FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

A prospective, cohort study of 50,282 mother-child pairs (the Collaborative Perinatal Project) assessing adverse outcomes by level of aspirin exposure did not report aspirin-induced teratogenicity, altered neonatal birth weight, or perinatal deaths at any exposure level. In a controlled, randomized trial, maternal risks during pregnancy were reported as low or absent, with no demonstrated increased risk of maternal bleeding or placental abruptio. A multinational study involving more than 9,000 women, CLASP (Collaborative Low-dose Aspirin Study in Pregnancy)], found that low-dose aspirin reduced fetal morbidity in a select population of women with early-onset preeclampsia, but did not identify adverse effects in the pregnant woman, fetus, or newborn (followed to 12 and 18 months of age) in association with the use of low-dose aspirin during pregnancy. In contrast, some case-control studies reported associations between human congenital malformations and aspirin use early in gestation, but these studies did not report a consistent outcome attributable to drug use.

A report from EAGeR trial (Effects of Aspirin in Gestation and Reproduction trial), which evaluated 1078 women who were attempting to become pregnant and had prior miscarriages, reported use of low-dose aspirin without adverse maternal or fetal effects except for vaginal bleeding. Another trial of 3294 pregnant women of 14 to 20 weeks of gestation treated with aspirin showed no effect in the mothers' incidence of pre-eclampsia, hypertension, HELLP syndrome or placental abruptio, or in the incidence of perinatal deaths or low birth weight below the 10th percentile. The incidence of maternal side effects was higher in the aspirin group, principally because of a significantly higher rate of hemorrhage.

Use of NSAIDs, including aspirin, during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus and use of high-dose aspirin for long periods in pregnancy may also increase the risk of bleeding in the brain of premature infants.

Omeprazole

Four published epidemiological studies compared the frequency of congenital abnormalities among infants born to women who used omeprazole during pregnancy with the frequency of abnormalities among infants of women exposed to H_2-receptor antagonists or other controls.

A population-based retrospective cohort epidemiological study from the Swedish Medical Birth Registry, covering approximately 99% of pregnancies, from 1995 to 1999, reported on 955 infants (824 exposed during the first trimester with 39 of these exposed beyond first trimester, and 131 exposed after the first trimester) whose mothers used omeprazole during pregnancy. The number of infants exposed in utero to omeprazole that had any malformation, low birth weight, low Apgar score, or hospitalization was similar to the number observed in this population. The number of infants born with ventricular septal defects and the number of stillborn infants was slightly higher in the omeprazole-exposed infants than the expected number in this population.

A population-based retrospective cohort study covering all live births in Denmark from 1996 to 2009, reported on 1,800 live births whose mothers used omeprazole during the first trimester of pregnancy and 837,317 live births whose mothers did not use any PPI. The overall rate of birth defects in infants born to mothers with first trimester exposure to omeprazole was 2.9% and 2.6% in infants born to mothers not exposed to any proton pump inhibitor during the first trimester.

A retrospective cohort study reported on 689 pregnant women exposed to either H_2-blockers or omeprazole in the first trimester (134 exposed to omeprazole) and 1,572 pregnant women unexposed to either during the first trimester. The overall malformation rate in offspring born to mothers with first trimester exposure to omeprazole, an H_2-blocker, or were unexposed was 3.6%, 5.5%, and 4.1% respectively.

A small prospective observational cohort study followed 113 women exposed to omeprazole during pregnancy (89% with first trimester exposures). The reported rate of major congenital malformations was 4% in the omeprazole group, 2% in controls exposed to non-teratogens, and 2.8% in disease-paired controls. Rates of spontaneous and elective abortions, preterm deliveries, gestational age at delivery, and mean birth weight were similar among the groups.

Several studies have reported no apparent adverse short-term effects on the infant when single dose oral or intravenous omeprazole was administered to over 200 pregnant women as premedication for cesarean section under general anesthesia.

Animal Data

Aspirin

Aspirin produced a spectrum of developmental anomalies when administered to Wistar rats as single, large doses (500 to 625 mg/kg) on gestational day (GD) 9, 10, or 11. These doses (500 to 625 mg/kg) in rats are about 15 to 19 times the maximum recommended human dose of aspirin (325 mg/day) based on body surface area. Many of the anomalies were related to closure defects and included craniorachischisis, gastroschisis and umbilical hernia, and cleft lip, in addition to diaphragmatic hernia, heart malrotation, and supernumerary ribs and kidneys. In contrast to the rat, aspirin was not developmentally toxic in rabbits.

Omeprazole

Reproductive studies conducted with omeprazole in rats at oral doses up to 138 mg/kg/day (about 34 times an oral human dose of 40 mg on a body surface area basis) and in rabbits at doses up to 69.1 mg/kg/day (about 34 times an oral human dose of 40 mg on a body surface area basis) during organogenesis did not disclose any evidence for a teratogenic potential of omeprazole. In rabbits, omeprazole in a dose range of 6.9 to 69.1 mg/kg/day (about 3.4 to 34 times an oral human dose of 40 mg on a body surface area basis) administered during organogenesis produced dose-related increases in embryo-lethality, fetal resorptions, and pregnancy disruptions. In rats, dose-related embryo/fetal toxicity and postnatal developmental toxicity were observed in offspring resulting from parents treated with omeprazole at 13.8 to 138 mg/kg/day (about 3.4 to 34 times an oral human doses of 40 mg on a body surface area basis), administered prior to mating through the lactation period.

Esomeprazole

The data described below was generated from studies using esomeprazole, an enantiomer of omeprazole. The animal to human dose multiples are based on the assumption of equal systemic exposure to esomeprazole in humans following oral administration of either 40 mg esomeprazole or 40 mg omeprazole.

No effects on embryo-fetal development were observed in reproduction studies with esomeprazole magnesium in rats at oral doses up to 280 mg/kg/day (about 68 times an oral human dose of 40 mg on a body surface area basis) or in rabbits at oral doses up to 86 mg/kg/day (about 42 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis) administered during organogenesis.

A pre- and postnatal developmental toxicity study in rats with additional endpoints to evaluate bone development was performed with esomeprazole magnesium at oral doses of 14 to 280 mg/kg/day (about 3.4 to 68 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis). Neonatal/early postnatal (birth to weaning) survival was decreased at doses equal to or greater than 138 mg/kg/day (about 34 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis). Body weight and body weight gain were reduced and neurobehavioral or general developmental delays in the immediate post-weaning timeframe were evident at doses equal to or greater than 69 mg/kg/day (about 17 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis). In addition, decreased femur length, width and thickness of cortical bone, decreased thickness of the tibial growth plate and minimal to mild bone marrow hypocellularity were noted at doses equal to or greater than 14 mg/kg/day (about 3.4 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis).

Physeal dysplasia in the femur was observed in offspring of rats treated with oral doses of esomeprazole magnesium at doses equal to or greater than 138 mg/kg/day (about 34 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis).

Effects on maternal bone were observed in pregnant and lactating rats in the pre- and postnatal toxicity study when esomeprazole magnesium was administered at oral doses of 14 to 280 mg/kg/day (about 3.4 to 68 times an oral human dose of 40 mg esomeprazole or 40 mg omeprazole on a body surface area basis). When rats were dosed from gestational day 7 through weaning on postnatal day 21, a statistically significant decrease in maternal femur

13.2 Animal Toxicology and/or Pharmacology

Aspirin

The acute oral 50% lethal dose in rats is about 1.5 g/kg and in mice 1.1 g/kg. Renal papillary necrosis and decreased urinary concentrating ability occur in rodents chronically administered high doses. Dose-dependent gastric mucosal injury occurs in rats and humans. Mammals may develop aspirin toxicosis associated with GI symptoms, circulatory effects, and central nervous system depression *[*see *Overdosage (10)]*.

Omeprazole

Reproductive Toxicology Studies

Reproductive studies conducted with omeprazole in rats at oral doses up to 138 mg/kg/day (about 34 times the human dose on a body surface area basis) and in rabbits at doses up to 69 mg/kg/day (about 34 times the human dose on a body surface area basis) did not disclose any evidence for a teratogenic potential of omeprazole. In rabbits, omeprazole in a dose range of 6.9 to 69.1 mg/kg/day (about 3.4 to 34 times the human dose on a body surface area basis) produced dose-related increases in embryo-lethality, fetal resorptions, and pregnancy disruptions. In rats, dose-related embryo/fetal toxicity and postnatal developmental toxicity were observed in offspring resulting from parents treated with omeprazole at 13.8 to 138.0 mg/kg/day (about 3.4 to 34 times the human doses on a body surface area basis).

Juvenile Animal Study

A 28-day toxicity study with a 14-day recovery phase was conducted in juvenile rats with esomeprazole magnesium at oral doses of 70 to 280 mg/kg/day (about 17 to 67 times a daily oral human dose of 40 mg on a body surface area basis). An increase in the number of deaths at the high dose of 280 mg/kg/day was observed when juvenile rats were administered esomeprazole magnesium from postnatal day 7 through postnatal day 35. In addition, doses equal to or greater than 140 mg/kg/day (about 34 times a daily oral human dose of 40 mg on a body surface area basis), produced treatment-related decreases in body weight (approximately 14%) and body weight gain, decreases in femur weight and femur length, and affected overall growth. Comparable findings described above have also been observed in this study with another esomeprazole salt, esomeprazole strontium, at equimolar doses of esomeprazole.

14 CLINICAL STUDIES

Aspirin Trials

Ischemic Stroke and Transient Ischemic Attack (TIA)

In clinical trials of subjects with TIA due to fibrin platelet emboli or ischemic stroke, aspirin has been shown to significantly reduce the risk of the combined endpoint of stroke or death and the combined endpoint of TIA, stroke, or death by about 13 to18%.

Prevention of Recurrent MI and Unstable Angina Pectoris

These indications are supported by the results of six large, randomized, multi-center, placebo-controlled trials of predominantly male post-MI subjects and one randomized placebo-controlled study of men with unstable angina pectoris. Aspirin therapy in MI subjects was associated with a significant reduction (about 20%) in the risk of the combined endpoint of subsequent death and/or nonfatal reinfarction in these patients. In aspirin-treated unstable angina patients the event rate was reduced to 5% from the 10% rate in the placebo group.

Chronic Stable Angina Pectoris

In a randomized, multi-center, double-blind trial designed to assess the role of aspirin for prevention of MI in patients with chronic stable angina pectoris, aspirin significantly reduced the primary combined endpoint of nonfatal MI, fatal MI, and sudden death by 34%. The secondary endpoint for vascular events (first occurrence of MI, stroke, or vascular death) was also significantly reduced (32%).

Advise patients to report to their health care provider if they develop liver problems (e.g. skin and eyes that appear yellowish, abdominal pain and swelling, itchy skin, dark urine color) *[see Warnings and Precautions (5.12)]*.

Cyanocobalamin (Vitamin B-12) Deficiency

Advise patients to report any clinical symptoms that may be associated with cyanocobalamin deficiency to their health care provider if they have been receiving [redacted] for longer than 3 years *[see Warnings and Precautions (5.13)]*.

Hypomagnesemia

Advise patients to report any clinical symptoms that may be associated with hypomagnesemia to their health care provider, if they have been receiving [redacted] for at least 3 months *[see Warnings and Precautions (5.14)]*.

Fetal Toxicity

Inform pregnant women to avoid use of [redacted] and other NSAIDs starting at 30 weeks gestation because of the risk of the premature closure of the fetal ductus arteriosus *[see Warnings and Precautions (5.18) and Use in Specific Populations (8.1)]*.

Lactation

Advise women that breastfeeding is not recommended during treatment with [redacted] *[see Use in Specific Populations (8.2)]*.

Infertility

Advise females of reproductive potential that NSAIDs, including [redacted], may be associated with reversible infertility *[see Use in Specific Populations (8.3)]*.

Administration *[see Dosage and Administration (2.2)]*

Advise patients:

- To take [redacted] orally daily at least 60 minutes before a meal.
- The tablets are to be swallowed whole with liquid. Do not split, chew, crush or dissolve the tablet.
- If a dose is missed, administer as soon as possible. However, if the next scheduled dose is due, do not take the missed dose, and take the next dose on time. Do not take two doses at one time to make up for a missed dose, unless advised by their health care provider.
- Not to stop taking [redacted] suddenly as this could increase the risk of heart attack or stroke.

Manufactured for: Innovida Pharmaceutique Corporation Charleston, WV 25301

MEDICATION GUIDE
Aspirin and Omeprazole
delayed-release tablets

What is the most important information I should know about Aspirin and Omeprazole?

You should take Aspirin and Omeprazole exactly as prescribed, at the lowest dose possible and for the shortest time needed.

Aspirin and Omeprazole may help reduce the risk of stomach ulcers from aspirin use, but you could still have bleeding and stomach or intestine ulcers, or other serious stomach or intestine problems. Talk with your doctor.
Tell your doctor if you have unexpected bleeding, if you bleed more than usual, or if your bleeding lasts longer than is normal for you, such as increased bruising or more frequent nose bleeds.
Aspirin and Omeprazole contains aspirin, a nonsteroidal anti-inflammatory drug (NSAID) and omeprazole, a proton pump inhibitor (PPI) medicine. Before taking Aspirin and Omeprazole, tell your doctor if you take:

- aspirin, or any prescription or over-the-counter medicines containing aspirin or other NSAIDs.
- clopidogrel bisulphate (PLAVIX®). You should not take clopidogrel bisulphate (PLAVIX®) if you take Aspirin and Omeprazole.
- ticagrelor (BRILINTA®).

Do not stop taking Aspirin and Omeprazole without talking with your doctor. Stopping Aspirin and Omeprazole suddenly could increase your risk of having a heart attack or stroke.

Aspirin and Omeprazole can cause serious side effects, including:

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including Aspirin and Omeprazole, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with Aspirin and Omeprazole. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea caused by an infection (*Clostridium difficile*) in your intestines.** Call your doctor right away if you have watery stools or stomach pain that does not go away. You may or may not have a fever.
- **Bone fractures (hip, wrist, or spine).** Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of PPI medicines and for a long period of time (a year or longer). Tell your doctor if you have a bone fracture, especially in the hip, wrist, or spine.
- **Certain types of lupus erythematosus.** Lupus erythematosus is an autoimmune disorder (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines, including Aspirin and Omeprazole, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

Talk to your doctor about your risk of these serious side effects.
Aspirin and Omeprazole can have other serious side effects. See **"What are the possible side effects of Aspirin and Omeprazole?"**

What is Aspirin and Omeprazole?

Aspirin and Omeprazole is a prescription medicine used:

- in people who have had heart problems or strokes caused by blood clots, to help reduce their risk of further heart problems or strokes, **and**
- who are at risk of developing stomach ulcers with aspirin.

The aspirin in Aspirin and Omeprazole is used:

- to help reduce the risk of strokes and death in people who have previously had certain types of "mini strokes" (transient ischemic attacks or TIAs) or strokes.
- to help reduce the risk of heart attack and death in people who have previously had a heart attack or a type of chest pain called unstable angina pectoris.
- to help reduce the risk of heart attack and sudden death in people with a type of ongoing chest pain called chronic stable angina pectoris.
- in people who have had surgery or a procedure to improve blood flow to their heart, such as coronary artery bypass grafting (CABG), or percutaneous transluminal coronary angioplasty (PTCA), and who already have another condition that is being treated with aspirin.

The omeprazole in Aspirin and Omeprazole is used:

- to help decrease the risk of developing stomach ulcers due to aspirin in people who are 55 years of age or older, or who have a history of stomach ulcers.

Aspirin and Omeprazole should not be used to treat sudden signs and symptoms of a heart attack or stroke. Aspirin and Omeprazole should only be used as directed by your doctor to help reduce the risk of further heart problems or strokes.

It is not known if Aspirin and Omeprazole is safe and effective in children.

Aspirin and Omeprazole has not been shown to reduce the risk of bleeding in the stomach or intestines that is caused by aspirin.

You should not take an aspirin tablet and an omeprazole tablet together instead of taking Aspirin and Omeprazole, because they will not work the same way.

Do not take Aspirin and Omeprazole if you:

- are allergic to aspirin, omeprazole, any other PPI medicine, or any of the ingredients in Aspirin and Omeprazole. See the end of this Medication Guide for a complete list of ingredients in Aspirin and Omeprazole.
- are allergic to any nonsteroidal anti-inflammatory drug (NSAID).
- have a medical condition with severe shortness of breath, chest tightness or pain, coughing or wheezing (asthma), sneezing, runny nose or itchy nose (rhinitis), and growths inside of your nose or sinuses (nasal polyps).
- are taking a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY) used to treat HIV-1 (Human Immunodeficiency Virus).

Do not give Aspirin and Omeprazole to a child who has a suspected viral infection, even if they do not have a fever. There is a risk of Reye's syndrome with Aspirin and Omeprazole because it contains aspirin.

Before taking Aspirin and Omeprazole, tell your doctor about all of your medical conditions, including if you: See **"What is the most important information I should know about Aspirin and Omeprazole?"**

- have any bleeding problems.
- drink 3 or more drinks that contain alcohol every day.
- have kidney or liver problems.
- have been told that you have low magnesium levels in your blood.
- are of Asian descent and have been told that your body's ability to break down (metabolize) omeprazole is poor or if your genotype called CYP2C19 is not known.
- are pregnant or plan to become pregnant. Talk to your doctor if you are considering taking Aspirin and Omeprazole during

pregnancy. **You should not take Aspirin and Omeprazole after 29 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed. The aspirin and omeprazole in Aspirin and Omeprazole can pass into your breast milk and may harm your baby. Breastfeeding is not recommended during treatment with Aspirin and Omeprazole. Talk to your doctor about the best way to feed your baby if you take Aspirin and Omeprazole.
- are a female who can become pregnant. Aspirin and Omeprazole may be related to infertility in some women that is reversible when treatment with Aspirin and Omeprazole is stopped.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Aspirin and Omeprazole and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your doctor first.**

Especially tell your doctor if you take:
- clopidogrel bisulphate (PLAVIX®)
- ticagrelor (BRILINTA®)
- St. John's Wort (Hypericum perforatum)
- rifampin (Rimactane, RIFATER®, RIFAMATE® RIFADIN®)
- methotrexate (Otrexup, Rasuvo, Trexall, XATMEP)
- digoxin (LANOXIN)
- a water pill (diuretic)

How should I take Aspirin and Omeprazole?
- Take Aspirin and Omeprazole exactly as prescribed by your doctor.
- Take 1 Aspirin and Omeprazole tablet 1 time each day.
- Take Aspirin and Omeprazole at least 1 hour before a meal.
- Swallow Aspirin and Omeprazole tablets whole with liquid. Do not split, chew, crush, or dissolve Aspirin and Omeprazole.
- If you miss a dose of Aspirin and Omeprazole, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time unless your doctor tells you to.
- If you take too much Aspirin and Omeprazole, call your doctor or your poison control center at 1-800-222-1222 right away or go to the nearest emergency room.

What should I avoid while taking Aspirin and Omeprazole?

Avoid heavy alcohol use during treatment with Aspirin and Omeprazole. People who drink three or more drinks that contain alcohol every day have a higher risk of bleeding during treatment with Aspirin and Omeprazole because it contains aspirin.

What are the possible side effects of Aspirin and Omeprazole can cause serious side effects, including:

See **"What is the most important information I should know about Aspirin and Omeprazole?"**

- **Stomach and intestine problems.** Stop taking Aspirin and Omeprazole and call your doctor right away if you have symptoms of stomach and intestine problems, including black, bloody, or tarry stools, coughing up blood or vomit that looks like coffee grounds, or severe nausea, vomiting, or stomach pain.
- **Kidney failure.** Long-lasting (chronic) kidney failure can happen with regular use of aspirin, a medicine in Aspirin and Omeprazole. This is more likely to happen in people who already have kidney problems before treatment with Aspirin and Omeprazole. Tell your doctor if you have symptoms of kidney failure, including changes in urination, swelling of the hands, ankles or feet, skin rash or itching, or your breath smells like ammonia.
- **Liver problems.** Long-term use of Aspirin and Omeprazole at certain doses may cause liver problems. Tell your doctor if you have symptoms of liver problems, including yellowing of your skin or your eyes, stomach-area (abdominal) pain and swelling, itchy skin, and dark (tea-colored) urine.
- **Low vitamin B-12 levels.** Low vitamin B-12 levels in your body can happen in people who have taken Aspirin and Omeprazole for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 levels, including shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness in the arms or legs.
- **Low magnesium levels.** Low magnesium levels in your body can happen in people who have taken Aspirin and Omeprazole for at least 3 months. Tell your doctor if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.
- **Stomach growths (fundic gland polyps).** People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year.

The most common side effects of Aspirin and Omeprazole include: indigestion or heartburn and stomach-area pain, nausea, diarrhea, and chest pain behind the breastbone, for example, with eating.

These are not all the possible side effects of Aspirin and Omeprazole. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Aspirin and Omeprazole?
- Store Aspirin and Omeprazole at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Aspirin and Omeprazole in the original container.
- Keep the container of Aspirin and Omeprazole tightly closed to protect from moisture.
- The Aspirin and Omeprazole container may contain a desiccant packet to help keep your medicine dry (protect it from moisture). Keep the desiccant packet in the container. Do not throw away the desiccant packet.

Keep Aspirin and Omeprazole and all medicines out of the reach of children.

General information about the safe and effective use of Aspirin and Omeprazole

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Aspirin and Omeprazole for a condition for which it was not prescribed. Do not give Aspirin and Omeprazole to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about Aspirin and Omeprazole that is written for health professionals.

What are the ingredients in Aspirin and Omeprazole?

Active ingredients: aspirin and omeprazole

Inactive ingredients: carnauba wax, colloidal silicon dioxide, corn starch, FD&C Blue #2, glyceryl monostearate, hydroxypropyl methycellulose, methacrylic acid copolymer dispersion, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, povidone, pre-gelatinized starch, sodium phosphate dibasic anhydrous, stearic acid,

talc, titanium dioxide, triacetin, triethyl citrate, yellow iron oxide.

Manufactured for: Innovida Pharmaceutique Corporation 1018 Kanawha Blvd. East Suite 200 Charleston, WV 25301
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For more information, go to www.innovidarx.com or call 1-888-818-0980.

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