PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

AVELON Tablets
AVELON IV Solution for Infusion

WHAT AVELON CONTAINS:

Avelon film coated tablet contains 400mg moxifloxacin, the active ingredient.
A single sterile unit of Avelon IV 250ml infusion solution contains 400 mg moxifloxacin.

Other ingredients are:
Tablets:
Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, ferric oxide, hypromellose, macrogol 4000, titanium dioxide.
Solution for infusion:
Sodium chloride, hydrochloric acid 1N, sodium hydroxide solution 2N, water for injection.

WHAT AVELON IS USED FOR?

- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis
- Community Acquired Pneumonia
- Uncomplicated Skin and soft tissue infections
- Complicated Skin and skin structure infections (including diabetic foot infections)
- Uncomplicated pelvic inflammatory disease (i.e. infections of female upper genital tract, including salpingitis and endometritis)
- Complicated intra-abdominal infections including polymicrobial infections such as abscesses

BEFORE YOU TAKE AVELON:

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

You should not take AVELON if you are pregnant.
You should not breastfeed.

AVELON is contra-indicated in children under 18 years, except where the benefits of treatment exceed the risk.

Do not take AVELON:

- If you are allergic to moxifloxacin or any of the other ingredients listed above.
- If you have severe liver disease.
- If you are pregnant or breastfeeding.

If you are taking other medicines on a regular basis, concomitant use of AVELON may cause undesirable effects. Please inform your doctor or pharmacist of any other medication you may be taking.

If you are taking any of the following medicines please consult your healthcare professional:

- Ranitidine
- Antacids, minerals and multi-vitamins
- Warfarin
- Antidiabetics
- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Charcoal

Please be advised:

- that AVELON may produce changes in the electrocardiogram (ECG).
- that AVELON should be avoided in patients receiving Class IA (e.g. quinidine, procainamide) or Class III (e.g. amiodarone, sotalol) antiarrhythmic agents.
- that AVELON may add to the QTc prolonging effects of other drugs such as cisapride, erythromycin, antipsychotics, and tricyclic antidepressants.
- to inform your medical practitioner of any personal or family history of QTc prolongation or proarrhythmic conditions such as recent hypokalaemia (low potassium), significant bradycardia (slowing heart rate), acute myocardial ischaemia (heart attack).
- to inform your medical practitioner of any other medications when taken concurrently with AVELON, including over-the-counter medications.
- to contact your medical practitioner if you experience palpitations (fast heart beat) or fainting spells while taking AVELON.
- that AVELON tablets may be taken with or without meals, and drink fluids liberally.
- that AVELON may be associated with hypersensitivity reactions, even following a single dose, and to discontinue AVELON at the first sign of a skin rash or other signs of an allergic reaction.
- to discontinue treatment; rest and refrain from exercise; and inform your medical practitioner if you experience pain, inflammation, or rupture of a tendon.
- that AVELON may cause dizziness and lightheadedness; therefore, you should observe how you react to this medicine before you operate a vehicle or machinery or engage in activities requiring mental alertness or coordination.
- that phototoxicity has been reported in patients receiving certain quinolones (the group of antibiotics that AVELON belongs to). There was no phototoxicity seen with AVELON at the recommended dose. In keeping with good medical practice,

avoid excessive sunlight or artificial ultraviolet light (e.g. tanning beds). If sunburn-like reaction or skin eruptions occur, contact your medical practitioner.
- that convulsions have been reported in patients receiving quinolones, and you should notify your medical practitioner before taking AVELON if there is a history of this condition.
- that in some instances, hypersensitivity and allergic reactions occurred after the first administration and that the doctor should be informed immediately. Anaphylactic reactions in very rare instances can progress to a life threatening shock, in some instances after the first administration. In these cases AVELON has to be discontinued, and medical treatment (e.g. treatment for shock) would be required.

HOW TO TAKE AVELON:

Always take AVELON exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Avelon tablets and intravenous solution:
The recommended dose for AVELON is 400 mg once-daily for all indications.

Duration of treatment
The duration of treatment should be determined by the severity of the indication or clinical response. In general, antibiotic therapy should be used for 3-4 days after the manifestations of the infection have cleared.

The following general recommendations for the treatment of upper and lower respiratory tract infections are made:

- Acute exacerbation of chronic bronchitis, 5 days
- Community acquired pneumonia, 7 - 14 days
- Acute sinusitis, 10 days

The recommended duration of treatment in Skin and soft tissue infections is as follows;
- Uncomplicated Skin and skin structure Infections 7 days
- Complicated skin and skin structure infections 7 – 21 days

The recommended duration for other infections are:
- Uncomplicated pelvic inflammatory disease: 14 days
- Complicated intra-abdominal infections total treatment duration for sequential therapy (intravenous followed by oral therapy): 5 – 14 days

The recommended duration of treatment for the indication being treated should not be exceeded.

Therapy may be initial intravenous administration, followed by oral tablet administration (Sequential Therapy), when clinically indicated. Alternatively, Avelon can be administered intravenously for the entire treatment duration.

Method of administration - Adults
The tablets are swallowed whole with a glass of water. They can be taken independent of food intake.

The infusion solution should be infused intravenously over 60 minutes. It can be administered directly or together with compatible infusion solutions. The following coinfusions were found to form stable mixtures over a period of 24 hours at room

temperature with moxifloxacin infusion solution, and can therefore be considered as compatible:
Water for Injections
Sodium Chloride 0,9 %
Sodium Chloride 1 molar
Glucose 5 %
Glucose 10 %
Glucose 40 %
Ringer solution
Lactated Ringer solution

The following coinfusions were found to be incompatible with moxifloxacin infusion solution:
Sodium Chloride 10 % and 20 % (Precipitation can occur at higher ratios)
Sodium Bicarbonate 4,2 % and 8,4 % (causes pH shift, and CO_2 bubbles can form)

If Avelon infusion solution is to be given with another drug, each drug should be given separately. Only clear solutions are to be used. Do not use if the solution is cloudy.

Do not double the dose.
Do not share medicines that are prescribed for you with any other person.
Do not change the dose prescribed by your doctor.

For how long should you take AVELON?

The attending doctor must decide on the length of the treatment.

What should you do if you have taken too few AVELON tablets or have forgotten to take a dose?

Do not take more AVELON next time; simply continue the treatment as prescribed.

What should you do if you want to interrupt the treatment or stop using AVELON before the end of the course?

You should always consult your doctor before deciding to interrupt the course of treatment or stop taking AVELON altogether.

POSSIBLE SIDE-EFFECTS:

Not all side-effects reported for AVELON are included in this leaflet. Should your general health worsen while taking AVELON, please consult your doctor, pharmacist or other health care professional for advice.

If any of these side-effects continue, are severe or bother you, tell your doctor or pharmacist.

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

Blood and lymphatic system
Uncommon: anaemia, decrease in white blood cells (leukocytes and neutrophils), reduced or increased blood platelet levels, increased numbers of certain white blood cells (eosinophilia), reduced blood

coagulation/rise in INR (certain parameters used for measuring blood coagulation)

Very rare: increased level of a specific blood coagulation factor (prothrombin)/ reduction in INR (certain parameters used for measuring blood coagulation)

Hypersensitivity reactions

Uncommon: allergic reactions

Rare: serious and sudden allergic reactions, including life-threatening shock (very rare: signs of shock include cold sweat, a drop in blood pressure and racing pulse), swelling as the result of an allergic reaction (including swelling of the larynx, potentially life-threatening; allergic oedema)

Metabolism and nutrition disorders

Uncommon: increased blood lipid (fat) levels

Rare: increased blood glucose levels, increased uric acid levels

Psychiatric disorders

Uncommon: anxiety, psychomotor hyperactivity/restlessness

Rare: mood swings, depression (to the point of self-endangerment on very rare occasions), hallucinations

Very rare: altered self-perception, psychotic reactions (possibly to the point of self- endangerment)

Nervous system

Common: headache, drowsiness

Uncommon: paraesthesia ("pins and needles"), change in pain sensitivity, impaired taste perception (including loss of taste in rare cases), confusion and disorientation, sleep disorders (mainly insomnia), trembling, dizziness, sleepiness

Rare: hypersensitivity to pain, temperature and touch stimuli, impaired sense of smell (including loss of sense of smell), abnormal dreams, impaired coordination (including unsteady gait, especially due to drowsiness and dizziness), seizures, impaired alertness, speech disorders, loss of memory

Very rare: sensitivity to touch

Eye

Uncommon: eyesight problems, including double and blurred vision (particularly during the course of central nervous system reactions)

Ear

Rare: ringing in the ears (tinnitus)

Cardiovascular system

Common: certain ECG changes (prolongation of the QT interval) in patients with preexisting low potassium levels.

Uncommon: certain ECG changes (prolongation of the QT interval), heart palpitations, racing heart, atrial fibrillation, angina pectoris, widening of the blood vessels

Rare: certain heart rhythm disorders (ventricular tachyarrhythmias), loss of consciousness, high blood pressure, low blood pressure

Very rare: heart rhythm disorders, torsade de pointes (a specific heart rhythm disorder), cardiac arrest

Respiratory tract

Uncommon: shortness of breath (including asthmatic conditions)

Gastrointestinal tract

Common:	nausea, vomiting, stomach ache and abdominal pain, diarrhoea
Uncommon:	loss of appetite, constipation, impaired digestion, flatulence, gastrointestinal inflammation, a rise in levels of a certain digestive enzyme (amylase) in the blood
Rare:	difficulties in swallowing, inflammation of the mucous membranes, very severe diarrhoea with the presence of blood and/or mucous (antibiotic-associated colitis incl. pseudomembranous colitis), in very rare cases with life-threatening complications

Liver

Common:	increased levels of certain liver enzymes in blood (transaminases)
Uncommon:	liver dysfunction (including increased levels of a certain liver enzyme in the blood (LDH)), increased levels of bilirubin (bile pigment) in blood, increase in certain liver enzymes in blood (gamma GT and alkaline phosphatase)
Rare:	jaundice, hepatitis
Very rare:	Fulminant inflammation of the liver potentially leading to life-threatening liver failure

Skin

Uncommon:	itching, skin rash, nettle rash (urticaria), dry skin
Very rare:	a severe skin rash running a feverish course, with blistering and the potential to affect the mucous membranes; potentially life-threatening (Stevens-Johnson syndrome, toxic epidermal necrolysis)

Musculoskeletal system

Uncommon:	joint pain, muscle pain Rare: inflamed tendons (tendonitis), muscular spasms, muscular twitching
Very rare:	ruptured tendons, inflamed joints, increased muscle tension

Kidneys

Uncommon:	dehydration
Rare:	kidney dysfunction (including a rise in urea and creatinine levels), kidney failure

General side effects

Uncommon:	general feeling of being unwell (mostly weakness or tiredness), pain (especially in the back, chest, pelvis and extremities), sweating
Rare:	swelling of the hands, feet, ankles, lips, mouth and neck (oedema)

Furthermore, the following side effects have been observed following treatment with other quinolones, and may possibly also occur when taking AVELON:
temporary loss of vision, increased sodium levels, increased calcium levels, breakdown of red blood cells, allergic skin reactions to light.

STORING AND DISPOSING OF AVELON:

<u>Avelon tablets and Avelon IV:</u>
Store at or below 25 °C, in a dry place.
Store all medicines out of the reach of children. Do not store in bathrooms.
Return unused or expired medicines to your pharmacist for safe disposal.
Do not remove from the original packaging until administered.
Do not use after the expiry date stated on the label.

Avelon IV:
Store at or below 25 °C.
Do not store below 15 ºC. At cool storage temperatures, precipitation may occur, which will re-dissolve at room temperature. It is therefore recommended not to store the infusion solution in a refrigerator. Protect from light. Keep the flexibags in the overwrap/pouch or the bottles in the outer cartons until required for use.

PRESENTATION OF AVELON:

AVELON tablets:	Blister packs of 5, 7 and 10 tablets.
AVELON IV:	250 ml Polyolefin flexibag.
AVELON IV:	250 ml Colourless glass bottle for infusion.

IDENTIFICATION OF AVELON:

AVELON tablets:	Dull red coated oblong, convex tablet. One side is embossed "BAYER" and the other "M400".
AVELON IV:	Clear yellow solution.

REGISTRATION NUMBER:

Avelon tablets:	34/20.1.1/0008
Avelon IV solution for infusion:	36/20.1.1/0052

NAME AND ADDRESS OF REGISTRATION HOLDER:

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