

## Package Leaflet: Information for the user

### Naproxen Apofri 250 mg tablets

naproxen

**[For medicines available only without prescription.]**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days of migraine and 5 days of pain.

**[For medicines available only on prescription.]**

**Read all of this leaflet carefully before you start using 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 Naproxen Apofri is and what it is used for
2. What you need to know before you use Naproxen Apofri
3. How to use Naproxen Apofri
4. Possible side effects
5. How to store Naproxen Apofri
6. Contents of the pack and other information

#### **1. What Naproxen Apofri is and what it is used for**

Naproxen Apofri is an anti-inflammatory and analgesic drug. Naproxen Apofri belongs to a group of medicine called NSAIDs (non-steroidal anti-inflammatory drugs). These work by reducing the formation of so-called prostaglandins, which cause pain and inflammation in the body.

**[OTC]**

Naproxen Apofri is used for short-term mild to moderate acute pain, e.g. headache, toothache, muscle and joint pain, back pain, and menstrual pain in adults and adolescents from 12 years of age.

Naproxen Apofri can also be used for acute attacks of migraine headaches in adults.

**[Rx]**

Naproxen Apofri is used for rheumatic diseases, menstrual pains, acute migraine attacks and for mild to moderate acute pain.

#### **2. What you need to know before you use Naproxen Apofri**

## **Do not use Naproxen Apofri**

- if you are allergic to naproxen or any of the other ingredients in this medicine (listed in section 6).
- if you have had allergic reactions such as asthma, runny nose or rash after taking analgesics containing acetylsalicylic acid or other anti-pain or inflammation medicines in the NSAID group.
- if you tend to bleed easily
- if you have or have had recurrent stomach or intestinal ulcers
- if you have had a stomach ulcer or intestinal ulcer during treatment with naproxen or similar medicines
- if you have severe liver or kidney disease
- if you have severe heart failure
- during the last trimester of pregnancy.

## **Special warnings and precautions for use**

Talk to your doctor or pharmacist before using Naproxen Apofri.

*Never use several different kinds of pain medications at the same time without consulting your doctor or pharmacist.*

*Always aim for using the lowest dose possible, and for the shortest duration to reduce the risk of side effects. Higher than recommended doses generally entail risks. This also means that taking a combination of several NSAIDs medicinal products at the same time must be avoided.*

Talk to your doctor before using Naproxen Apofri if you have or have had any of the following diseases:

- inflammatory bowel diseases (such as ulcerative colitis, Crohn's disease)
- conditions causing an increased tendency to bleed
- SLE (connective tissue disease)
- asthma
- impaired kidney or liver function
- heart failure
- high blood pressure
- stomach or intestinal ulcer

Caution should be taken by elderly, as there is an increased risk of side effects due to high age

Patients who have previously had gastrointestinal tract problems, particularly the elderly, must inform their doctor if they have abdominal symptoms, especially at the beginning of treatment,

Naproxen Apofri may in rare cases affect the white blood cells and impair the immune system. If you get an infection with symptoms such as fever with a severely reduced general condition or fever with local infection symptoms such as soreness in the throat, pharynx or mouth, or urinary problems, you should immediately see a doctor to rule out a lack of white blood cells (agranulocytosis) via a blood test. It is important to inform the doctor about your medication.

In very rare cases, serious skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported after use of NSAIDs. Stop taking Naproxen Apofri and contact a doctor immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Do not take this medicine if you have chickenpox.

Use of naproxen can temporarily make it difficult to become pregnant. Consult a doctor if you are planning a pregnancy or if you have problem getting pregnant (see Pregnancy, breast-feeding and fertility).

Medicines such as Naproxen Apofri can entail a small increased risk of heart attack or stroke. Such a risk is more likely with high doses and long-term treatment. Do not exceed the recommended dose or duration of treatment (see How to take Naproxen Apofri).

Ask your doctor or pharmacist about your treatment if you have heart problems, if you previously have had a stroke or if you think you are at risk of these conditions (for example if you have high blood pressure, diabetes, high cholesterol or if you smoke).

### **Children and adolescents**

[OTC]

Children under 12 years of age or weighing less than 50 kg should not be treated with Naproxen Apofri.

[RX]

Children under 50 kg should not be treated with Naproxen Apofri, as the score line on Apofri Naproxen 250 mg tablets is not intended for dividing the tablet. Naproxen Apofri is not recommended for children under 12 years experiencing acute pain.

### **Other medicines and Naproxen Apofri**

Tell the doctor or pharmacist if you are taking or have recently taken other medicines, including non-prescription. Never use several different kinds of pain killers at the same time without consulting a doctor or pharmacist.

Some medicines may affect or be affected by treatment with Naproxen Apofri, such as medicines for:

- blood clots (e.g. ticlopidine, warfarin, clopidogrel, aspirin)
- bipolar disorder (lithium)
- cancer and immune system disturbances (methotrexate)
- hypertension and heart failure (so-called beta-blockers, ACE inhibitors, angiotensin II antagonists, diuretics)
- rejection of organs after transplantation (immunosuppressants, such as cyclosporine, tacrolimus)
- gout (probenecid)
- depression (so-called SSRIs, e.g. fluoxetine, sertraline, paroxetine, escitalopram, citalopram)
- pain, such as acetylsalicylic acid, ibuprofen and diclofenac
- swelling and inflammation, such as prednisolone and dexamethasone

### **Naproxen Apofri with food and drink**

If taking Naproxen Apofri with food, the effect will be the same but possibly delayed.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist before taking this medicine.

#### *Pregnancy*

Do not take Naproxen Apofri if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take Naproxen Apofri during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Naproxen Apofri can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

#### *Breast-feeding*

Naproxen passes into breast milk and should therefore not be used during breast-feeding.

#### *Fertility*

Taking Naproxen Apofri should be avoided by women who are planning to have a baby or are pregnant. Naproxen can make it harder to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems getting pregnant.

#### **Driving and using machines**

During treatment with Naproxen Apofri, reaction time may be reduced in some people. This should be considered when sharpened attentiveness is required, for example when operating motor vehicles.

#### **Naproxen Apofri contains lactose monohydrate and sodium**

The medicine contains lactose monohydrate. If you do not tolerate some types of sugars, you should talk with your doctor before you take this medicine.

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

### **3. How you use Naproxen Apofri**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

*[OTC]*

*Adults and adolescents from 12 years weighing more than 50 kg:*

#### Short-term pain

1 tablet (250 mg) as needed to a maximum of 2 tablets (500 mg) per day. Contact a doctor if Naproxen Apofri has not helped against your pain within 5 days.

Adults:

#### Acute migraine attacks

3 tablets (750 mg) at the onset of a migraine attack, then 1 tablet (250 mg) as needed, but never more than 5 tablets (1250 mg) the first day. Contact a doctor if Naproxen Apofri has not helped relieving your migraine pain within 3 days.

The score line is not intended for dividing the tablet.

*[Rx]*

Your dose will be determined by your doctor and it will be adjusted by your individual needs. Do not exceed the prescribed dose, as the risk of side effects increases.

Recommended dose:

*The usual dose for adults with rheumatic disorders and acute pain* is 250–500 mg in the morning and evening, with a maximum dose of 1000 mg per day. If your symptoms are most acute in the early morning or when getting out of bed in the morning, it is best to take the 500-mg dose in the evening. Some patients, however, can take 750–1000 mg once a day to achieve best effect. In these cases, it is recommended that the tablets are taken in the evening.

*For menstrual pain* 250–500 mg as needed to a maximum of 1250 mg per day. Start treatment at the first sign of menstruation.

*For acute migraine*, 750 mg at the first sign of a migraine attack. Then take 250 mg as needed, but not more than 1250 mg per day.

The score line is not intended for dividing the tablet.

**[Rx only] Use in children:**

Children over 50 kg should be given the adult dose. Must not be given to children below 50 kg, since the score line on Naproxen Apofri 250 mg tablet is not designed for dividing the tablet. Naproxen Apofri is not recommended for children under 12 year experiencing acute pain.

**[Rx only] The elderly and people with liver and/or kidney problems**

A lower dose is recommended, because of the increased risk of side effects. Your doctor will decide the dose for you.

If you sense that the effect of Naproxen Apofri is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Naproxen Apofri than you should**

If you or an adolescent has taken more medicine than you should or, if a child has taken the medicine accidentally, talk to a doctor or go to a hospital straight away.

**If you forget to take Naproxen Apofri**

Do not take a double dose to make up for the forgotten tablet.

If you have any further questions about this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine may cause side effects, although not everybody gets them.

**Stop taking Naproxen Apofri and immediately seek a doctor or emergency room if you experience the following symptoms:**

*Rare: (may affect up to 1 in 1,000 people)*

- such swelling of the face, tongue or throat, difficulty in swallowing, hives or difficulties in breathing.
- extremely severe allergic reaction with rash usually in the form of blisters or ulcers of in the mouth and eyes and other mucous membranes such as the genitalia.
- fever and severe deterioration of your general condition, or fever with local infection such as pain in the neck, throat or mouth, or difficulty in urinating.

*Not known: (frequency cannot be estimated from the available data)*

- widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS). See also section 2.
- a distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching.

**Other side effects that may occur:**

*Common: (may affect up to 1 in 10 users)*

- stomach pains
- heartburn
- nausea
- diarrhoea
- constipation
- inflammation in your mouth
- skin rash
- superficial skin lesions

- drowsiness, headache
- dizziness
- thirst
- sweating
- buzzing in one's ears (tinnitus)
- visual disturbances
- fluid retention in the body (oedema)
- palpitations

*Uncommon: (may affect up to 1 in 100 users)*

- difficulty breathing
- asthma
- nettle rash
- skin changes (increased pigmentation or blisters) due to an increased sensitivity to light
- inflammation and ulcers in the mouth
- inflammation in the stomach's lining
- gastric bleeding and ulcers
- fever
- loss of hair
- abnormal liver function
- abnormal kidney function
- hearing impairment
- difficulty falling asleep
- difficulty in concentration

*Rare: (may affect up to 1 in 1,000 users)*

- seizures
- muscular weakness.
- changes in blood test results
- “burst” gastric ulcer
- inflammation of the colon
- vomiting
- inflammation of the oesophagus
- wind
- inflammation of the pancreas
- severe skin reactions with inflammation and high fever
- pneumonia
- inflammation of the liver
- blood in urine or stools
- memory loss
- depression
- nightmares
- muscle pain
- minor anxiety
- meningitis
- vasculitis
- heart failure
- increase in blood pressure
- water in the lungs
- elevated amounts of potassium in the blood
- worsening of colitis and Chron's disease

A few isolated cases of elevated liver enzymes are known.  
Naproxen Apofri prolongs bleeding time.

In rare cases, severe skin infections appear in association with chickenpox.  
Medicines such as Naproxen Apofri can entail a small increased risk of heart attack or stroke.

### **Reporting of suspected adverse reactions**

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 Naproxen Apofri**

Keep this medicine out of the sight and reach of children.  
No special storage conditions.

Use before the expiry date which is stated on the outer carton after “Exp. date” or “EXP” on the blister card. The expiry date is the last day of the stated month.

Do not throw away the medicine in wastewater or in household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Naproxen Apofri contains**

- The active ingredient is naproxen. Each tablet contains 250 mg.  
The other ingredients are hydroxypropylcellulose; cellulose, microcrystalline; magnesium trisilicate; croscarmellose sodium; silica, colloidal anhydrous; lactose monohydrate; magnesium stearate and iron oxide yellow (E172).

### **What Naproxen Apofri looks like and package sizes**

The tablets are round, yellow and flat with a bevelled edge. Diameter of 10 mm and embossed “250” on one side and with a score line on the other side. The score line is not intended breaking the tablet.

[\[OTC\] Pack sizes: 10, 20 tablets \(blister packs\).](#)

[\[Rx\] Pack sizes: 10, 20, 30, 40, 50, 100, 105, 200, 300, 400 and 500 tablets \(blister packs\).](#)

Not all pack sizes are necessarily marketed.

### **Market Authorisation Holder and Manufacturer**

*[To be completed nationally]*

### **This leaflet was last revised in**

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