

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) - 1986**

This medicine is dispensed with a doctor's prescription only

**NEXIUM® 20 mg  
Tablets**

**Composition**

Each tablet contains:  
esomeprazole 20 mg  
(as magnesium trihydrate)

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Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

**Read this leaflet carefully in its entirety before using the medicine.**

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

**In adults, Nexium 20 mg and 40 mg are intended:**

For treatment of heartburn, with or without inflammation of the gullet, caused by reflux of gastric acid. Nexium reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

Treatment of ulcers in the upper part of the gut or stomach caused by *Helicobacter pylori* bacteria. Nexium in combination with suitable antibiotics, treats the infection and leads to healing of the ulcer and prevention of recurrence.

Healing of gastric ulcer caused by use of non-steroidal anti-inflammatory drugs (NSAIDs), such as preparations to treat arthritis (rheumatism).

Prevention of formation of gastric ulcers, if you might possibly develop them as a result of taking non-steroidal anti-inflammatory drugs (NSAIDs), such as preparations to treat arthritis (rheumatism).

Prolonged treatment with Nexium tablets to prevent recurrent bleeding of a gastric or duodenal ulcer, after primary intravenous Nexium treatment.

**In adolescents, Nexium 20 mg is intended:**

For treatment of heartburn, with or without inflammation of the gullet, caused by reflux of gastric acid. Nexium reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

Treatment of ulcers in the upper part of the gut or stomach caused by *Helicobacter pylori* bacteria. Nexium in combination with suitable antibiotics, treats the infection and leads to healing of the ulcer and prevention of recurrence.

**In adolescents, Nexium 40 mg is intended:**

For treatment of heartburn with inflammation of the gullet, caused by reflux of gastric acid. Nexium reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

**Therapeutic group:**

Proton pump inhibitor (the gastric acid pump).

## 2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You have a known sensitivity to any of its ingredients (listed in section 6 'Further information').
- You have a known sensitivity to another preparation of the proton pump inhibitors group (preparations to treat ulcer-like symptoms, e.g., pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are being treated with nelfinavir (a medicine to treat immune deficiency syndrome [HIV]).

### Special warnings regarding use of Nexium

**Before treatment with Nexium, tell the doctor if:**

- You are suffering, or have suffered in the past, from severe liver dysfunction.
- You are suffering, or have suffered in the past, from severe kidney dysfunction.
- You have suffered in the past from a skin reaction after treatment with a medicine similar to Nexium, which lowers gastric acidity.
- You are due to have a specific blood test (Chromogranin A).

Nexium may mask the symptoms of other diseases. **Therefore, if any of the following occur to you before starting treatment with Nexium or during treatment with Nexium, refer to the doctor immediately:**

- You are suffering from unexplained weight loss or you have difficulty swallowing
- You are suffering from abdominal pain or from indigestion
- You are vomiting food or blood
- You have black stools (bloody stools)

If you are taking the medicine as needed (according to the doctor's instructions), please inform your doctor, you must also tell your doctor if there is any change in your symptoms.

There is an increased risk of fractures of the hip, wrist and back upon prolonged use for one year or more. Please inform the doctor if you have been diagnosed with osteoporosis (bone depletion – those having the disease are more prone to fractures) or if you are taking corticosteroids.

### Rash and skin symptoms

If you have a skin rash, especially in areas exposed to the sun, please tell the doctor as soon as possible since you may need to stop treatment with Nexium. If you experience additional disease symptoms, such as joint pains, please report to the doctor as well.

Serious skin rashes have occurred in patients who took the medicine (see section 4). The rash can include ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes generally come after flu-like symptoms such as fever, headaches and body aches. The rash may cover large parts of the body with blistering and peeling of the skin. If during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this medicine and contact your doctor immediately.

### Other medicines and Nexium

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements tell your doctor or pharmacist.**

Do not take Nexium if you are being treated with a preparation that contains nelfinavir (a medicine to treat immune deficiency syndrome [HIV]).

Tell the doctor or the pharmacist if you are taking:

- Atazanavir (to treat immune deficiency syndrome – HIV)
- Medicines to treat fungal infection (ketoconazole or itraconazole and voriconazole)
- Antidepressants (citalopram, imipramine or clomipramine)
- Erlotinib (a medicine to treat cancer)
- Sedatives (diazepam)
- Medicines for epilepsy (phenytoin). If you are taking phenytoin, your doctor will have to monitor your treatment at the beginning and end of Nexium treatment
- Blood thinners (warfarin), your doctor will have to monitor your treatment at the beginning and end of Nexium treatment
- Clopidogrel (a medicine used to prevent blood clots)
- Medicines for heart problems (digoxin)
- If you are taking medicinal treatment for tuberculosis (rifampicin)
- A preparation for treatment of depression: St. John's Wort (*Hypericum perforatum*)
- Medicines intended to treat arterial diseases in the legs that cause intermittent claudication (cilostazol)
- Methotrexate (a medicine used at high dosages to treat cancer); if you are taking a high dosage of methotrexate, your doctor may instruct you to temporarily stop treatment with Nexium
- A medicine to prevent transplant rejection after an organ transplantation (tacrolimus)
- Medicines to accelerate gastric emptying (cisapride) in combined treatment with Nexium.

If you are receiving Nexium together with clarithromycin and amoxicillin to treat an ulcer caused by *Helicobacter pylori* bacteria, it is important that you tell the doctor of any other medicine you are taking.

### **Use of Nexium and food**

The tablet can be taken with food or on an empty stomach.

### **Pregnancy and breastfeeding**

If you are pregnant, think you are pregnant or are planning to become pregnant, consult the doctor before taking this medicine. Your doctor will decide whether you can take the medicine during this time.

It is not known whether Nexium passes into breast milk. Therefore, do not use Nexium if you are breastfeeding.

### **Driving and use of machinery**

Nexium shouldn't affect your ability to drive or use machinery. However, side effects such as dizziness or blurred vision may occur. If you suffer from these side effects, do not drive and do not use machinery.

### **Important information regarding some of the ingredients of the medicine**

The tablets contain sucrose (a certain type of sugar) and sodium. If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.

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

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The doctor will tell you about taking the medicine (how many tablets and when to take).

The strength of the tablet and duration of treatment are determined by the doctor in accordance with the disease from which you are suffering.

If you are taking this medicine for a long time (particularly if you are taking it for more than a year) the doctor may want to perform certain tests.

If your doctor has told you to take this medicine as needed, tell your doctor if your symptoms change.

#### **Instructions for use**

- The tablet can be taken at any time during the day.
- The tablet can be taken with food or on an empty stomach.
- Swallow the medicine whole, with liquid. Do not chew or crush the parts of the tablet. The tablet contains coated pellets to prevent breakdown of the medicine by the gastric acid and it is therefore important not to crush the particles.
- Patients with difficulties swallowing the tablet can crumble the tablet in half a glass of water (do not use fizzy water or any other liquid). Stir until the tablet disintegrates (a cloudy solution will be obtained). Mix well before drinking; can be drunk immediately or within 30 minutes at the most. Rinse the glass with water and drink to ensure the remainder of the medicine is taken. The solid pieces contain the medicine – do not chew or crush them.
- If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

#### **Elderly**

Dose adjustment is not required in the elderly.

**If you accidentally took a higher dosage** or if a child has accidentally swallowed the medicine, immediately refer to the doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

**If you forgot to take this medicine** at the designated time, take a dose as soon as you remember. However, if you remembered close to the time for the next dose, do not take the forgotten dose; take the next dose at the designated time.

#### **How can you contribute to the success of the treatment?**

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Care should be taken to implement the dosing instructions accurately and ask the doctor in case of any doubt.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Nexium may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

##### **Side effects requiring special attention:**

Stop treatment and refer to the doctor immediately in the following cases:

- yellowing of the skin, dark urine and tiredness can be symptoms of liver problems. These effects are rare and may affect up to 1 in 1,000 people.
- sudden wheezing, swelling of the lips, tongue and throat or body, rash, fainting or difficulties in swallowing – these are signs of a severe allergic reaction. These effects are rare and may affect up to 1 in 1,000 people.
- sudden appearance of a severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be blisters and bleeding in the lips, eyes, mouth, nose and genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences. This could be erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms. These effects are rare and may affect up to 1 in 1,000 people.

##### **Common side effects, occur frequently (affect up to one patient in 10):**

- headache
- diarrhea, stomach pain, constipation, flatulence
- nausea and vomiting
- benign polyps in the stomach

##### **Uncommon side effects (affect up to one patient in 100):**

- swelling of the legs and ankles
- sleeping problems (insomnia)
- dizziness, tingling feelings (“pins and needles”)
- sleepiness
- spinning feeling (vertigo)
- dry mouth
- changes in liver function blood tests
- skin rash, lumpy rash (hives) and itchy skin
- fractures of the hip, wrist or spine (when using Nexium at a high dosage for a long time)

##### **Rare side effects (affect up to one patient in 1,000):**

- blood problems such as a reduced number of white cells or platelets - can cause weakness, bruising or increased risk of infections
- low levels of sodium in the blood - may cause weakness, vomiting and cramps
- agitation, confusion, depression
- taste changes
- eyesight problems such as blurred vision
- sudden wheeziness or shortness of breath (bronchospasm)
- an inflammation inside the mouth
- a fungal infection that may affect the gut
- liver problems, including jaundice, that may cause yellowing of the skin, dark urine and tiredness
- hair loss
- skin rash on exposure to sun
- joint pains
- muscle pains

- feeling ill and lacking energy
- increased sweating

**Very rare side effects (affect up to one in 10,000 patients):**

- sudden onset of a severe rash, skin blistering or peeling. This may be accompanied by high fever and joint pains (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), drug reaction with eosinophilia and systemic symptoms
- changes in blood count, agranulocytosis (reduction in white blood cells)
- aggression
- seeing, feeling or hearing things that are not there (hallucinations)
- severe liver problems leading to liver failure and inflammation of the brain
- muscle weakness
- severe kidney problems
- enlarged breasts in men

**Side effects of unknown frequency (side effects whose frequency has not been established yet):**

- low magnesium levels in the body: If you are on Nexium for more than three months, the levels of magnesium in your blood may fall. The symptoms that may indicate lowered levels of magnesium include involuntary muscle contractions, disorientation, convulsions, dizziness, or increased heart rate. If you feel any of these symptoms, please tell your doctor immediately. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- inflammation in the gut (causes diarrhea)
- rash, usually with joint pain
- in very rare cases, Nexium may affect the white blood cells and lead to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with signs of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, consult the doctor immediately to rule out the possibility of lack of white blood cells (agranulocytosis) by a blood test. You must tell the doctor that you are taking Nexium.

**If a side effect occurs, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

**5. HOW SHOULD THE MEDICINE BE STORED?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not induce vomiting unless explicitly instructed to do so by the doctor!

**Storage conditions:**

- Store this medicine below 25°C.
- Even when stored as per the recommended packaging/storage conditions, medicines may be kept for a limited period only. Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to

the last day of that month. In any case of doubt, consult the pharmacist who dispensed the medicine to you.

- Do not store different medicines in the same package.

## **6. FURTHER INFORMATION**

### **In addition to the active ingredient, the medicine also contains:**

Microcrystalline cellulose, methacrylic acid ethylacrylate copolymer (1:1), sugar spheres, hypromellose, talc, triethyl citrate, hypromellose, crospovidone, macrogols, titanium dioxide (E 171), glycerol monostearate 40-55, magnesium stearate, polysorbate 80, sodium stearyl fumarate, iron oxide (20 mg and 40 mg tablets: reddish-brown; 20 mg tablets: yellow) (E 172), synthetic paraffin.

### **What the medicine looks like and contents of the pack:**

Nexium 20 mg tablets – a rectangular, biconvex, light pink tablet, with 20 mg

imprinted on one side and <sup>A</sup><sub>EH</sub> imprinted on the other side. Packages contain 7, 14, or 28 tablets.

Nexium 40 mg tablets – a rectangular, biconvex, pink tablet, with 40 mg imprinted on

one side and <sup>A</sup><sub>EI</sub> imprinted on the other side. Packages contain 7 or 28 tablets.

Not all pack sizes may be available.

### **Manufacturer's name and address:**

Astra Zeneca AB., S-151 85 Sodertalje, Sweden

### **Registration holder's name and address:**

Taro International Ltd., 14 Hakitor Street, Haifa Bay, 2624761

**Revised in April 2022 according to MOH guidelines.**

### **Registration number of the medicine in the National Drug Registry of the Ministry of Health**

Nexium 20 mg: 122 52 30237

Nexium 40 mg: 122 53 30238