Effective and Meaningful Fair Balance/Risk Disclosure

Panelists

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Disclaimer

The views and opinions expressed in the following session are those of the individual presenters and do not reflect the views or opinions of our respective organizations

Objectives

- Discuss FDA's approach to risk information in product advertisements, including fair balance and anticipated final rule on the Major Statement for Direct-to-Consumer Advertisements
- Explore how companies are disclosing risk information in product advertisements

Overview of Risk Principles

FDA REGULATIONS AND GUIDANCES

Section 201(n) of the FD&C Act

- Advertising misleading not only due to representations made but to the extent material facts are omitted in light of those representations

Section 502(n) of the FD&C Act

- A Rx drug is misbranded if its advertising does not contain a “true statement” (in brief summary) of the **side effects**, **contraindications**, and **effectiveness** as delineated by implementing regulations

21 C.F.R. § 202.1(e)

- Provides several requirements for an advertisement to make a “true statement” relating to **side effects**, **contraindications**, and **effectiveness**

21 C.F.R. § 202.1(e)(3)

- "Risk in each part"
  - The requirement for a true statement relating to side effects, contraindications, and effectiveness applies to the **entire** advertisement
  - Qualifying safety or other pertinent information to accompany claims; discussion can be **concise** if there's a **prominent** reference to a more complete discussion of this information within the advertisement

21 C.F.R. § 202.1(e)(5)(ii)

- An advertisement does not present “true information” (in brief summary) regarding side effects, contraindications, and effectiveness if there’s no “**fair balance**” between risk information and efficacy information

21 C.F.R. § 202.1(e)(7)(viii)

- An advertisement may be false, lacking in **fair balance**, or otherwise misleading if it fails to present **safety** information with a prominence & readability "*reasonably comparable*" with the presentation of efficacy information

Draft Major Statement Rule 03/29/2010

- FDAAA requires that the major statement in DTC television or radio ads be presented in a ***clear***, ***conspicuous***, and ***neutral*** manner and for FDA to establish standards for determining this. . . .
  - Presented in a language readily understandable by consumers;
  - Audio information is understandable in terms of volume, articulation, and pacing;

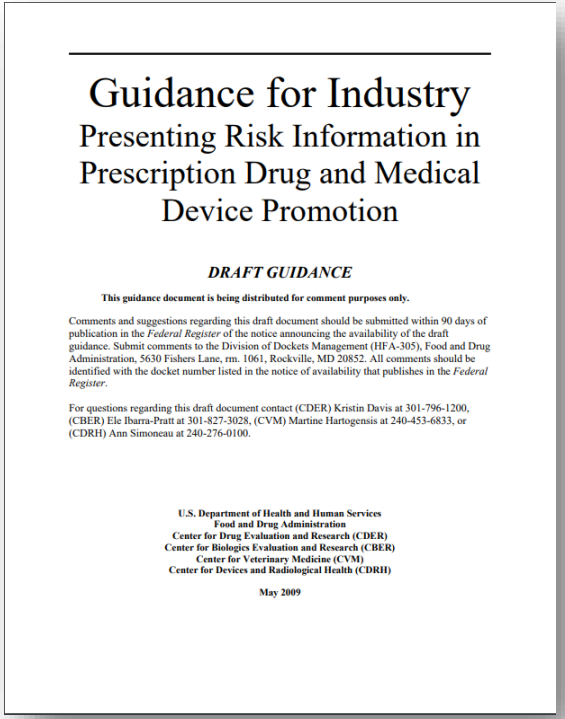
Draft Major Statement Rule

- Textual information can be read easily (size and style) and is presented against a contrasting background for sufficient duration
- No distracting statements, sounds, visuals that would detract from the major statement communication

Final Rule

- Most likely will retain the same standards
- Perhaps, further clarification on the meaning of “neutral”

Presenting Risk Information Draft Guidance



Guidance for Industry

Presenting Risk Information in Prescription Drug and Medical Device Promotion

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

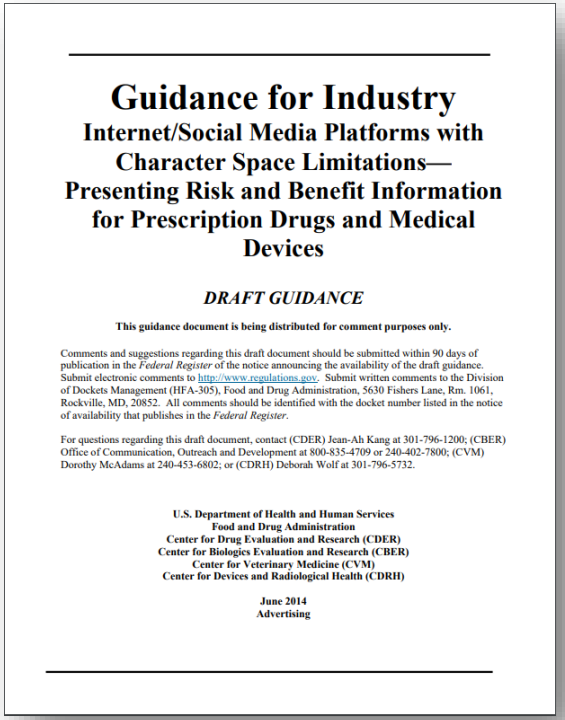
For questions regarding this draft document contact (CDER) Kristin Davis at 301-796-1200, (CBER) Ele Ibarra-Pratt at 301-827-3028, (CVM) Martine Hartogensis at 240-453-6833, or (CDRH) Ann Simoneau at 240-276-0100.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

May 2009

- Discusses factors that are relevant to the disclosure of risk information
  - Hierarchy of risk information
  - Quantity
  - Overall location of risk information

Character Space Limitations Draft Guidance



Guidance for Industry

Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices

DRAFT GUIDANCE

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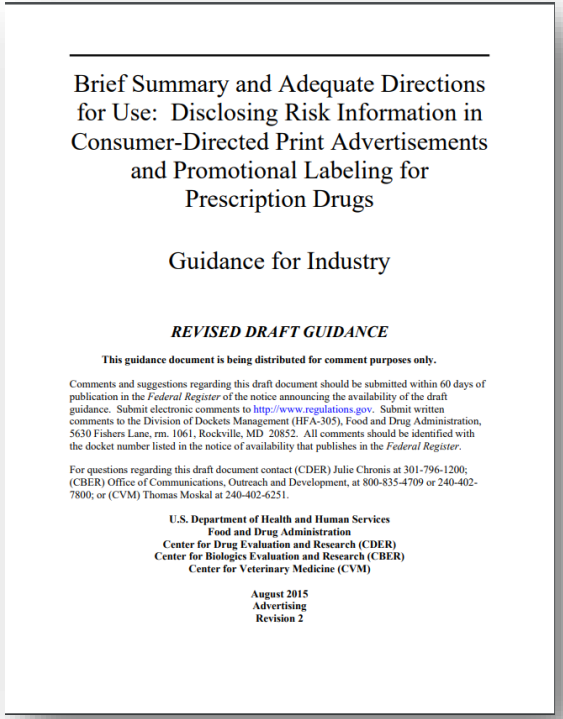
For questions regarding this draft document, contact (CDER) Jean-Ah Kang at 301-796-1200; (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800; (CVM) Dorothy McAdams at 240-453-6802; or (CDRH) Deborah Wolf at 301-796-5732.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)

June 2014
Advertising

- Benefit information to be accompanied by risk information within each individual character-space-limited communication
  - Content of risk information should, at a minimum, include the most serious risks associated with the product
  - Hyperlink should be included within each communication to allow direct access to a more complete discussion of risk
  - Prominence of risk information should be comparable to the benefit information

Consumer Brief Summary Draft Guidance



Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs

Guidance for Industry

REVISED DRAFT GUIDANCE

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Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

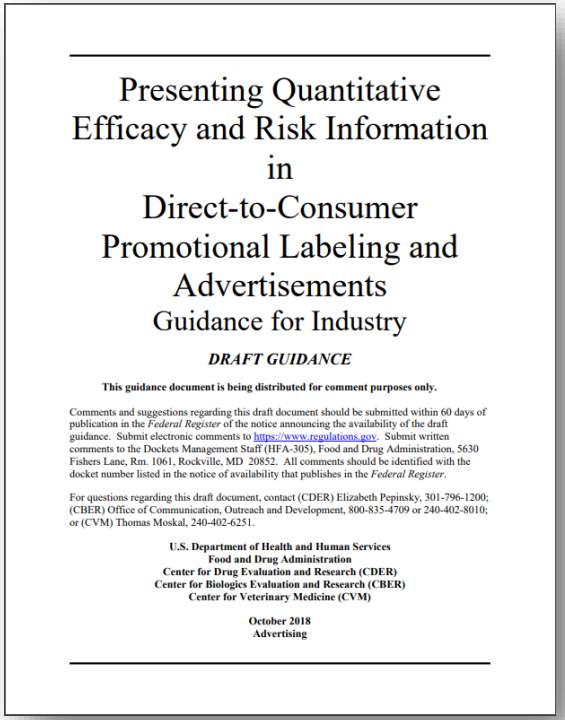
For questions regarding this draft document contact (CDER) Julie Chronis at 301-796-1200; (CBER) Office of Communications, Outreach and Development, at 800-835-4709 or 240-402-7800; or (CVM) Thomas Moskal at 240-402-6251.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

August 2015
Advertising
Revision 2

- *Retention* and *readability* of risk information is as important as the *amount* of risk information
- The *familiarity* of a format increases patient's confidence to use the risk information

Presenting Quantitative Information in DTC Promotion Draft Guidance



Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Elizabeth Pepinsky, 301-796-1200; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CVM) Thomas Moskal, 240-402-6251.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

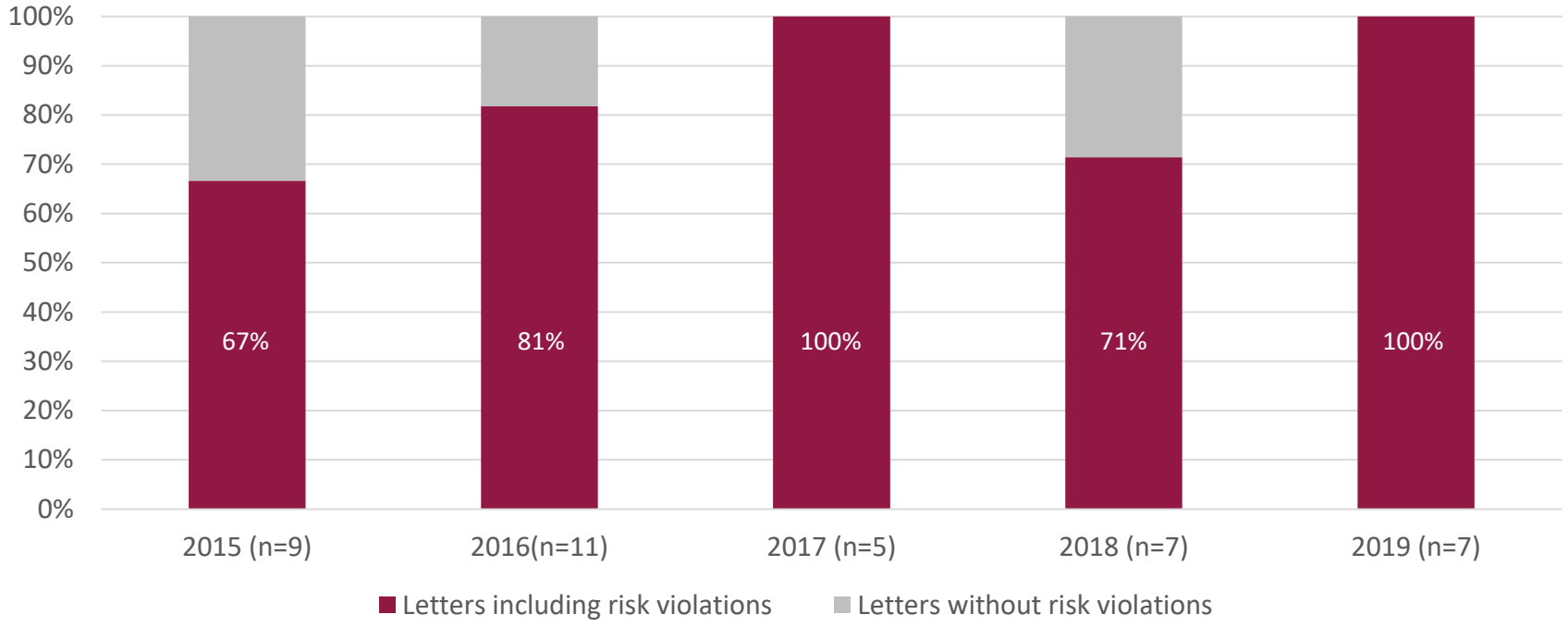
October 2018
Advertising

- *Consistency* and *clarity* of risk information aids in information *retention*
- Visual aids can reduce the *cognitive load* needed to interpret risk information
- Recommendations applicable to both advertisements and promotional labeling

Violation Letters and Social Science Research

OPDP ACTIVITY

82% of all OPDP violation letters in the past 5 years have included risk violations



False or Misleading Risk Presentation: Qsymia

The results presented here are from the combined studies supporting FDA approval of Qsymia. The dosing schedule in those studies differ from the dosing schedule that your physician may recommend. As a result of this dosing differential, your results may vary depending on your BMI, diet, activity, dose of Qsymia, and other factors.[1] Please see additional study design information below.

Important Safety Information

Do not take Qsymia if you are pregnant, planning to become pregnant, or become pregnant during Qsymia treatment; have glaucoma; have thyroid problems (hyperthyroidism); are taking certain medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the past 14 days; are allergic to topiramate, sympathomimetic amines such as phentermine, or any of the ingredients in Qsymia. See the end of the Medication Guide for a complete list of ingredients in Qsymia.

QSYMIA CAN CAUSE SERIOUS SIDE EFFECTS, INCLUDING:

Birth defects (cleft lip/cleft palate). If you take Qsymia during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant. Women who are pregnant must not take Qsymia. Women who can become pregnant should have a negative pregnancy test before taking Qsymia and every month while taking Qsymia and use effective birth control (contraception) consistently while taking Qsymia. Talk to your healthcare provider about how to prevent pregnancy. If you become pregnant while taking Qsymia, stop taking Qsymia immediately, and tell your healthcare provider right away. Healthcare providers and patients should report all cases of pregnancy to FDA MedWatch at 1-800-FDA-1088, and the Qsymia Pregnancy Surveillance Program at 1-888-998-4887.

Increases in heart rate. Qsymia can increase your heart rate at rest. Your healthcare provider should check your heart rate while you take Qsymia. Tell your healthcare provider if you experience, while at rest, a racing or pounding feeling in your chest lasting several minutes when taking Qsymia.

Suicidal thoughts or actions. Topiramate, an ingredient in Qsymia, may cause you to have suicidal thoughts or actions. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you: thoughts about suicide or dying; attempts to commit suicide; new or worse depression; new or worse anxiety; feeling agitated or restless; panic attacks; trouble sleeping (insomnia); new or worse irritability; acting aggressive, being angry, or violent; acting on dangerous impulses; an extreme increase in activity or talking (mania); other unusual changes in behavior or mood.

Serious eye problems, which include any sudden decrease in vision, with or without eye pain and redness or a blockage of fluid in the eye causing increased pressure in the eye (secondary angle closure glaucoma). These problems can lead to permanent vision loss if not treated. Tell your healthcare provider right away if you have any new eye symptoms.

POSSIBLE SIDE EFFECTS OF QSYMIA INCLUDE:

Mood changes and trouble sleeping. Qsymia may cause depression or mood problems, and trouble sleeping. Tell your healthcare provider if symptoms occur.

False or Misleading Risk Presentation: Eskata

False or Misleading Risk Presentation: Paragard

FRAME 4

Women: No hormones...

FRAME 5

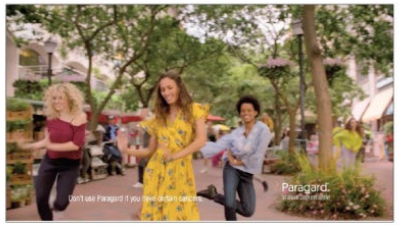
LIZA: ...not an ounce! With an ingredient I can pronounce.

FRAME 6

NARRATOR: Paragard is a hormone-free IUD that's over 99% effective at preventing pregnancy.

Paragard 30 sec DTC Ad (Musical)

US-PAR-1800079



FRAME 7

NARRATOR: If you experience pain, pelvic infection, or miss a period, call your healthcare provider.

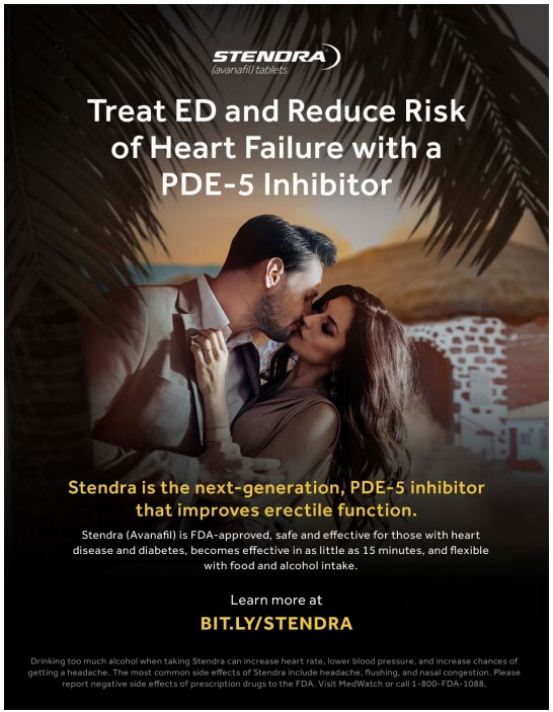
FRAME 8

NARRATOR: Pregnancy is rare but serious and can cause infertility or loss of pregnancy.

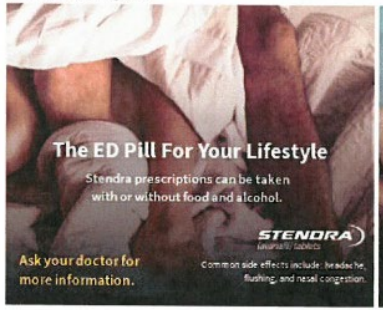
FRAME 9

NARRATOR: Rarely, Paragard may attach to or go through the uterus.

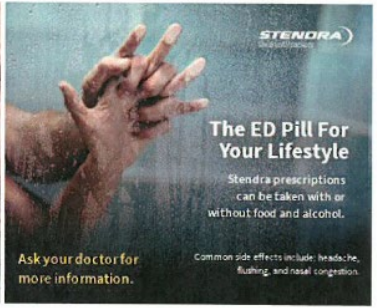
False or Misleading Risk Presentation: Stendra



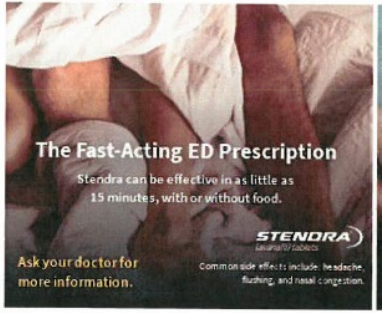
Version A Image A



Version A Image B



Version B Image A



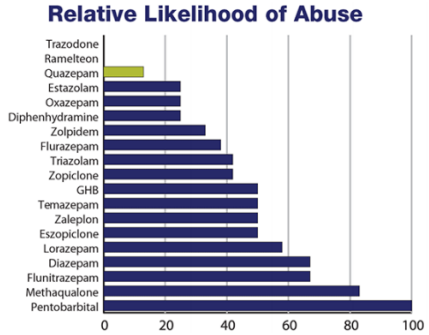
Version B Image B

False or Misleading Risk Presentation: Doral

Concerned about Abuse potential of sleep medications?

Researchers at the John Hopkins University used over 100 studies to evaluate the abuse potential for various sleep-aids and found[1] :

- Doral's relative likelihood of abuse is considerably lower than some of the widely used sleep aids (i.e. Zolpidem & Temazepam)*
- Doral was ranked even lower than OTC product Diphenhydramine for relative abuse potential*



*Please see complete prescribing information for detailed information on each product. The above chart is not intended for efficacy comparison. The authors

/Campaigns/Emails/Doral_Least_Abuse_Potential/

Doral Efficacy

algorithm, while comprehensive, does lack prospective abuse data in human subjects and had not been validated in subsequent research.

Indication:

Doral (Quazepam) is indicated for the treatment of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings, and/or early morning awakenings.

Important Safety Information (ISI):

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS
Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death [see Warnings and Precautions (5.1), Drug Interactions (7)]. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Doral can produce daytime impairment, and this risk increases with dose and concomitant use of other CNS depressants. If insomnia worsens or fails to remit after 7 to 10 days of treatment, this might be indication of an underlying illness. Doral is contraindicated in patients with a known hypersensitivity to quazepam or other benzodiazepines, established or suspected sleep apnea, or chronic pulmonary insufficiency. Rare cases of severe anaphylactic reactions including angioedema and dyspnea have been reported. Complex behaviors, such as sleep driving or sleep eating, have been reported with the use of sedative-hypnotics. Immediately evaluate the onset of any new behavioral changes. Benzodiazepines may worsen depression, and appropriate precautions should be considered in at risk patients. For a full list of warnings and precautions, please refer to the full prescribing information.

False or Misleading Risk Presentation: Kowa

The video includes patient testimonials such as the following (emphasis original):

Debbie D.

VOICEOVER (VO) (:04 - :06): “When I did the cholesterol panel, mine was extremely high.”
SUPER: **my** switch to **LIVALO®**
Debbie D. Switched statins 6 times due to side effects

VO (:45 - :48): “After I took LIVALO, I've had no pain and my cholesterol levels are down.”
SUPER: **my** switch to **LIVALO®**
Debbie D. Taking LIVALO for 3 years

Donnie W.

VO (:07 - :10): “My doctor recommended I start with a statin. We started with one, we had a lot of side effects.”
SUPER: **my** switch to **LIVALO®**
Donnie W. Switched statins 4 times due to side effects

VO (:31 - :35): “LIVALO definitely made a positive impact in reducing my cholesterol and reduced side effects.”
SUPER: **my** switch to **LIVALO®**
Donnie W. Taking LIVALO for 8 years

Robert M.

VO (:11 - :19): “The first medication I went on came with a lot of side effects, so I tried other ones after that and it was even worse.”
SUPER: **my** switch to **LIVALO®**
Robert M. Switched statins 3 times due to side effects

VO (:36 - :44): “I wish I was put on LIVALO years ago, because I'm not having the side effects that I was having with the other statins.”
SUPER: **my** switch to **LIVALO®**
Robert M. Taking LIVALO for 4 years

Research Pending Peer Review

- Animation in DTC Promotion
- Experimental Study of DTC Advertising Directed at Adolescents
- General Population Survey on Prescription Drug Promotion
- Risk and Benefit Perception Scale Development
- Superimposed Text in DTC Promotion

Ongoing Research

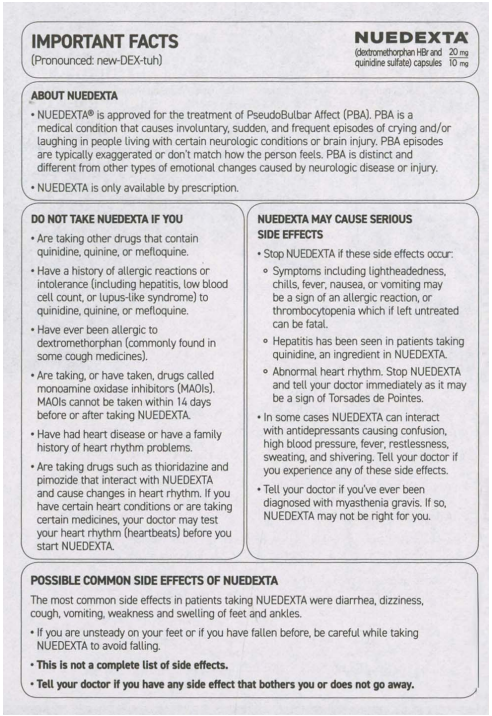
- Character-Space Limited Online Prescription Drug Communications
- Consumer and Healthcare Professional Identification of and Response to Deception Prescription Drug Advertising
- Disclosures in Professional and Consumer Prescription Drug Promotion
- Disclosure of Descriptive Presentations in Professional Oncology Prescription Drug Promotion
- Disease Awareness and Prescription Drug Promotion on Television
- Experimental Study of an Accelerated Approval Disclosure
- Healthcare Professional Interviews: Risk Processing for Newly Promoted Prescription Drugs
- Healthcare Professional Survey of Professional Prescription Drug Promotion
- Physician Interpretation of Information about Prescription Drugs in Scientific Publications v. Promotional Pieces
- Quantitative Information in Direct-to-Consumer Television Advertisements
- Risk Information Amount and Location in Direct-to-Consumer Print Ads
- Utilization of Adequate Provision among Low to Non-Internet Users

Risk Disclosure and Fair Balance

INDUSTRY INTERPRETATION

Consumer Brief Summary – Drug Facts

FOOD AND DRUG LAW INSTITUTE



IMPORTANT FACTS
(Pronounced: new-DEX-tuh)

NUEDEXTA
(dextromethorphan HBr and quinidine sulfate) capsules 20 mg 10 mg

ABOUT NUEDEXTA

- NUEDEXTA® is approved for the treatment of PseudoBulbar Affect (PBA). PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.
- NUEDEXTA is only available by prescription.

DO NOT TAKE NUEDEXTA IF YOU

- Are taking other drugs that contain quinidine, quinine, or mefloquine.
- Have a history of allergic reactions or intolerance (including hepatitis, low blood cell count, or lupus-like syndrome) to quinidine, quinine, or mefloquine.
- Have ever been allergic to dextromethorphan (commonly found in some cough medicines).
- Are taking, or have taken, drugs called monoamine oxidase inhibitors (MAOIs). MAOIs cannot be taken within 14 days before or after taking NUEDEXTA.
- Have had heart disease or have a family history of heart rhythm problems.
- Are taking drugs such as thioridazine and pimozide that interact with NUEDEXTA and cause changes in heart rhythm. If you have certain heart conditions or are taking certain medicines, your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA.

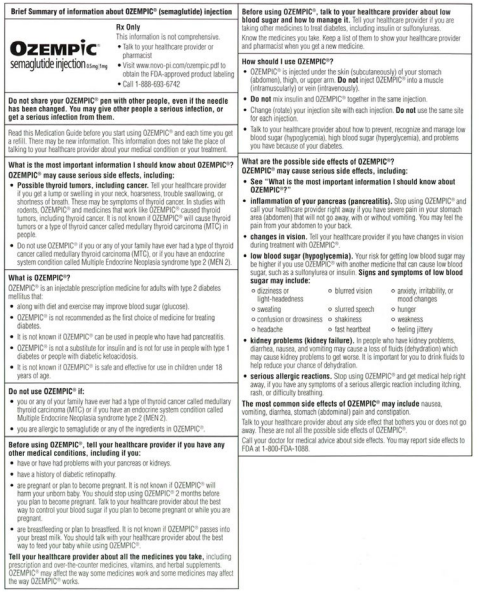
NUEDEXTA MAY CAUSE SERIOUS SIDE EFFECTS

- Stop NUEDEXTA if these side effects occur:
  - Symptoms including lightheadedness, chills, fever, nausea, or vomiting may be a sign of an allergic reaction, or thrombocytopenia which if left untreated can be fatal.
  - Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.
  - Abnormal heart rhythm. Stop NUEDEXTA and tell your doctor immediately as it may be a sign of Torsades de Pointes.
- In some cases NUEDEXTA can interact with antidepressants causing confusion, high blood pressure, fever, restlessness, sweating, and shivering. Tell your doctor if you experience any of these side effects.
- Tell your doctor if you've ever been diagnosed with myasthenia gravis. If so, NUEDEXTA may not be right for you.

POSSIBLE COMMON SIDE EFFECTS OF NUEDEXTA

The most common side effects in patients taking NUEDEXTA were diarrhea, dizziness, cough, vomiting, weakness and swelling of feet and ankles.

- If you are unsteady on your feet or if you have fallen before, be careful while taking NUEDEXTA to avoid falling.
- **This is not a complete list of side effects.**
- **Tell your doctor if you have any side effect that bothers you or does not go away.**



Brief Summary of information about OZEMPIC® (semaglutide) injection

OZEMPIC®
semaglutide injection 0.5 mg/3 mg

Rx Only
This information is not comprehensive.

- Talk to your healthcare provider or pharmacist
- Visit www.novo-pi.com/ozempic.pdf to obtain the FDA-approved product labeling
- Call 1-888-693-6742

Do not share your OZEMPIC® pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Read this Medication Guide before you start using OZEMPIC® and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about OZEMPIC®?
OZEMPIC® may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rodents, OZEMPIC® and medicines that work like OZEMPIC® caused thyroid tumors, including thyroid cancer. It is not known if OZEMPIC® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use OZEMPIC® if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

What is OZEMPIC®?
OZEMPIC® is an injectable prescription medicine for adults with type 2 diabetes mellitus that:

- along with diet and exercise may improve blood sugar (glucose).
- OZEMPIC® is not recommended as the first choice of medicine for treating diabetes.
- It is not known if OZEMPIC® can be used in people who have had pancreatitis.
- OZEMPIC® is not a substitute for insulin and is not for use in people with type 1 diabetes or people with diabetic ketoacidosis.
- It is not known if OZEMPIC® is safe and effective for use in children under 18 years of age.

Do not use OZEMPIC® if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you are allergic to semaglutide or any of the ingredients in OZEMPIC®.

Before using OZEMPIC®, tell your healthcare provider if you have any other medical conditions, including if you:

- have or have had problems with your pancreas or kidneys.
- have a history of diabetic retinopathy.
- are pregnant or plan to become pregnant. It is not known if OZEMPIC® will harm your unborn baby. You should stop using OZEMPIC® 2 months before you plan to become pregnant. Talk to your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if OZEMPIC® passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using OZEMPIC®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. OZEMPIC® may affect the way some medicines work and some medicines may affect the way OZEMPIC® works.

Before using OZEMPIC®, talk to your healthcare provider about low blood sugar and how to manage it. Tell your healthcare provider if you are taking other medicines to treat diabetes, including insulin or sulfonylureas. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use OZEMPIC®?

- OZEMPIC® is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. **Do not** inject OZEMPIC® into a muscle (intramuscularly) or vein (intravenously).
- **Do not** mix insulin and OZEMPIC® together in the same injection.
- Change (rotate) your injection site with each injection. **Do not** use the same site for each injection.
- Talk to your healthcare provider about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.

What are the possible side effects of OZEMPIC®?
OZEMPIC® may cause serious side effects, including:

- **See "What is the most important information I should know about OZEMPIC®?"**
- **inflammation of your pancreas (pancreatitis).** Stop using OZEMPIC® and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **changes in vision.** Tell your healthcare provider if you have changes in vision during treatment with OZEMPIC®.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use OZEMPIC® with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include:**
  - dizziness or light-headedness
  - blurred vision
  - anxiety, irritability, or mood changes
  - sweating
  - slurred speech
  - hunger
  - confusion or drowsiness
  - shakiness
  - weakness
  - headache
  - fast heartbeat
  - feeling jittery
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.
- **serious allergic reactions.** Stop using OZEMPIC® and get medical help right away, if you have any symptoms of a serious allergic reaction including itching, rash, or difficulty breathing.

The most common side effects of OZEMPIC® may include nausea, vomiting, diarrhea, stomach (abdominal) pain and constipation.
Talk to your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of OZEMPIC®.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark
OZEMPIC® is a registered trademark of Novo Nordisk A/S.
Revised: December 2017
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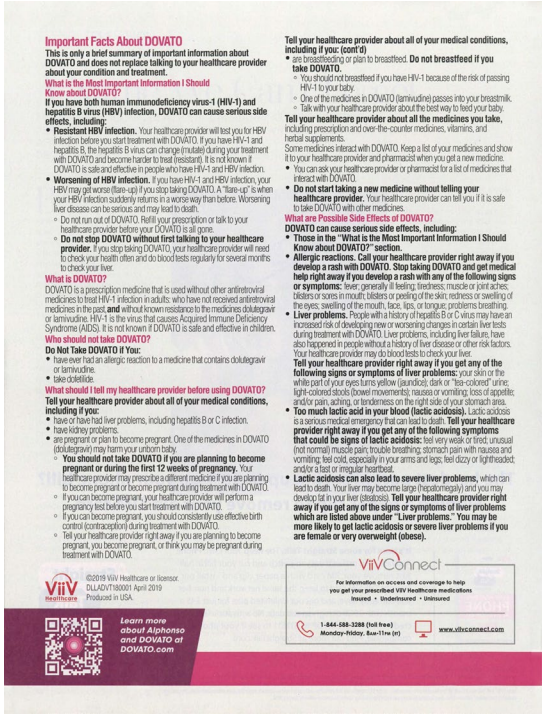
novo nordisk®

Consumer Brief Summary – Light Integration

FOOD AND DRUG LAW INSTITUTE



Important Facts About DOVATO

This is only a brief summary of important information about DOVATO and does not replace talking to your healthcare provider about your condition and treatment.

What is the Most Important Information I Should Know about DOVATO?

If you have both human immunodeficiency virus-1 (HIV-1) and hepatitis B virus (HBV) infection, DOVATO can cause serious side effects, including:

- **Resistant HBV infection.** Your healthcare provider will test you for HBV infection before you start treatment with DOVATO. If you have HIV-1 and hepatitis B, the hepatitis B virus can change (mutate) during your treatment with DOVATO and become harder to treat (resistant). It is not known if DOVATO is safe and effective in people who have HIV-1 and HBV infection.
- **Worsening of HBV infection.** If you have HIV-1 and HBV infection, your HBV may get worse (flare-up) if you stop taking DOVATO. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Worsening liver disease can be serious and may lead to death.
  - Do not run out of DOVATO. Refill your prescription or talk to your healthcare provider before your DOVATO is all gone.
  - **Do not stop DOVATO without first talking to your healthcare provider.** If you stop taking DOVATO, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your liver.

What is DOVATO?

DOVATO is a prescription medicine that is used without other antiretroviral medicines to treat HIV-1 infection in adults: who have not received antiretroviral medicines in the past, **and** without known resistance to the medicines dolutegravir or lamivudine. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if DOVATO is safe and effective in children.

Who should not take DOVATO?

Do Not Take DOVATO if You:

- have ever had an allergic reaction to a medicine that contains dolutegravir or lamivudine.
- take dofetilide.

What should I tell my healthcare provider before using DOVATO?

Tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems, including hepatitis B or C infection.
- have kidney problems.
- are pregnant or plan to become pregnant. One of the medicines in DOVATO (dolutegravir) may harm your unborn baby.
  - **You should not take DOVATO if you are planning to become pregnant or during the first 12 weeks of pregnancy.** Your healthcare provider may prescribe a different medicine if you are planning to become pregnant or become pregnant during treatment with DOVATO.
  - If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with DOVATO.
  - If you can become pregnant, you should consistently use effective birth control (contraception) during treatment with DOVATO.
  - Tell your healthcare provider right away if you are planning to become pregnant, you become pregnant, or think you may be pregnant during treatment with DOVATO.

Tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take DOVATO.**
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - One of the medicines in DOVATO (lamivudine) passes into your breastmilk.
  - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines interact with DOVATO. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DOVATO.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take DOVATO with other medicines.

What are Possible Side Effects of DOVATO?

DOVATO can cause serious side effects, including:

- **Those in the "What is the Most Important Information I Should Know about DOVATO?" section.**
- **Allergic reactions. Call your healthcare provider right away if you develop a rash with DOVATO. Stop taking DOVATO and get medical help right away if you develop a rash with any of the following signs or symptoms:** fever; generally ill feeling; tiredness; muscle or joint aches; blisters or sores in mouth; blisters or peeling of the skin; redness or swelling of the eyes; swelling of the mouth, face, lips, or tongue; problems breathing.
- **Liver problems.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with DOVATO. Liver problems, including liver failure, have also happened in people without a history of liver disease or other risk factors. Your healthcare provider may do blood tests to check your liver. **Tell your healthcare provider right away if you get any of the following signs or symptoms of liver problems:** your skin or the white part of your eyes turns yellow (jaundice); dark or "tea-colored" urine; light-colored stools (bowel movements); nausea or vomiting; loss of appetite; and/or pain, aching, or tenderness on the right side of your stomach area.
- **Too much lactic acid in your blood (lactic acidosis).** Lactic acidosis is a serious medical emergency that can lead to death. **Tell your healthcare provider right away if you get any of the following symptoms that could be signs of lactic acidosis:** feel very weak or tired; unusual (not normal) muscle pain; trouble breathing; stomach pain with nausea and vomiting; feel cold, especially in your arms and legs; feel dizzy or lightheaded; and/or a fast or irregular heartbeat.
- **Lactic acidosis can also lead to severe liver problems,** which can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis). **Tell your healthcare provider right away if you get any of the signs or symptoms of liver problems which are listed above under "Liver problems." You may be more likely to get lactic acidosis or severe liver problems if you are female or very overweight (obese).**

ViiVConnect

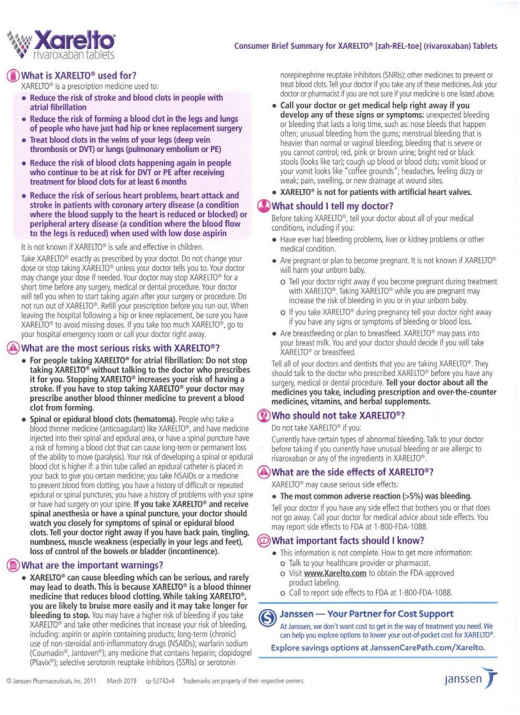
For information on access and coverage to help you get your prescribed ViiV Healthcare medications
Insured • Underinsured • Uninsured

1-844-588-3288 (toll free)
Monday–Friday, 8AM–11PM (ET)
www.viivconnect.com

ViiV Healthcare

DLLADVT180001 April 2019
Produced in USA.

Learn more about Alphonso and DOVATO at DOVATO.com



Xarelto® rivaroxaban tablets

Consumer Brief Summary for XARELTO® (zah-REL-toe) (rivaroxaban) Tablets

What is XARELTO® used for?

XARELTO® is a prescription medicine used to:

- **Reduce the risk of stroke and blood clots in people with atrial fibrillation**
- **Reduce the risk of forming a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery**
- **Treat blood clots in the veins of your legs (deep vein thrombosis or DVT) or lungs (pulmonary embolism or PE)**
- **Reduce the risk of blood clots happening again in people who continue to be at risk for DVT or PE after receiving treatment for blood clots for at least 6 months**
- **Reduce the risk of serious heart problems, heart attack and stroke in patients with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) or peripheral artery disease (a condition where the blood flow to the legs is reduced) when used with low dose aspirin**

It is not known if XARELTO® is safe and effective in children.

Take XARELTO® exactly as prescribed by your doctor. Do not change your dose or stop taking XARELTO® unless your doctor tells you to. Your doctor may change your dose if needed. Your doctor may stop XARELTO® for a short time before any surgery, medical or dental procedure. Your doctor will tell you when to start taking again after your surgery or procedure. Do not run out of XARELTO®. Refill your prescription before you run out. When leaving the hospital following a hip or knee replacement, be sure you have XARELTO® to avoid missing doses. If you take too much XARELTO®, go to your hospital emergency room or call your doctor right away.

What are the most serious risks with XARELTO®?

- **For people taking XARELTO® for atrial fibrillation: Do not stop taking XARELTO® without talking to the doctor who prescribes it for you. Stopping XARELTO® increases your risk of having a stroke. If you have to stop taking XARELTO® your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.**
- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like XARELTO®, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if: a thin tube called an epidural catheter is placed in your back to give you certain medicine; you take NSAIDs; or a medicine to prevent blood from clotting; you have a history of difficult or repeated epidural or spinal punctures; you have a history of problems with your spine or have had surgery on your spine. **If you take XARELTO® and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have back pain, tingling, numbness, muscle weakness (especially in your legs and feet), loss of control of the bowels or bladder (incontinence).**

What are the important warnings?

- **XARELTO® can cause bleeding which can be serious, and rarely may lead to death. This is because XARELTO® is a blood thinner medicine that reduces blood clotting. While taking XARELTO®, you are likely to bruise more easily and it may take longer for bleeding to stop.** You may have a higher risk of bleeding if you take XARELTO® and take other medicines that increase your risk of bleeding, including: aspirin or aspirin containing products; long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs); warfarin sodium (Coumadin®, Jantoven®); any medicine that contains heparin; clopidogrel (Plavix®); selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs); other medicines to prevent or treat blood clots. Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.
- **Call your doctor or get medical help right away if you develop any of these signs or symptoms:** unexpected bleeding or bleeding that lasts a long time, such as: nose bleeds that happen often; unusual bleeding from the gums; menstrual bleeding that is heavier than normal or vaginal bleeding; bleeding that is severe or you cannot control; red, pink or brown urine; bright red or black stools (looks like tar); cough up blood or blood clots; vomit blood or your vomit looks like "coffee grounds"; headaches, feeling dizzy or weak; pain, swelling, or new drainage at wound sites.
- **XARELTO® is not for patients with artificial heart valves.**

What should I tell my doctor?

Before taking XARELTO®, tell your doctor about all of your medical conditions, including if you:

- Have ever had bleeding problems, liver or kidney problems or other medical condition.
- Are pregnant or plan to become pregnant. It is not known if XARELTO® will harm your unborn baby.
  - Tell your doctor right away if you become pregnant during treatment with XARELTO®. Taking XARELTO® while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
  - If you take XARELTO® during pregnancy tell your doctor right away if you have any signs or symptoms of bleeding or blood loss.
- Are breastfeeding or plan to breastfeed. XARELTO® may pass into your breast milk. You and your doctor should decide if you will take XARELTO® or breastfeed.

Tell all of your doctors and dentists that you are taking XARELTO®. They should talk to the doctor who prescribed XARELTO® before you have any surgery, medical or dental procedure. **Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.**

Who should not take XARELTO®?

Do not take XARELTO® if you:

Currently have certain types of abnormal bleeding. Talk to your doctor before taking if you currently have unusual bleeding or are allergic to rivaroxaban or any of the ingredients in XARELTO®.

What are the side effects of XARELTO®?

XARELTO® may cause serious side effects:

- **The most common adverse reaction (>5%) was bleeding.**

Tell your doctor if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What important facts should I know?

- This information is not complete. How to get more information:
  - Talk to your healthcare provider or pharmacist.
  - Visit **www.Xarelto.com** to obtain the FDA-approved product labeling.
  - Call to report side effects to FDA at 1-800-FDA-1088.

Janssen — Your Partner for Cost Support

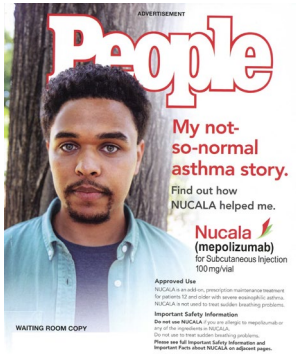
At Janssen, we don't want cost to get in the way of treatment you need. We can help you explore options to lower your out-of-pocket cost for XARELTO®.

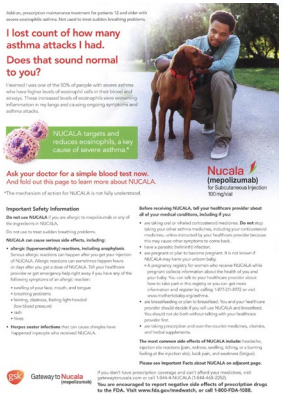
Explore savings options at JanssenCarePath.com/Xarelto.

janssen

Consumer Brief Summary – Full Integration

FOOD AND DRUG LAW INSTITUTE





Consumer Brief Summary as Risk Balance

FOOD AND DRUG LAW INSTITUTE

Risk Information Throughout Email

From: MS Update <MSUpdate@mail.clinicalnews.net>
To:
Sent: Thu, Aug 29, 2019 2:00 pm
Subject: Call to equip your patients with educational resources

Prescribing Information | Important Safety Information

INDICATION

COPAXONE® is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindication: COPAXONE® is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol.

Read more Important Safety Information.

COPAXONE® RESOURCE ORDERING IS NOW AVAILABLE

- Replenish your supply of patient resources, including COPAXONE® Patient Starter Kits and brochures, and COPAXONE® Prescription and Service Request Tear Pads.
- Please call Teva's **Shared Solutions®** at 1-800-887-8100 to place your order today.

1

FIND AVAILABLE RESOURCES

TAKE ADVANTAGE OF THE COPAXONE® SAMPLE PROGRAM

- Order COPAXONE® 40 mg/mL samples for your relapsing multiple sclerosis (RMS) patients online.
- Click below to create or connect to your account.

ORDER SAMPLES TODAY

TEVA'S LIFT MS® BLOG AND FACEBOOK COMMUNITY ARE HERE TO INFORM AND INSPIRE

- A source of support, advice, and encouragement for those living with RMS.
- Designed for current COPAXONE® patients as well as those navigating a recent MS diagnosis.
- Information provided by MS healthcare specialists, Patient Advocates, and Care Partners.

VISIT LIFT MS® FOR MORE INFO

INDICATION

COPAXONE® is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated

2

progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindication: COPAXONE® is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol.

Immediate Post-Injection Reaction: Approximately 16% of patients exposed to COPAXONE® 20 mg per mL compared to 4% of those on placebo, and approximately 2% of patients exposed to COPAXONE® 40 mg per mL compared to none on placebo experienced a constellation of symptoms that may occur immediately (within seconds to minutes, with the majority of symptoms observed within 1 hour) after injection and included at least 2 of the following: flushing, chest pain, palpitations, tachycardia, anxiety, dyspnea, throat constriction, and urticaria. In general, these symptoms have their onset several months after the initiation of treatment, although they may occur earlier, and a given patient may experience 1 or several episodes of these symptoms. Typically, the symptoms were transient and self-limited and did not require treatment; however, there have been reports of patients with similar symptoms who received emergency medical care.

Chest Pain: Transient chest pain was noted in 13% of COPAXONE® 20 mg per mL patients compared to 6% of placebo patients, and approximately 2% of COPAXONE® 40 mg per mL patients compared to 1% on placebo. While some episodes of chest pain occurred in the context of the Immediate Post-Injection Reaction described above, many did not. The temporal relationship of this chest pain to an injection was not always known. The pain was usually transient, often unassociated with other symptoms, and appeared to have no clinical sequelae. Some patients experienced more than 1 such episode, and episodes usually began at least 1 month after the initiation of treatment.

Lipoatrophy and Skin Necrosis: At injection sites, localized lipoatrophy and, rarely, injection site skin necrosis may occur. Lipoatrophy may occur at various times after treatment onset (sometimes after several months) and is thought to be permanent. There is no known therapy for lipoatrophy.

3

Risk Information at End of Email

FOOD AND DRUG LAW INSTITUTE

From: Takeda-Lundbeck <tak@hce.takeda.us>
Subject: Important information about an online TV ad airing soon
Date: September 24, 2019 at 7:03:22 AM CDT
To:

Can't see the images? View Online.

Trintellix vortioxetine 5mg 10mg 20mg tablets

TRINTELLIX is indicated for the treatment of major depressive disorder (MDD) in adults.

Please see Important Safety Information, including Boxed Warning for Suicidal Thoughts and Behaviors, below.

Introducing the latest TV ad airing for TRINTELLIX

Introducing the latest ad for TRINTELLIX available online, on YouTube, and more

Hello

Takeda and Lundbeck are excited to introduce a new ad for TRINTELLIX (vortioxetine)! The new ad started appearing online on July 9, 2019. It includes information regarding SSRI-induced sexual dysfunction, a common issue many of your major depressive disorder (MDD) patients may face[1,2] and shows how TRINTELLIX may help.

For MDD patients with SSRI-induced sexual dysfunction, a switch to TRINTELLIX improved sexual dysfunction while maintaining efficacy[3,4]

- Based on an 8-week, head-to-head, randomized, double-blind study in which well-treated patients experiencing SSRI-induced sexual dysfunction as measured by the CSFQ-14 were switched from citalopram, paroxetine, or sertraline to either TRINTELLIX (n=217) or escitalopram (n=207). Both groups started on 10 mg once daily, then increased to 20 mg at Week 1, followed by flexible dosing[3,4]
- CSFQ-14 mean total score at baseline: TRINTELLIX 36.5, escitalopram 36.3[4]

baseline to Week 8 as measured by mean change in the CSFQ-14 total score (8.8 vs 6.6; *P*=0.013)[4]

- Both TRINTELLIX and escitalopram maintained efficacy during the study, based on mean change from baseline in total MADRS scores[3,4]

In MDD short-term efficacy studies, sexual dysfunction reported with TRINTELLIX was voluntarily and prospectively assessed[3]

- Voluntary reports of sexual dysfunction with TRINTELLIX in 6- to 8-week controlled trials were ≤5%
- Because voluntary reports of sexual dysfunction are known to be underreported, a separate, self-rated questionnaire was provided to patients prospectively in TRINTELLIX clinical studies
- When assessed proactively in patients without sexual dysfunction at baseline, reports of treatment emergent sexual dysfunction across doses of TRINTELLIX 5 mg, 10 mg, 20 mg were 16%, 20%, 29% in males (N=212) and 22%, 23%, and 34% in females (N=226) respectively, compared to placebo rates of 14% in males (N=162) and 20% in females (N=135)

The efficacy of TRINTELLIX for the treatment of MDD in adults was established in six 6- to 8-week studies and one maintenance study[3]

Abbreviations: CSFQ-14, Changes in Sexual Functioning Questionnaire; MADRS, Montgomery-Åsberg Depression Rating Scale; MDD, Major Depressive Disorder; SSRI, Selective Serotonin Reuptake Inhibitor.

Learn more about these results and how TRINTELLIX may help your patients at trintellixhcp.com.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a trend toward reduced risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

TRINTELLIX has not been evaluated for use in pediatric patients.

CONTRAINDICATIONS

Hypersensitivity: Hypersensitivity to vortioxetine or any components of the TRINTELLIX formulation. Hypersensitivity reactions including anaphylaxis, angioedema, and urticaria have been reported in patients treated with

TRINTELLIX.

Monoamine Oxidase Inhibitors (MAOIs): Due to an increased risk of serotonin syndrome, do not use MAOIs intended to treat psychiatric disorders with TRINTELLIX or within 21 days of stopping treatment with TRINTELLIX. Do not use TRINTELLIX within 14 days of stopping an MAOI intended to treat psychiatric disorders. Do not start TRINTELLIX in a patient who is being treated with linezolid or intravenous methylene blue.

WARNINGS AND PRECAUTIONS

Clinical Worsening and Suicide Risk: All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality (anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania), especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. **Families and caregivers of patients being treated with antidepressants for MDD or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients daily.**

Serotonin Syndrome: The development of a potentially life-threatening serotonin syndrome has been reported with serotonergic antidepressants (SNRIs, SSRIs, and others), including TRINTELLIX, when used alone but more often when used concomitantly with other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort), and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, delirium, and coma), autonomic instability (eg, tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (eg, tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). If such symptoms occur, discontinue TRINTELLIX and any concomitant serotonergic agents, and initiate supportive symptomatic treatment. If concomitant use of TRINTELLIX is clinically warranted, patients should be made aware of and monitored for potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases.

Abnormal Bleeding: Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when TRINTELLIX is coadministered with NSAIDs, aspirin, or other drugs that affect coagulation.

Activation of Mania/Hypomania: Activation of mania/hypomania can occur with antidepressant treatment. Prior to initiating treatment with an antidepressant, screen patients for bipolar disorder. As with all antidepressants, use TRINTELLIX cautiously in patients with a history or family history of bipolar disorder, mania, or hypomania.

Angle-Closure Glaucoma: The pupillary dilation that occurs following use

of many antidepressant drugs, including TRINTELLIX, may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

Hyponatremia: Hyponatremia has occurred as a result of serotonergic drugs and in many cases, appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Elderly patients and patients taking diuretics or who are otherwise volume-depleted can be at greater risk. More severe or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. Discontinue TRINTELLIX in patients with symptomatic hyponatremia and initiate appropriate medical intervention.

Adverse Reactions: The most commonly observed adverse reactions for TRINTELLIX in 6- to 8-week placebo-controlled studies (incidence ≥5% and at least twice the rate of placebo) were by dose (5 mg, 10 mg, 15 mg, 20 mg) vs placebo: nausea (21%, 26%, 32%, 32% vs 9%), constipation (3%, 5%, 6%, 6% vs 3%), and vomiting (3%, 5%, 6%, 6% vs 1%).

Drug Interactions: Concomitant administration of TRINTELLIX and strong CYP2D6 inhibitors or strong CYP inducers may require a dose adjustment of TRINTELLIX.

INDICATION

TRINTELLIX is indicated for the treatment of major depressive disorder (MDD) in adults.

Please see full Prescribing Information and Medication Guide for TRINTELLIX.

Please visit TRINTELLIXHCP.com to learn more

Sincerely,
The TRINTELLIX Team

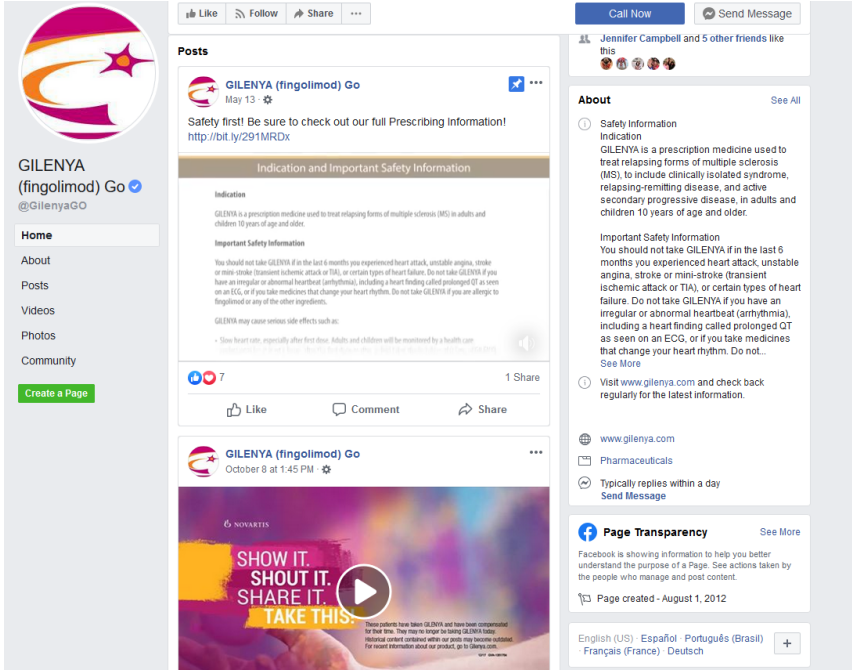
Reference:
1. Serretti A, Chiesa A. *J Clin Psychopharmacol*. 2009;29(3):259-266.
2. Hu XH, Bull SA, Hunkeler EM, Ming E, Lee JY, Fireman B, Markson, LE. *J Clin Psychiatry*. 2004;65(7):959-965.
3. TRINTELLIX (vortioxetine) Prescribing Information. Takeda Pharmaceuticals.
4. Jacobsen PL, Mahableshwarkar AR, Chen Y, Chrones L, Clayton AH. *J Sex Med*. 2015;12(10):2036-2048.

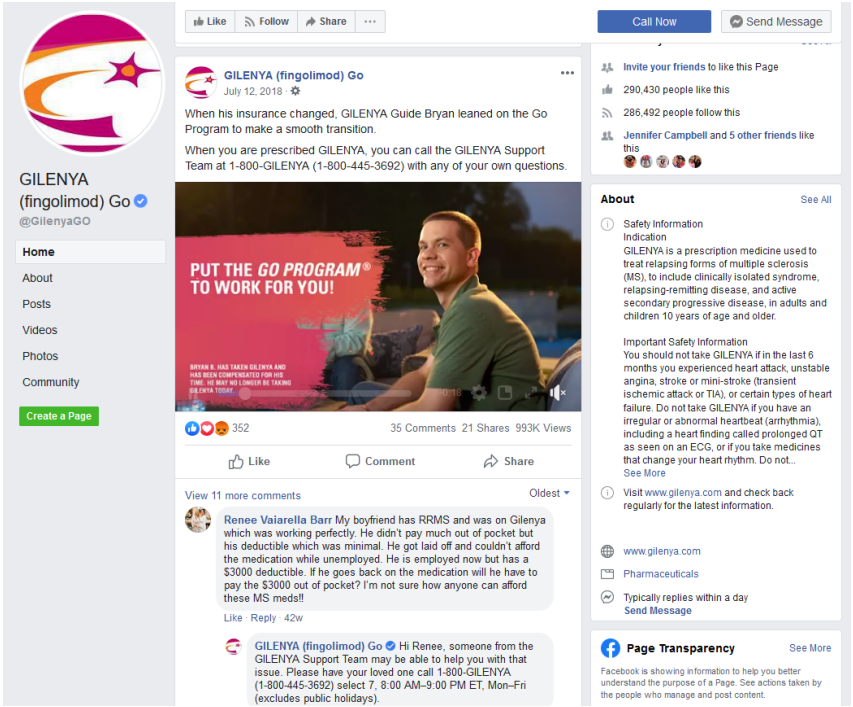
Trintellix vortioxetine 5mg 10mg 20mg tablets

Takeda

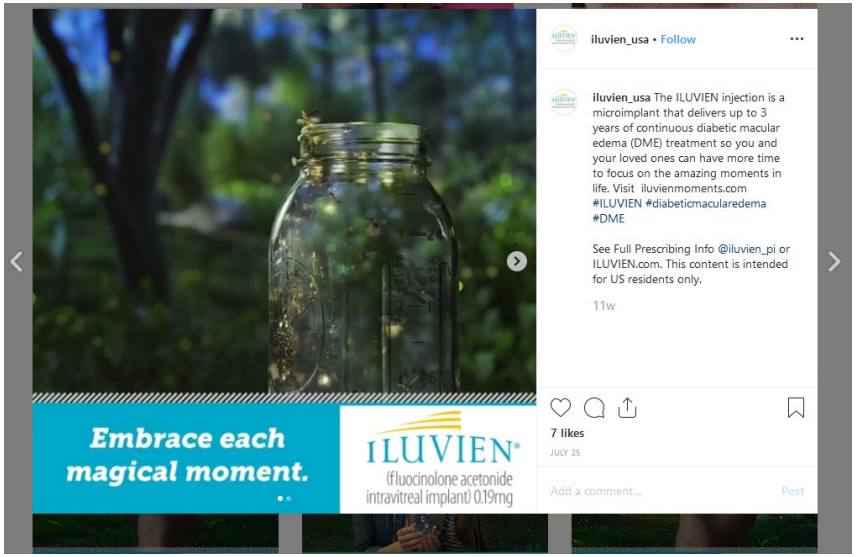
Lundbeck

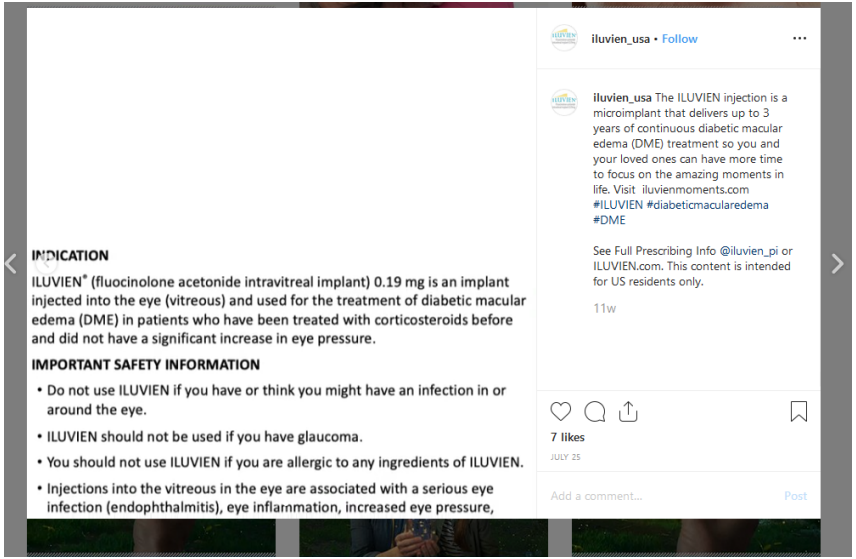
Social Media – Desktop Platform



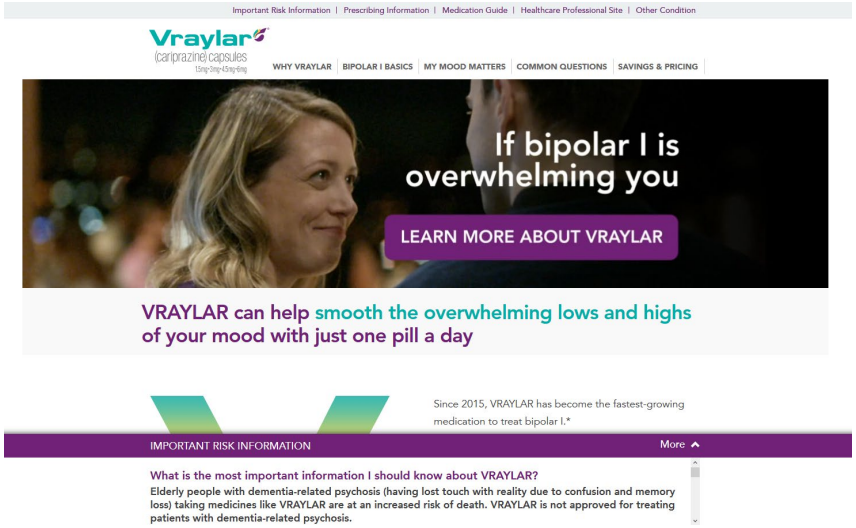


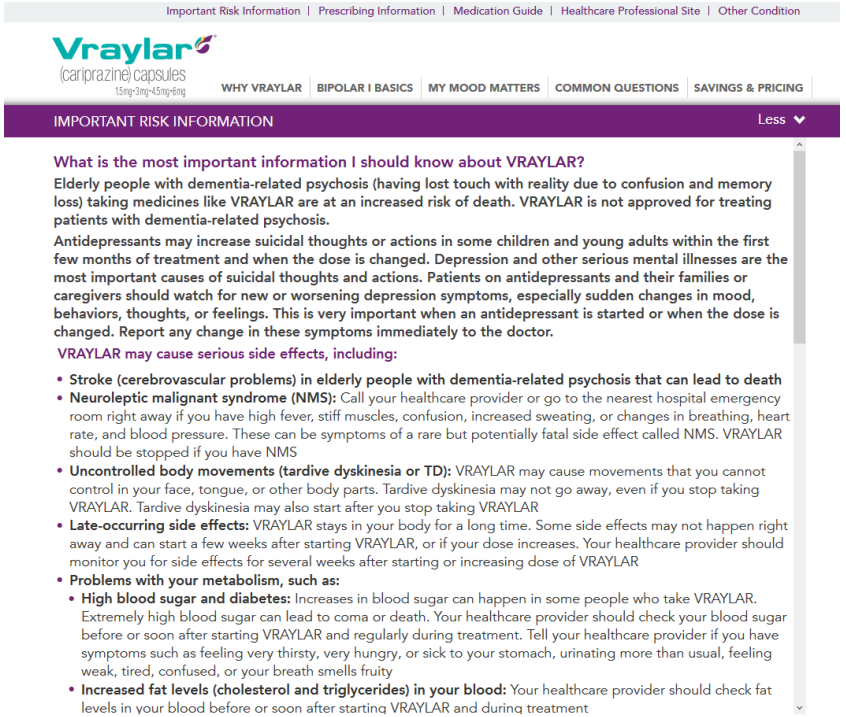
Social Media – Mobile Platform



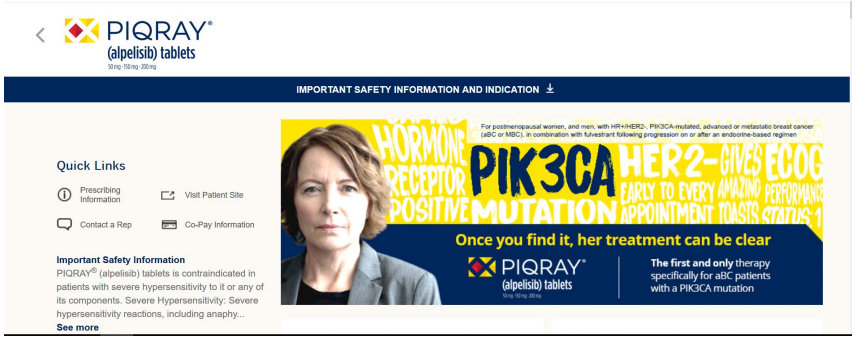


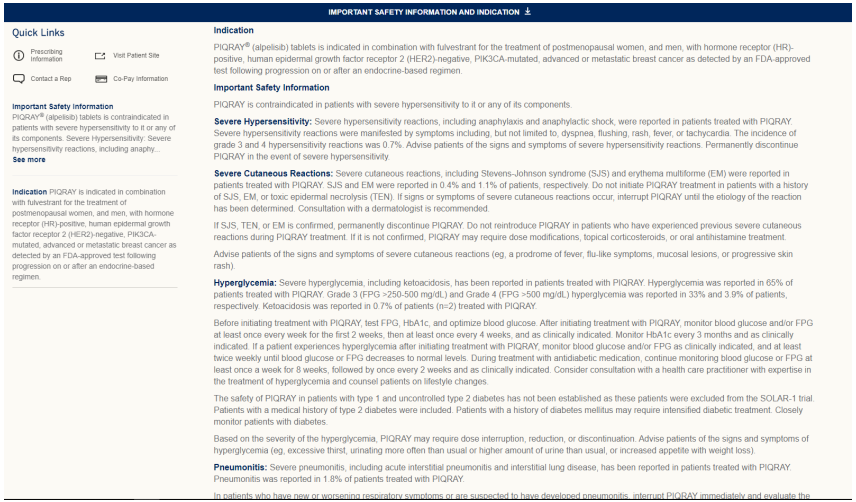
Website: “Sticky” ISI





Website: Side/Top ISI





QUESTIONS?