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1063 FACTIVE is a registered trademark of LG Life Sciences.

1064 **Rx only**

1065
1066 Manufactured for:
1067 Oscient Pharmaceuticals
1068 Waltham, MA 02451-1478 USA

1069
1070 Licensed from LG Life Sciences, Ltd. Seoul, Korea

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1073 **Patient Information**

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1075 **FACTIVE®** 1076 **(gemifloxacin mesylate) Tablets**

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1078 This leaflet summarizes the most important information about FACTIVE. Read the
1079 Patient Information that comes with FACTIVE each time you get a new prescription.
1080 There may be new information. This leaflet does not list all benefits and risks of
1081 treatment and does not take the place of talking with your healthcare provider about your
1082 condition or your treatment.

1083

1084 **What is FACTIVE?**

1085 FACTIVE is an antibiotic. It is used to treat adults 18 years or older with bronchitis or
1086 pneumonia (lung infections) caused by certain bacteria (germs).

1087

1088 Sometimes, other germs called viruses infect the lungs. The common cold is a virus.
1089 FACTIVE, like other antibiotics, does not treat viruses.

1090

1091 **Who should not take FACTIVE?**

- 1092 • **Do not take FACTIVE if you are allergic to any of the ingredients in FACTIVE**
1093 **or to any antibiotic called a “quinolone”.** If you develop hives, difficulty
1094 breathing, or other symptoms of a severe allergic reaction, seek emergency treatment
1095 right away. If you develop a skin rash, stop taking FACTIVE and call your
1096 healthcare professional. The ingredients in FACTIVE are listed at the end of this
1097 leaflet. Ask your healthcare provider or pharmacist if you need a list of quinolone
1098 antibiotics.

1099

1100 **FACTIVE may not be right for you. Tell your healthcare provider if you:**

- 1101 • are pregnant, planning to become pregnant, or are breast feeding. The effects of
1102 FACTIVE on unborn children and nursing infants are unknown;
- 1103 • or any family members have a rare heart condition known as congenital prolongation
1104 of the QTc interval;
- 1105 • have low potassium or magnesium levels;
- 1106 • have a slow heart beat called bradycardia;

-
- 1107 • have had a recent heart attack;
1108 • have a history of seizures or epilepsy;
1109 • have kidney problems.

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1111 FACTIVE has not been studied in children under the age of 18. Quinolones, such as
1112 FACTIVE may cause joint problems (arthropathy) in children.

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1114 **What about other medicines I am taking?**

1115 Tell your healthcare provider about all the medicines you take including prescription and
1116 nonprescription medicines, vitamins, and dietary supplements. FACTIVE and other
1117 medicines may affect each other, causing serious side effects. **Be sure to tell your**
1118 **healthcare provider if you take:**

- 1119
- 1120 • medicines for your heart rhythm called “antiarrhythmics”
 - 1121 • erythromycin
 - 1122 • medicines for your mental health called “antipsychotics” or “tricyclic
1123 antidepressants”
 - 1124 • medicines called “corticosteroids”, taken by mouth or by injection
 - 1125 • medicines called “water pills” (diuretics) such as furosemide and
1126 hydrochlorothiazide;
 - 1127 • medicines to thin your blood (called oral anticoagulants) such as Coumadin[®] or
1128 warfarin.

1129
1130 **How should I take FACTIVE?**

- 1131 • Take 1 FACTIVE tablet a day for 5 or 7 days, exactly as prescribed.
- 1132 • Take FACTIVE at the same time each day.
- 1133 • FACTIVE can be taken with or without food.
- 1134 • Swallow the FACTIVE tablet whole, and drink plenty of fluids with it. Do not chew
1135 the FACTIVE tablet.
- 1136 • If you miss a dose of FACTIVE, take it as soon as you remember. **Do not take more**
1137 **than 1 dose of FACTIVE in a day.**
- 1138 • To make sure all bacteria are killed, take all the medicine that was prescribed for you
1139 even if you begin to feel better.
- 1140 • Call your healthcare provider if your condition does not improve while taking
1141 FACTIVE.

1142
1143 **Do not take the following medicines within 3 hours before FACTIVE or 2 hours**
1144 **after FACTIVE.** They may interfere with the absorption of FACTIVE and may prevent
1145 it from working properly:

- 1146
- 1147 • antacids that contain magnesium or aluminum
 - 1148 • ferrous sulfate (iron)
 - 1149 • multivitamin that contains zinc or other metals
 - 1150 • Videx[®] (didanosine)

1151

1152 **FACTIVE should be taken at least 2 hours before sucralfate.**

1153

1154 **What are possible side effects of FACTIVE?**

1155 FACTIVE is generally well tolerated. The most common side effects with FACTIVE
1156 include diarrhea, rash, nausea, headache, vomiting, stomach pain, dizziness, and a change
1157 in the way things taste in your mouth.

1158

1159 Rash occurs more commonly in women, especially those on hormone replacement
1160 therapy and anyone under 40. The likelihood of getting a rash increases if FACTIVE is
1161 taken for longer than 7 days. The rash is usually mild to moderate, but may occasionally
1162 be severe. If you get a rash while taking FACTIVE, stop FACTIVE, and call your
1163 healthcare provider right away.

1164

1165 **FACTIVE and other quinolone antibiotics may cause the following serious side effects:**

1166

- 1167
- 1168 • **a rare heart problem known as prolongation of the QTc interval.** This condition
1169 can cause an abnormal heartbeat and result in sudden death. The chances of this
1170 event are increased in those with a family history of prolonged QT interval, low
1171 potassium (hypokalemia), and who are taking drugs to control heart rhythm, called
1172 Class IA (quinidine, procainamide) or Class III (amiodarone, sotalol) antiarrhythmic
1173 agents.

1174

1175 You should call your healthcare provider right away if you have any symptoms of
1176 prolongation of the QTc interval including:

- 1177 • heart palpitations (a change in the way your heart beats)
- 1178 • a loss of consciousness (fainting spells)

1179

- 1180 • **allergic reactions.** Get medical help right away if you develop hives, trouble
1181 breathing, wheezing, or other symptoms of a severe allergic reaction.

1182

- 1183 • **tendon problems including pain, swelling (tendonitis) or rupture (“tears”) of**
1184 **Achilles, shoulder or hand tendons.** The risk for tendon problems is higher if you
1185 are over 65 years old and/or are taking corticosteroids. If you experience pain,
1186 swelling, or rupture of a tendon, you should stop taking FACTIVE, avoid exercise
1187 and strenuous use of the affected area, and call your healthcare provider;

1188

- 1189 • **diarrhea** that usually ends after treatment is a common problem caused by
1190 antibiotics. A more serious form of diarrhea with inflammation of the colon
1191 (pseudomembranous colitis) can occur during or up to 2 months after the use of
1192 antibiotics. This has been reported with all antibiotics including with FACTIVE. If
1193 you develop a watery and bloody stool with or without stomach cramps and fever,
1194 contact your physician as soon as possible.

1195

-
- 1196 • **central nervous system problems** including body shakes (tremors), restless feeling,
1197 lightheaded feelings, confusion, and hallucinations (seeing or hearing things that are
1198 not there);
1199
- 1200 • **dizziness.** FACTIVE can make you dizzy. Do not drive or operate heavy machinery
1201 until you know how FACTIVE affects you.
1202
- 1203 • **phototoxicity.** FACTIVE may rarely make your skin sunburn more easily. Do not
1204 use a sunlamp or tanning bed while taking FACTIVE. Use a sunscreen and wear
1205 protective clothing if you must be out in the sun.
1206

1207 These are not all the side effects you may experience with FACTIVE. If you get any side
1208 effects that concern you, call your healthcare provider.
1209

1210 **How should I store Factive?**

- 1211 • Store FACTIVE at room temperature between 59° and 86° F (15° to 30° C). Protect
1212 from light.
1213 • **Keep FACTIVE and all medicines out of the reach of children.**
1214

1215 **General information about the safe and effective use of FACTIVE:**

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1217 Medicines are sometimes prescribed for conditions other than those described in patient
1218 information leaflets. Do not use FACTIVE for a condition for which it was not
1219 prescribed. Do not give FACTIVE to other people, even if they have the same symptoms
1220 that you have. It may harm them.
1221

1222 **What are the ingredients in FACTIVE?**

1223 Active ingredient: gemifloxacin

1224 Inactive ingredients: crospovidone, hydroxypropyl methycellulose, magnesium stearate,
1225 microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.
1226

1227 **FACTIVE tablets are white to off-white and imprinted with GE 320 on both sides.**
1228

1229 **This leaflet summarizes the most important information about FACTIVE. If you would**
1230 **like more information, talk with your healthcare provider. You can ask your healthcare**
1231 **provider or pharmacist for information about FACTIVE that is written for healthcare**
1232 **professionals. For more information, visit our website at www.factive.com.**
1233

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