Package leaflet: Information for the patient

Normolox 400 mg film-coated tablets
moxifloxacin

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 Normolox is and what it is used for

Normolox contains the active substance moxifloxacin, which belongs to a group of antibiotics called fluoroquinolones. Moxifloxacin works by killing bacteria that cause infections.

Antibiotics are used to treat bacterial infections and do not serve to treat viral infections such as flu or cold.

It is important that you follow the instructions related to doses, dosage interval and duration of treatment indicated by your doctor.

Do not store or reuse this medicine. If once treatment is completed you have antibiotic left, bring it back to the pharmacy for its correct disposal. Medicines should not be disposed of via wastewater or household waste.

Moxifloxacin is used in patients 18 years of age and older for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Moxifloxacin should only be used to treat these infections when usual antibiotics cannot be used or have not worked.
Infection of the sinuses, sudden worsening of long-term inflammation of the airways or infection of the lungs (pneumonia) acquired outside the hospital (except severe cases).
Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane. Moxifloxacin is not sufficient on its own for treating this kind of infection. Therefore, another antibiotic in addition to moxifloxacin should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see Section 2. *What you need to know before you take Normolox*).

If the following diseases have shown improvement during initial treatment with moxifloxacin solution for infusion, moxifloxacin film-coated tablets may also be prescribed by your doctor to complete the course of therapy: Infection of the lungs (pneumonia) acquired outside the hospital, infections of the skin and soft tissues.

Moxifloxacin should not be used to initiate therapy for any type of infections of the skin and soft tissue or in severe infections of the lungs.

2. What you need to know before you take Normolox

Talk to your doctor if you are not sure if you belong to any of the patient groups described below.

Do not take Normolox

- If you are allergic to moxifloxacin, any other quinolones or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breastfeeding.
- If you are younger than 18 years of age.
- If you have previously had problems with your tendons related to treatment with quinolone antibiotics (see *Warnings and precautions* and Section 4. *Possible side effects*). If you were born with or have any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart), if you have a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood), if you have a very slow heart rhythm (called "bradycardia"), if you have a weak heart (heart failure), if you have a history of abnormal heart rhythms, if you are taking other medicines that result in abnormal ECG changes (see *Other medicines and Normolox*). This is because moxifloxacin can cause changes on the ECG, such a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.
- If you have a severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and precautions

Before you start taking Normolox

If you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone, you should not take fluoroquinolone/quinolone antibacterial medicines, including moxifloxacin. If this applies to you, you should tell your doctor as soon as possible.

Talk to your doctor or pharmacist before taking Normolox:

- Moxifloxacin **can change your heart's ECG**, especially if you are female, or if you are elderly. If you are currently taking any medicine that decreases your blood potassium levels, consult your doctor before taking this medicine (see *Do not take Normolox* and *Other medicines and Normolox)*
- If you suffer from epilepsy or a condition which makes you likely to have **convulsions**, tell your doctor before taking moxifloxacin.
- If you have or have ever had any **mental health problems**, consult your doctor before taking moxifloxacin.
- If you suffer from **myasthenia gravis**, taking moxifloxacin may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your doctor, who will advise whether moxifloxacin is suitable for you.
- If you have a **complicated infection of the female upper genital tract** (associated with an abscess of the fallopian tubes and ovaries or of the pelvis), for which your doctor considers an intravenous treatment necessary, treatment with moxifloxacin tablets is not appropriate.

- For the treatment of a **mild to moderate infection of the female upper genital tract**, your doctor should prescribe another antibiotic in addition to moxifloxacin. If there is no improvement in symptoms after three days of treatment, consult your doctor.
- If you have been diagnosed with an **enlargement or "bulge" of a large blood vessel** (aortic aneurysm or large vessel peripheral aneurysm).
- If you have had a previous episode of **aortic dissection** (tear in the wall of the aorta).
- If you are diabetic because you may experience a risk of change in blood sugar levels with moxifloxacin.
  If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking moxifloxacin.
- If you have been diagnosed with leaking heart valves (heart valve regurgitation).
- If you have a family history of aortic aneurysm or aortic dissection congenital heart valve disease, or other risk factors or predisposing conditions (e.g., connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome, Turner syndrome, Sjögren's syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu's arteritis, giant cell arteritis, Behçet's disease, hypertension, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).

When taking Normolox

- If you experience **palpitations or irregular heartbeat** during the period of treatment, you should inform your doctor immediately. He/she may wish to perform an ECG to measure your heart rhythm.
- The **risk of heart problems** may increase with increase of the dose. Therefore, the recommended dosage should be followed.
- There is a rare chance that you may experience a **severe, sudden allergic reaction** (anaphylactic reaction/shock) even with the first dose. Symptoms include tightness in the chest, feeling dizzy, feeling sick or faint, or dizziness when standing up. If these symptoms occur, stop taking moxifloxacin and consult your doctor immediately.
- Moxifloxacin may cause a **rapid and severe inflammation of the liver**, which could lead to life-threatening liver failure (including fatal cases, see Section 4. *Possible side effects*). If you suddenly feel unwell and/or are being sick and also have yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or liver induced disease of the brain (symptoms of a reduced liver function or a rapid and severe inflammation of the liver) please contact your doctor before taking any more tablets.
- Quinolone antibiotics, including moxifloxacin, may cause **convulsions**. If this happens, stop taking moxifloxacin and contact your doctor immediately.
- **Prolonged, disabling and potentially irreversible serious side effects.** Fluoroquinolone or quinolone antibacterial medicines, including moxifloxacin, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue and severe sleep disorders.
  If you experience any of these side effects after taking moxifloxacin, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.
- You may rarely experience symptoms of **nerve damage** (neuropathy) such as pain, burning, tingling, numbness and/or weakness, especially in the feet and legs or hands and arms. If this happens, stop taking moxifloxacin and inform your doctor immediately in order to prevent the development of a potentially irreversible condition.
- You may experience **mental health problems** even when taking quinolone antibiotics, including moxifloxacin. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts (see Section 4. *Possible side effects*). If you develop such reactions, stop taking moxifloxacin and inform your doctor immediately.

- You may develop **diarrhoea** whilst or after taking antibiotics including moxifloxacin. If this diarrhoea is severe or persistent, or you notice that your stool contains blood or mucus you should stop taking moxifloxacin immediately and consult your doctor. You should not take medicines that stop or slow down bowel movement.
- **Pain and swelling in the joints and inflammation or rupture of tendons** may occur rarely. The risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Tendon inflammation and rupture may occur within 48 hours of starting treatment and have even been reported up to several months after discontinuation of treatment with moxifloxacin. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking moxifloxacin, contact your doctor and rest the painful area. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture.
- If you are elderly and have **kidney problems** make sure that you drink plenty whilst taking moxifloxacin, since dehydration may increase the risk of kidney failure.
- If your **eyesight becomes impaired of if your eyes seem to be affected** whilst taking moxifloxacin, consult an eye specialist immediately (see Sections 2. *Driving and using machines* and 4. *Possible side effects*).
- Fluoroquinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia) or lowering of your blood sugar levels below normal levels (hypoglycaemia), potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases. If you suffer from diabetes, careful monitoring of blood glucose is recommended (see Section 4. *Possible side effects*).
- Quinolone antibiotics may make your **skin become more sensitive to sunlight or UV**. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking moxifloxacin.
- The efficacy of moxifloxacin in the treatment of severe burns, infections of deep tissue and diabetic foot infections with osteomyelitis (infections of the bone marrow) has not been established.
- Serious skin reactions: Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), and acute generalised exanthematous pustulosis (AGEP) have been reported with the use of moxifloxacin.
  - SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Ulcers on the mouth, throat, nose, genitals and eyes (red or swollen eyes) may also appear. These severe skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
  - AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localised on the skin folds, trunk, and upper extremities.
- If you experience sudden and severe pain in your abdomen chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.

- **If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.**

  If you develop a severe rash or any of these skin symptoms, stop taking moxifloxacin and contact your doctor or seek medical attention immediately.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because efficacy and safety have not been established for this age group (see section *Do not take Normolox*).

Other medicines and Normolox

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines.

When taking moxifloxacin, be aware of the following:
- If you are taking moxifloxacin and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, do not take moxifloxacin together with the following medicines: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), antipsychotic drugs (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride), tricyclic antidepressants, some antimicrobials (e.g. saquinavir, sparfloxacin, intravenous erythromycin, pentamidine, antimalarials particularly halofantrine), some antihistamines (e.g. terfenadine, astemizole, mizolastine) and other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).
- You must tell your doctor if you are taking other medicines that can lower your blood potassium levels (e.g. some diuretics, some laxatives and enemas (high doses) or corticosteroids (anti-inflammatory drugs), amphotericin B) or cause a slow heart rate because these can also increase the risk of serious heart rhythm disturbances while taking moxifloxacin.
- Any medicine containing magnesium or aluminium, such as antacids for indigestion, or any medicine containing iron, zinc or didanosine or any medicine containing sucralfate to treat stomach disorders can reduce the action of moxifloxacin tablets. Therefore, take your moxifloxacin tablets 6 hours before or after taking the other medicine.
- Taking any medicine containing charcoal at the same time as moxifloxacin tablets reduces the action of moxifloxacin.
- If you are currently taking oral anti-coagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting time.

Normolox with food and drink
The effect of moxifloxacin is not altered by food (including dairy products).

Pregnancy, breast-feeding and fertility
Do not take moxifloxacin 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 using any medicine.
Animal studies do not indicate that your fertility will be impaired by taking this medicine.

Driving and using machines
Moxifloxacin may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision, or you may faint for a short period. If you experience these symptoms, do not drive or operate machinery.

3. How to take Normolox

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

The recommended dose is one 400 mg film-coated tablet once daily.

Moxifloxacin tablets are for oral use. Swallow the tablet whole without chewing (to mask the bitter taste) and with plenty of liquid. You can take moxifloxacin with or without food. Tray to take the tablet at approximately the same time each day.

It is not necessary to adjust the dosage in elderly patients, patients with a low body weight or in patients with kidney problems.

Duration of treatment depends on your infection. Unless your doctor tells you otherwise, your treatment with moxifloxacin will be as follows:

- Acute exacerbation of chronic obstructive pulmonary disease (including bronchitis): 5 - 10 days.
- For infections of the lungs (pneumonia) acquired outside the hospital except severe cases: 10 days.
- For acute infection of sinuses (acute bacterial sinusitis): 7 days.
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane: 14 days.

When moxifloxacin 400 mg tablets is used to complete a course of therapy started with moxifloxacin solution for infusion (intravenous treatment), the recommended durations of use are:

- Infection of the lungs (pneumonia) acquired outside the hospital (total duration of the intravenous treatment followed by tablets): 7 - 14 days.
  Most patients with pneumonia were switched from intravenous treatment to oral treatment after 4 days.
- Infections of the skin and soft tissue (total duration of the intravenous treatment followed by tablets): 7 - 21 days.
  Most patients with infections of the skin and soft tissue were switched from intravenous treatment to oral treatment after 6 days.

It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking moxifloxacin too soon, your infection may not be completely cured, and the infection return, or your condition may get worse. The bacteria causing your infection may become resistant to the antibiotic.

The recommended dose and duration of treatment should not be exceeded (see Section 2. *Warnings and precautions*).

If you take more Normolox than you should
If you take more than the prescribed one tablet a day, consult your doctor immediately and, if possible, take any remaining tablets, the packaging or this leaflet with you to show the doctor or pharmacist what you have taken.

In the event of an overdose or accidental ingestion, call your doctor or pharmacist at once, or go to the nearest hospital, indicating the medicine and the amount taken.

If you forget to take Normolox
If you forget to take your tablet, you should take it as soon as you remember on the same day. If you do not remember on the same day, take your normal dose (one tablet) on the next day. Do not take a double dose to make up for a forgotten dose.

If you are unsure about what to do, ask your doctor or pharmacist.

If you stop taking Normolox
If you stop taking this medicine too soon, your infection may not be completely cured. Talk to your doctor if you wish to stop taking your tablets before the end of the course of treatment.

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

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

4. Possible side effects

Like all medicines, moxifloxacin can cause side effects, although not everybody gets them.

The following side effects have been observed during treatment with moxifloxacin.

Assessment of side effects has been based on the following frequency data:
Not known
Common: May affect up to 1 in 10 patients
Uncommon: May affect up to 1 in 100 patients
Rare: May affect up to 1 in 1,000 patients
Very rare: May affect up to 1 in 10,000 patients

Infections
Common: Infections caused by resistant bacteria or fungi, e.g. oral and vaginal infections caused by *Candida*.

Blood and lymphatic system disorders
Uncommon: Low red blood cell count, low white blood cells count, low numbers of special white blood cells (neutrophils), decrease or increase of special blood cells necessary for blood clotting, increased specialised white blood cells (eosinophils), decreased blood clotting.
Very rare: Increased blood clotting, significant decrease of special white blood cells (agranulocytosis). A drop in the number of red and white blood cells and platelets (pancytopenia).

Allergic reactions
Uncommon: Allergic reactions.
Rare: Severe, sudden and generalised allergic reaction, including very rarely life-threatening shock (e.g. Difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway).

Alteration in laboratory tests
Uncommon: Increased blood lipids (fats).
Rare: Increased blood glucose, increased blood uric acid.
Very rare: Decreased blood glucose.

Psychiatric disorders
Uncommon: Anxiety, restlessness/agitation.
Rare: Feeling particularly emotional, depression (which in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, or suicide attempts), hallucination.
Very rare: A feeling of self-detachment (not being yourself), dementia (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts).

Nervous system
Common: Headache, dizziness.

Uncommon: Tingling sensation (pins and needles) and/or numbness, change in taste (in very rare cases loss of taste), confusion and disorientation, sleep disorders (predominantly insomnia), tremor, sensation of vertigo (spinning or falling over), somnolence.
Rare: Problems with skin sensations, changes in smell (including loss of smell), unusual dreams, problems with balance and co-ordination (due to dizziness), convulsions, disturbed concentration, problems with speech, partial or total loss of memory, troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities.
Very rare: Skin feeling more sensitive.

Eyes
Uncommon: Problems with vision, including double or blurred vision.
Very rare: Transient vision loss.

Ears
Rare: ringing or noise in the ears, hearing impairment including deafness (usually reversible).

Cardiac system (see Section 2. *What you need to know before you take Normolox*)
Common: Change of the heart rhythm (ECG) in patients with low blood potassium level.
Uncommon: Change of the heart rhythm (ECG), palpitations, irregular and fast heartbeat, severe heart rhythm abnormalities, angina pectoris.
Rare: Abnormal fast heart rhythm, fainting.
Very rare: Abnormal heart rhythms, life-threatening irregular heartbeat, stopping of heartbeat.

Vascular system
Uncommon: Widening of the blood vessels.
Rare: Hypertension, hypotension.
Very rare: Inflammation of blood vessels (signs may be red spots on the skin, usually in the legs, or effects such as joint pain).

Respiratory system
Uncommon: Difficulty in breathing, including asthmatic conditions.

Gastrointestinal system
Common: Nausea, vomiting, stomach and abdominal ache, diarrhoea.
Uncommon: Decreased appetite and food intake, flatulence and constipation, stomach upset (indigestion/heartburn), inflammation of the stomach, increase of a special digestive enzyme in the blood (amylase).
Rare: Difficulty in swallowing, inflammation of the mouth, severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis) which very rarely may develop into complications that are life-threatening.

Liver
Common: Increased of a special liver enzyme in the blood (transaminases).
Uncommon: Problems with liver function (including increase of a special liver enzyme in the blood, LDH), increase of bilirubin in the blood, increase of a special liver enzyme in the blood (gamma-glutamyltransferase and/or alkaline phosphatase).
Rare: Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver.
Very rare: Severe inflammation of the liver potentially leading to life-threatening liver failure (including fatal cases).

Skin
Uncommon: Itching, rash, skin hives, dry skin.
Very rare: Severe skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening).
Not known: a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

Musculoskeletal system
Uncommon: Joint pain, muscle pain.
Rare: Pain and swelling of the tendons (tendonitis), muscle cramps or twitching, muscle weakness.
Very rare: Rupture of tendons, inflammation of joints, muscles feeling stiff, worsening of symptoms of myasthenia gravis.
Not known: muscle weakness, tenderness or pain and particularly, if at the same time you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems (a condition called rhabdomyolysis).

Kidneys
Uncommon: Dehydration.
Rare: Kidney problems (including an increase in special kidney laboratory test results like urea and creatinine), kidney failure.
Very rare: Syndrome associated with impaired water excretion and low levels of sodium (SIADH).

Endocrine system
Very rare: Loss of consciousness due to a severe decrease in blood sugar levels (hypoglycaemic coma)

General side effects
Uncommon: Feeling unwell (usually weakness or tiredness), aches and pains such as back, chest, pelvic pains and pains in the extremities, sweating.
Rare: Swelling (of the hands, feet, ankles, lips, mouth or throat).

Very rare cases of long-lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also Section 2.

Also, there have been very rare cases of the following side effects reported following treatment with other quinolone antibiotics, which might possible also occur during treatment with moxifloxacin: increased blood sodium and calcium levels, a special type of reduced red blood cell count (haemolytic anaemia), increased sensitivity of the skin to sunlight or UV light.

Reporting 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Normolox

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

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

Store below 30ºC.

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. Contents of the pack and other information

What Normolox contains
- The active substance is moxifloxacin. Each film-coated tablet contains 400 mg of moxifloxacin (as moxifloxacin hydrochloride).
- The other ingredients are: *Tablet core*: Croscarmellose sodium, cellulose microcrystalline, colloidal anhydrous silica, talc and magnesium stearate; *Film-coating*: Hydroxypropyl methylcellulose (E-464), titanium dioxide (E-171), macrogol 6000, talc and red iron oxide (E-172).

What Normolox looks like and contents of the pack
Pale red, oblong, biconvex, film-coated tablets marked with "M400" on one side.
Normolox 400 mg film-coated tablets comes in packs of 5 and 7 tablets.
Not all pack sizes are marketed in all countries.

Marketing Authorisation Holder and Manufacturer
LABORATORIOS NORMON, S.A.
Ronda de Valdecarrizo, 6
28760 Tres Cantos, Madrid
Spain

This leaflet was las revised in: December 2020