

PACKAGE LEAFLET: Information for the patient

AVACYN

Film-coated tablets – 400 mg

(Moxifloxacin hydrochloride)

Read this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Avacyn is and what it is used for
2. Before you take Avacyn
3. How to take Avacyn
4. Possible side effects
5. How to store Avacyn
6. Further information

1. WHAT AVACYN IS AND WHAT IT IS USED FOR

Avacyn contains the active substance moxifloxacin hydrochloride, which belongs to a group of antibiotics called fluoroquinolones. Avacyn works by killing bacteria that cause infections. It is used in patients aged 18 years and above for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active.

Avacyn is used for treating the following bacterial infections, when usual antibiotics cannot be used or have not worked:

- infection of the sinuses (acute bacterial sinusitis);
- acute exacerbations of chronic bronchitis;
- community acquired pneumonia 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; Avacyn film-coated tablets are not sufficient on their own for treating this kind of infection, therefore, another antibiotic in addition to Avacyn film-coated tablets should be prescribed by your doctor for the treatment of infections of the female upper genital tract.

Avacyn film-coated tablets may also be used to complete a course of therapy in patients who have shown improvement during initial treatment with intravenous moxifloxacin for the following indications:

- complicated skin and skin structure infections;
- community acquired pneumonia.

Avacyn tablets 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.

Your doctor may have given you Avacyn for another purpose. Ask your doctor if you want to know why you were given Avacyn.

2. BEFORE YOU TAKE AVACYN

Do not take Avacyn if you:

- are hypersensitive to moxifloxacin hydrochloride, other quinolones or to any of the excipients of the tablet;
- are pregnant or breast-feeding;
- are under 18 years old;
- have a history of tendon disease/disorder related to quinolone treatment;
- were born with or have had: any condition with abnormal heart rhythm (noted on ECG), salt imbalance in the blood (low level of potassium or magnesium in the blood), a very low heart rhythm (bradycardia), heart failure, a history of abnormal heart rhythms or are taking other drugs that prolong the QT interval;
- have a severe liver disease or transaminases level 5 times higher than the upper normal limit.

Take special care with Avacyn

You should not take fluoroquinolone / quinolone antibacterial medicines, including Avacyn, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.

- Avacyn 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 Avacyn.
- If you suffer from **epilepsy** or a condition which makes you likely to have **convulsions**, talk to your doctor before taking Avacyn.
- If you have or have ever had any **mental health problems**, consult your doctor before taking Avacyn.
- If you suffer from **myasthenia gravis**, using Avacyn 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), inform your doctor, who will advise whether Avacyn is suitable for you.
- If you are a female and have a complicated infection of the upper genital tract (e.g. 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 Avacyn film-coated tablets is not appropriate.
- For the treatment of mild to moderate infections of the female upper genital tract your doctor should prescribe another antibiotic in addition to Avacyn. If there is no improvement of symptoms after 3 days of treatment, please consult your doctor.

Inform your doctor also before taking Avacyn:

- 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 experienced a previous episode of aortic dissection (a tear in the aorta wall);
- if you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or

vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis);

- 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 feel sudden, severe pain in your abdomen, chest or back, go immediately to an emergency room.

When using Avacyn:

- if you experience **palpitations or irregular heart beat** 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 the 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** (an anaphylactic reaction/shock) even with the first dose, with symptoms that may include: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing (orthostatic hypotension); **if this happens, treatment with Avacyn film-coated tablets has to be discontinued immediately;**
- Avacyn may cause a **rapid and severe inflammation of the liver** which could lead to life-threatening liver failure; if you suddenly start to feel unwell 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 Avacyn, may cause **convulsions**; if this happens, treatment with Avacyn has to be discontinued;
- you may rarely experience **symptoms of nerve damage (neuropathy)** such as pain, burning, numbness and/or weakness especially in the feet and legs or hands and arms; if this happens,

stop taking Avacyn and inform your doctor immediately in order to prevent the development of potentially irreversible condition;

- you may experience **mental health problems** even when taking quinolone antibiotics, including Avacyn, for the first time; in very rare cases, depression or mental health problems have led to suicidal thoughts and self-injuries behaviour such as suicide attempts; if you develop such reactions, treatment with Avacyn has to be discontinued;
- you may develop **diarrhoea** whilst taking, or after taking antibiotics including Avacyn; if this becomes severe or persistent, or you notice that your stool contains blood or mucus you should stop using Avacyn immediately and consult your doctor; in this situation, you should not take medicines that stop or slow down bowel movement;
- Avacyn may cause rarely **pain and swelling in the joints and inflammation or rupture of your tendons**; your 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; inflammation and ruptures of tendons may occur within the first 48 hours after starting treatment and even up to several months after stopping the therapy; at the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop using Avacyn, contact your doctor and rest the affected limb(s); avoid any unnecessary exercise, as this might increase the risk of a tendon rupture;
- if you are elderly with existing **kidney problems**, take care that your fluid intake is sufficient because dehydration may increase the risk of kidney failure;
- if your **eyesight becomes impaired** or if your eyes seem to be otherwise affected, consult an eye specialist immediately;
- fluoroquinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycemia), or lowering of your blood sugar levels below normal levels (hypoglycaemia), potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4. Possible side effects). If you suffer from diabetes, your blood sugar should be carefully monitored;
- quinolone antibiotics may make your **skin** become more **sensitive to sunlight or UV light**; you should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while using Avacyn;

- there is limited experience in the use of moxifloxacin orally / intravenously on a continuous basis for the treatment of lung infections (pneumonia) acquired outside the hospital.

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, 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. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious 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 localized on the skin folds, trunk, and upper extremities.

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

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone / 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 Avacyn, 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.

Children and adolescents

This medicine must not be administered to children and adolescents under the age of 18 because efficacy and safety have not been established for this age group.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Avacyn.

Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Avacyn if you take any other medicine during treatment.

If you are using Avacyn and other medicines that affect your heart, there is an increased risk for altering your heart rhythm, therefore, do not use Avacyn concomitantly with:

- medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide);
- antipsychotics (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);
- other medicines (e.g. cisapride, intravenous vincamycin, 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 [large 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 using Avacyn.

Any medicine containing magnesium or aluminium (such as antacids for indigestion), iron, zinc or didanosine or any medicine containing sucralfate (to treat stomach disorders) can reduce the effect of Avacyn film-coated tablets. Take your Avacyn tablet 6 hours before or after taking the other medicine.

Taking any medicine containing charcoal at the same time as Avacyn film-coated tablets reduces the effect of Avacyn. It is recommended that these medicines are not used together.

If you are currently taking oral anti-coagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting time.

Taking Avacyn with food and drinks

The effect of Avacyn is not influenced by food including dairy products.

Pregnancy and breastfeeding

Do not use Avacyn if you are pregnant or breastfeeding.

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 this medicine.

Animal studies do not indicate that your fertility will be impaired by using this medicine.

Driving and using machines

Avacyn may make you feel dizzy, you may experience a sudden, transient loss of vision, or you might faint for a short period. If you are affected in this way do not drive or operate machinery.

Important information about some of the excipients of Avacyn

Avacyn film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Avacyn film-coated tablets contain less than 1 mmol sodium (23 mg) per each tablet, that is to say essentially sodium-free.

3. HOW TO TAKE AVACYN

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

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

Avacyn film-coated tablets are for oral use. Swallow the film-coated tablet whole and with plenty of liquid.

You can take Avacyn with or without food. Try to take the film-coated tablet at approximately the same time each day.

The same dose can be taken by elderly patients, patients with a low bodyweight or patients with kidney problems. The duration of your treatment with Avacyn depends on your infection.

Unless your doctor tells you otherwise, your treatment will be as follows:

- sudden worsening (acute exacerbation) of chronic bronchitis: 5-10 days;
- infection of the lungs (pneumonia) except for pneumonia which starts during a stay in hospital: 10 days;
- acute infection of the sinuses (acute bacterial sinusitis): 7 days;
- mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infection of the fallopian tubes and infection of the uterus mucous membrane: 14 days.

When Avacyn film-coated tablets are used to complete a course of therapy started with Avacyn solution for infusion, the recommended durations of use are:

- infection of the lungs (pneumonia) acquired outside the hospital, 7 -14 days;
most patients with pneumonia were switched to oral treatment with moxifloxacin film-coated tablets within 4 days;
- infections of the skin and soft tissue, 7 -21 days;
most patients with infections of the skin and soft tissue were switched to oral treatment with moxifloxacin film-coated tablets within 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 Avacyn too soon, your infection may not be completely cured. The infection may return or your condition may get worse.

The bacteria causing your infection may become resistant to Avacyn.

The recommended dose and duration of treatment should be followed rigorously.

If you take more Avacyn than you should

If you take more than the prescribed one tablet a day, get **medical help immediately**. Try to take any remaining tablet, the packaging or this leaflet with you to show the doctor or pharmacist what you have taken.

If you forget to take Avacyn

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 film-coated tablet) on the next day. Do not take a double dose to make up for a forgotten dose. If you are not sure about what to do, ask your doctor or pharmacist.

If you stop taking Avacyn

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 Avacyn before the end of the course of treatment.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, moxifloxacin can cause side effects, although not everybody gets them. The most serious side effects observed during the treatment with moxifloxacin are listed below.

If you notice the below mentioned situations, **stop taking Avacyn and immediately inform your doctor because you may need urgent medical advice:**

- an abnormal fast heart rhythm (rare side effect);
- that you suddenly start feeling unwell or notice yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or disturbances of thought or wakefulness (these

can be signs and symptoms of fulminant inflammation of the liver potentially leading to life-threatening liver failure (very rare side effect, fatal cases have been observed));

- serious skin rashes 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 mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening);
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency of this side effect is 'not known');
- syndrome associated with impaired water excretion and low levels of sodium (SIADH) (very rare side effect);
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma) (very rare side effect);
- inflammation of blood vessels (signs could be red spots on your skin, usually on your lower legs or effects like joint pain) (very rare side effect);
- a severe, sudden generalised allergic reaction, including very rarely a life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse) (rare side effect);
- swelling including swelling of the airways (rare side effect, potentially life-threatening);
- convulsions (rare side effect);
- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (rare side effect);
- depression (in very rare cases leading to self-harm, such as suicidal ideations / thoughts) (rare side effect);
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis e.g. pseudomembranous colitis), which in very rare circumstances, may develop into complications that are life-threatening (rare side effects);
- pain and swelling of the tendons (tendonitis) (rare side effect) or a tendon rupture (very rare side effect);
- 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) (frequency of this side effect is 'not known').

In addition, if you notice:

- transient loss of vision (very rare side effect), contact an eye specialist immediately.

If you have experienced life-threatening irregular heart beat (Torsade de Pointes) or stopping of heart beat while taking Avacyn (very rare side effects), tell your treating doctor immediately that you have taken Avacyn and do not restart the treatment.

A worsening of the symptoms of myasthenia gravis has been observed in very rare cases. If this happens, consult your doctor immediately.

If you suffer from diabetes and you notice that your blood sugar is increased or decreased (rare or very rare side effect), inform your doctor immediately.

If you are elderly with existing kidney problems and you notice decrease in urine output, swelling in your legs or ankles, fatigue, nausea, drowsiness, shortness of breath or confusion (these can be signs and symptoms of kidney failure, a rare side effect), consult your doctor immediately.

Other side effects which have been observed during treatment with moxifloxacin are listed below by frequency:

Common (may affect up to 1 in 10 people):

nausea, diarrhoea, dizziness, stomach and abdominal ache, vomiting, headache, increase of a special liver enzyme in the blood (transaminases), infections caused by resistant bacteria or fungi e.g. oral and vaginal infections caused by *Candida*, change of the heart rhythm (ECG) in patients with low blood potassium level.

Uncommon (may affect up to 1 in 100 people):

rash, stomach upset (indigestion / heartburn), changes in taste (in very rare cases loss of taste), sleep problems (predominantly sleeplessness), increase of a special liver enzyme in the blood (gamma-glutamyl-transferase and/or alkaline phosphatase), low number of special white blood cells (leukocytes, neutrophils), constipation, itching, sensation of dizziness (spinning or falling

over), sleepiness, wind, change of the heart rhythm (ECG), impaired liver function (e.g. increase of a special liver enzyme in the blood (LDH)), decreased appetite and food intake, low white blood cells count, aches and pains such as back, chest, pelvic and extremities pain, increase of special blood cells necessary for blood clotting, sweating, increased specialised white blood cells (eosinophils), anxiety, feeling unwell (predominantly weakness or tiredness), shaking, joint pain, palpitations, irregular and fast heart beat, difficulty in breathing e.g. asthmatic conditions, increase of a special digestive enzyme in the blood (amylase), restlessness / agitation, tingling sensation and/or numbness, skin hives, widening of blood vessels, confusion and disorientation, decrease of special blood cells necessary for blood clotting, visual disturbances e.g. double and blurred vision, decreased blood clotting, increased blood lipids (fats), low red blood cell count, muscle pain, allergic reaction, increase of bilirubin in the blood, inflammation of a vein, inflammation of the stomach, dehydration, severe heart rhythm abnormalities, dry skin, angina pectoris.

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

muscle twitching, muscle cramps, hallucinations, high blood pressure, swelling (of the hands, feet, ankles, lips, mouth, throat), low blood pressure, kidney impairment (e.g. increase in special kidney laboratory test results like urea and creatinine), inflammation of the liver, inflammation of the mouth, ringing/noise in the ears, jaundice (yellowing of the whites of the eyes or skin), impairment of skin sensation, abnormal dreams, disturbed concentration, difficulty in swallowing, changes in smell (e.g. loss of smell), balance disorder and poor co-ordination (due to dizziness), partial or total loss of memory, hearing impairment including deafness (usually reversible), increased blood uric acid, emotional instability, impaired speech, fainting, muscle weakness.

Very rare (may affect up to 1 in 10,000 people):

inflammation of joints, abnormal heart rhythm, increase of skin sensitivity, a feeling of self-detachment (not being yourself), increased blood clotting, muscle rigidity, significant decrease of special white blood cells (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia).

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

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. When any of the above-mentioned side effects appears, the treatment with Avacyn should be discontinued and you should consult your doctor or pharmacist.

5. HOW TO STORE AVACYN

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 blister and on the carton.

Do not store above 25°C.

Store in the original package in order to protect from moisture!

6. FURTHER INFORMATION

What Avacyn 400 mg film-coated tablets contain

The active substance is moxifloxacin hydrochloride.

Each film-coated tablet contains 400 mg moxifloxacin (as hydrochloride).

The excipients are:

Tablet core: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, sodium starch glycolate, magnesium stearate.

Film-coating: polyvinyl alcohol, macrogol, titanium dioxide, talc, red iron oxide, yellow iron oxide.

Content of the pack: Box with 10 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

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