars, before you start using this medicine, make sure you seek the advice of your doctor.

3. HOW TO TAKE NOMIGREN

Apply the medicine according to the enclosed instructions.

If you think that the action of the medicine is too strong or too weak, you should consult with a doctor or pharmacist.

Method of administration

Nomigren film-coated tablets are applied orally (by mouth).

Film-coated tablets should be swallowed whole, with a glass of water.

Dosing

It is best to apply it in early, prodromal stage of the headaches.

Adults:

The powerful attacks of migraine

The usual dose for adults is 1-2 tablets at the beginning of the attack. Dosing is continued, if needed, with a single tablet every half an hour up to a maximum of 4 film-coated tablets per attack. The total weekly dose should not exceed 10 film-coated tablets.

It is not recommended to have more than two therapeutic treatments per month. It is advisable to use it no more often than twice weekly, best with an interval of at least four days between the applications of the medicine.

Moderate migraine attacks

The usual dose is 1 tablet. The maximum daily dose is 4 film-coated tablets, and the total weekly dose should not exceed 10 film-coated tablets.

Children under 12 years of age should not use the medicine.

Older patients

Older adults are more sensitive to the side effects of Nomigren. Therefore, this medicine should be given with special caution to the elderly.

If you use more Nomigren film-coated tablets than you should

If you have taken a larger amount of prescribed medicine, talk to your doctor or pharmacist.

If you have taken more of the medicine than recommended in these instructions, please contact your doctor or go to the nearest health institution for assistance. Take with you this leaflet or the box of the medicine, as this will facilitate its identification.

Too large doses of Nomigren film-coated tablets, can cause nausea, vomiting, weakness, muscle stiffness, ringing in the ears, pain and blue extremities (with a reduction or complete absence of the peripheral pulse), high or low blood pressure, rapid heartbeat, sleepiness, confusion, dizziness, immobility, muscle spasms, shock.

Toxic effects occur when the dose of ergotamine exceeds 15 mg in 24 hours or 40 mg in a few days.

If you forget to take Nomigren film-coated tablets

If you forget to take the medicine, do not double the amount of the medicinal product subsequently, but continue to use of the medicinal product according to the regular schedule.

Never use a double dose to make up for the missed dose. The next dose of medicine applies according to the normal schedule and the recommended way.

If you stop using Nomigren film-coated tablets

Use this medicine for as long as your doctor has prescribed.

If you suddenly stop using this medicine do not expect any negative effects. In any case, observe the therapeutic regime and, if necessary, consult with your doctor about the suspension of treatment.

In case of any concerns related to the use of the medicinal product, seek the advice of your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines and Nomigren film-coated tablets may cause side effects.

With long-term use medicine can cause tiredness, drowsiness, dry mouth, reduced sweating, blurred vision as a result of adaptation disturbances, skin redness, the appearance of green stars in the visual field which may indicate the beginning of the development of glaucoma, rapid heartbeat, abnormal urination, occasional nausea and vomiting, numbness of fingers and toes and circulatory disorders.

Hypersensitivity reactions such as shock or agranulocytosis occur rarely after applying film-coated tablets. Other hypersensitivity reactions occur on the skin and the mucous membranes of the eye, nose and throat, as well as in the form of a nettle rash. In the case of these side effects immediately stop taking the medicinal product and go to see the doctor.

The shock is manifested in the following warning signs: a cold sweat, dizziness, nausea, pallor, difficulty in breathing, swelling of the face, itching, heart failure, weak pulse, feeling cold. These side effects can arise immediately or one hour after administration of the medicine. If you notice any of these symptoms should take the following measures: provide first aid, inform the doctor, take a deep breath, lay your head and upper body, relieve the airways.

Agranulocytosis is manifested by the appearance of fever, feeling cold, inflammation of the throat, swallowing, and mucosal inflammation aggravated the mouth, nose and throat and genitals. Sedimentation is much accelerated, granulocytes significantly reduced or missing, have been increased by the values of hemoglobin, red blood cells and platelets. If the suspicion of agranulocytosis occurs one should check the blood work. It is necessary to terminate the use of the medicinal product.

Reporting of side effects

In case of any adverse reaction following the administration of the medicinal product, it is necessary to inform your doctor or pharmacist. This implies all possible unwanted reactions, which are not mentioned in this instruction leaflet, as well as those that are.

5. HOW TO STORE NOMIGREN

Keep out of reach and sight of children.

Keep at temperature up to 25 ° c.

Shelf life: 2 years.

Nomigren must not be used after the expiry date stated on the carton.

6. FURTHER INFORMATION

What do Nomigren film-coated tablets contain?

One Nomigren film-coated tablet contains: Ergotamine 0.75 mg, Mekloxamine 20.00 mg, Kamilofin 25 mg, caffeine 80 mg, Andtinidazole 200 mg.

Nomigren film-coated tablets contain the following auxiliary substances: corn starch, lactose, talc, crospovidone, magnesium stearate, gelatin, silicon dioxide colloidal, tartaric acid, red iron oxide E 172, titanium dioxide E171, MACROGOL 6000, polyacrylic emulsion 30%, polysorbate 80, and sodium carmellose.

What Nomigren film-coated tablets look like and contents of the Pack

Nomigren film-coated tablets are dark pink in color, round biconvex.

Nomigren film-coated tablets are packaged in boxes with a content of 10 and 20 film-coated tablet.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Bosnalijek d.d. Jukićeva 53 , Sarajevo, Bosnia and Herzegovina

Manufacturer of the medicinal product

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