M-PROVE®

Maximizing Patient Reported Outcomes and Vigilance Efforts

Utilizing the modern patient to increase participation and signal detection in pharmacovigilance

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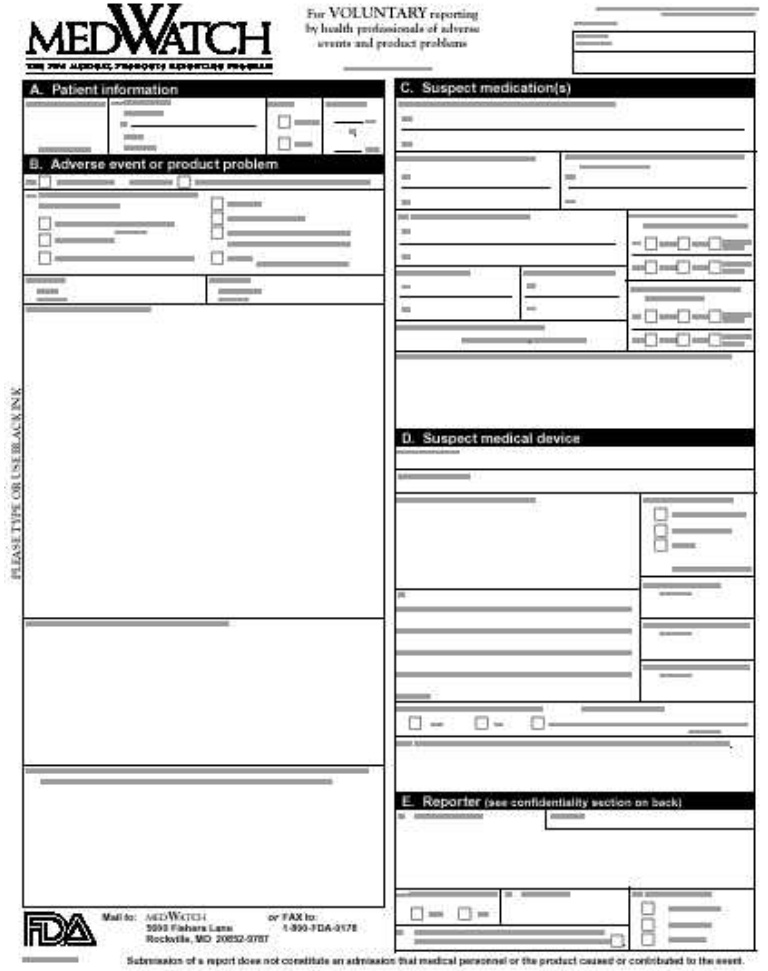
Jillian Aquino

Current Challenges

Only 1 in 10 adverse events are captured by FDA's surveillance system.

- Public awareness
- Passive
- Time and effort



Goals of M-PROVE® :

- To help 21st century patients become proactive leaders of their own health and safety, and to provide drug safety information in a learner-friendly manner.
- To encourage public's active participation in FDA's pharmacovigilance efforts by **making reporting tools readily accessible and easier to use**

W[illegible]oes
afte[illegible]tion?

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Loperamide - Wikipedia, the free encyclopedia

https://en.wikipedia.org/wiki/**Loperamide** ▾ Wikipedia ▾

Loperamide, sold under the brand name Imodium among others, is a medication used to decrease the frequency of diarrhea. It is often used for this purpose in ...

Biological half-life: 9-14 hours **Formula**: $C_{29}H_{33}ClN_2O_2$

Pregnancy category: AU: B3; US: C (Risk ... **Metabolism**: Liver (extensive)

Imodium (Loperamide Hcl) Drug Information: Indications ...

www.rxlist.com/imodium-drug/indications-dosage.htm ▾ RxList ▾

IMODIUM® (**loperamide** hydrochloride) is indicated for the control and symptomatic relief of acute nonspecific diarrhea and of chronic diarrhea associated with inflammatory bowel disease. IMODIUM® (**loperamide** hcl) is also indicated for reducing the volume of discharge from ...

loperamide oral : Uses, Side Effects, Interactions, Pictures ...

www.webmd.com/drugs/2/.../**loperamide**.../**loperamide**.../details ▾ WebMD ▾

Find patient medical information for **loperamide** oral on WebMD including its uses, side effects and safety, interactions, pictures, warnings and user ratings.

Loperamide: Indications, Side Effects, Warnings - Drugs.com

www.drugs.com/cdi/**loperamide**.html ▾

Easy to read patient leaflet for **loperamide**. Includes indications, proper use, special instructions, precautions, and possible side effects.

Dosage - Side Effects - Loperamide Drug Interactions - Pregnancy Warnings

Loperamide

Common brands: Imodium, Select, Fad

Antidiarrheal

It can treat diarrhea. It can also decrease the amount of drainage in patients with ostomies.

SIDE EFFECTS INTERACTIONS WARNINGS

Brands: Imodium, Select, and Fad

Availability: Prescription sometimes needed

Pregnancy: Consult a doctor

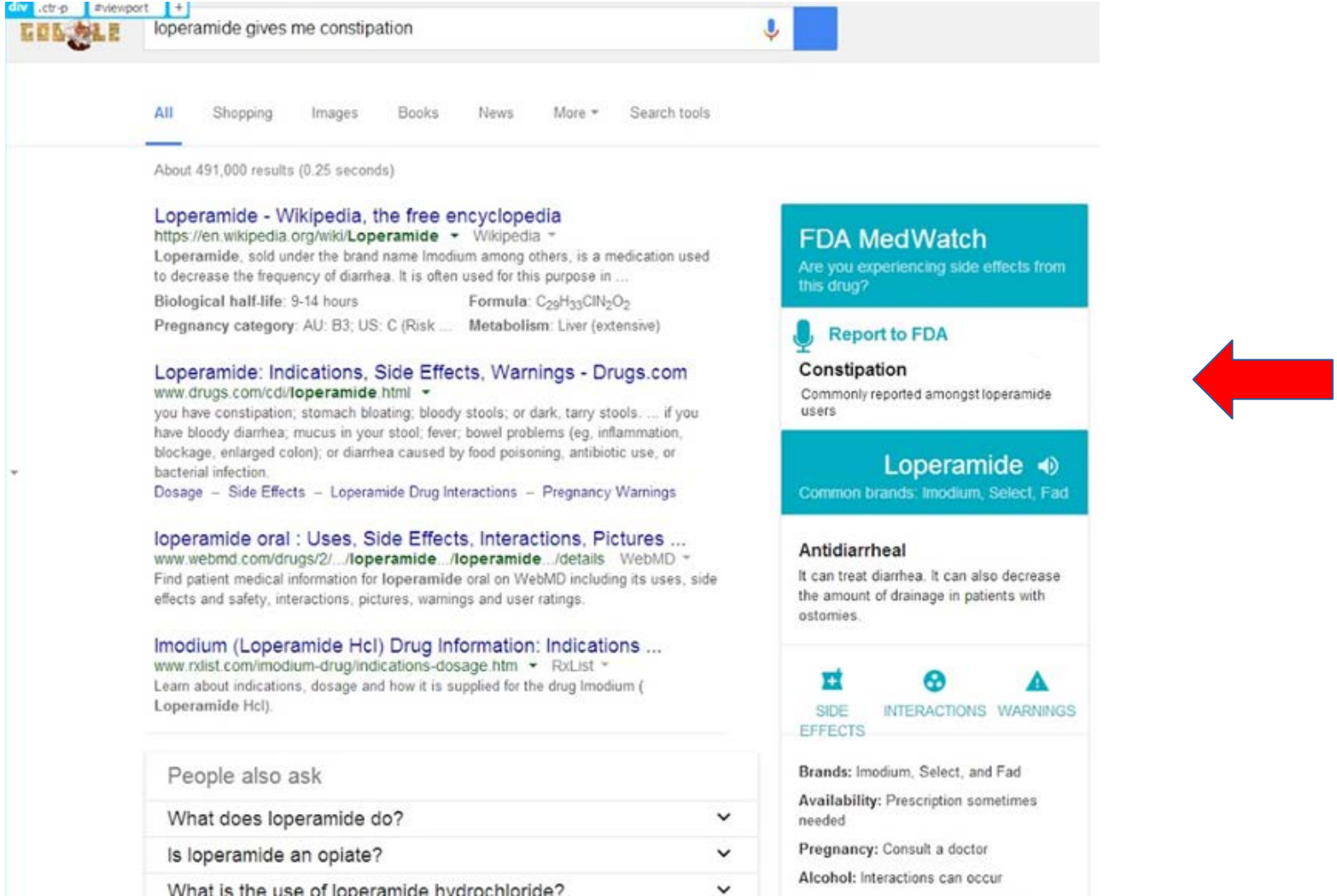
Alcohol: Interactions can occur

Drug class: Peripheral opioid receptor agonist

May treat

Novel approaches to increase MedWatch participation 1

- **Intelligent patient targeting**
- Streamlined data collection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you have constipation; stomach bloating; bloody stools; or dark, tarry stools. ... if you have bloody diarrhea; mucus in your stool; fever; bowel problems (eg, inflammation, blockage, enlarged colon); or diarrhea caused by food poisoning, antibiotic use, or bacterial infection.
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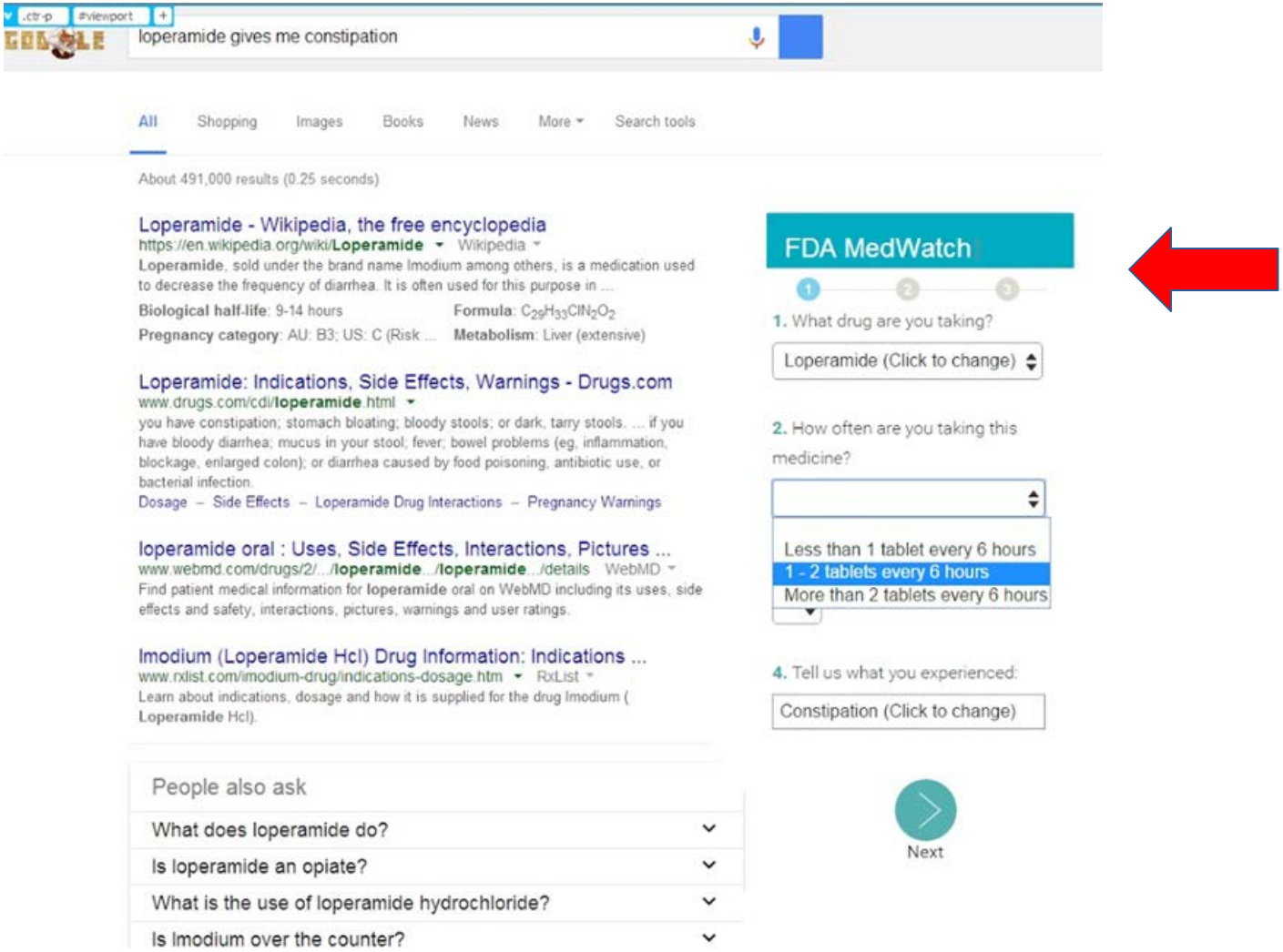
RxList
Learn about indications, dosage and how it is supplied for the drug Imodium (Loperamide Hcl).
People also ask
What does loperamide do?
Is loperamide an opiate?
What is the use of loperamide hydrochloride?
FDA MedWatch
Are you experiencing side effects from this drug?
Report to FDA
Constipation
Commonly reported amongst loperamide users
Loperamide
Common brands: Imodium, Select, Fad
Antidiarrheal
It can treat diarrhea. It can also decrease the amount of drainage in patients with ostomies.
SIDE EFFECTS
INTERACTIONS
WARNINGS
Brands: Imodium, Select, and Fad
Availability: Prescription sometimes needed
Pregnancy: Consult a doctor
Alcohol: Interactions can occur

Novel approaches to increase MedWatch participation 2

- Intelligent patient targeting
- **Streamlined data collection**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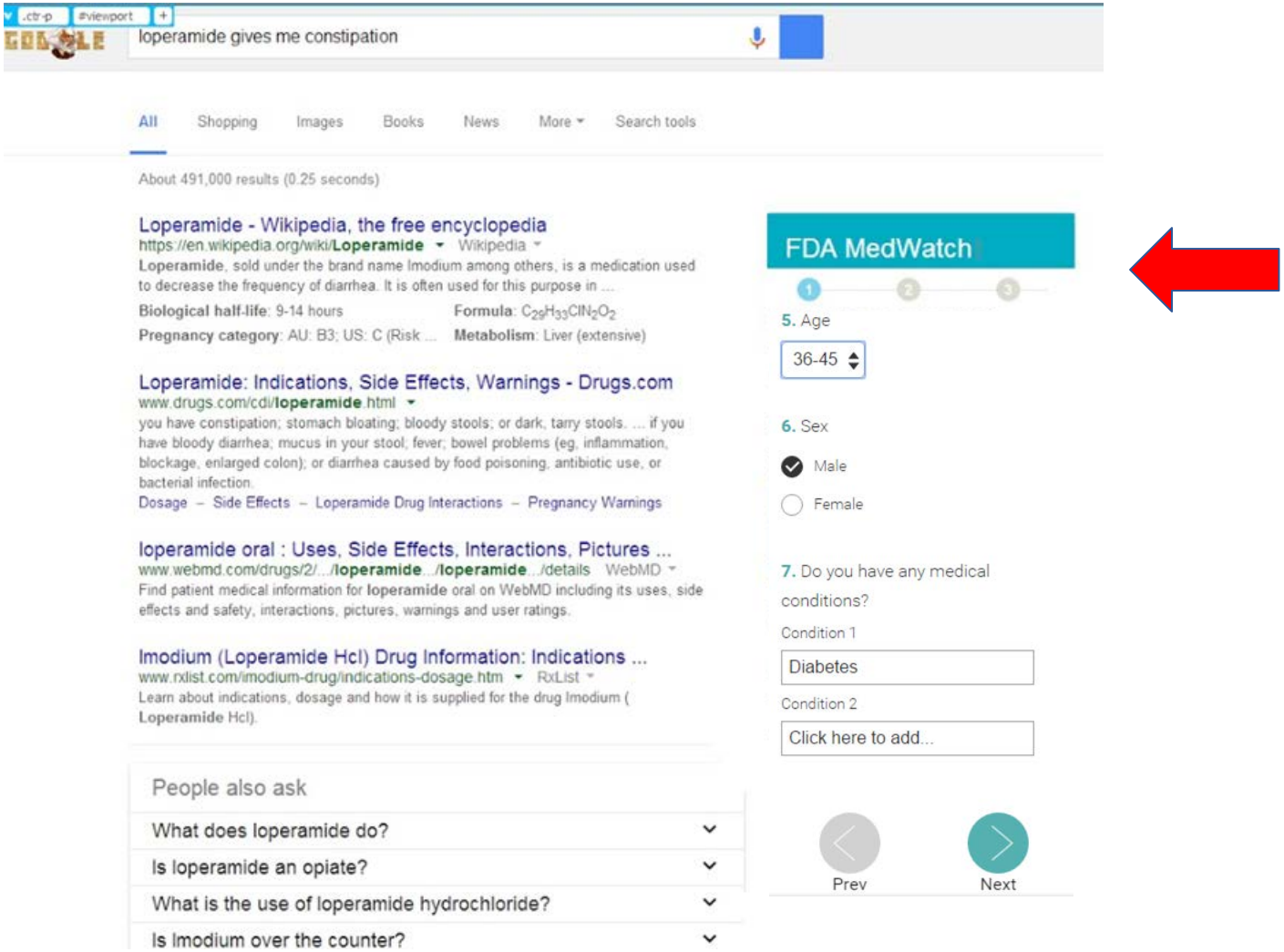
What does loperamide do?
Is loperamide an opiate?
What is the use of loperamide hydrochloride?
Is Imodium over the counter?
FDA MedWatch
1. What drug are you taking?
Loperamide (Click to change)
2. How often are you taking this medicine?
Less than 1 tablet every 6 hours
1 - 2 tablets every 6 hours
More than 2 tablets every 6 hours
4. Tell us what you experienced:
Constipation (Click to change)
Next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What is the use of loperamide hydrochloride?
Is Imodium over the counter?
FDA MedWatch
5. Age
36-45
6. Sex
Male
Female
7. Do you have any medical conditions?
Condition 1
Diabetes
Condition 2
Click here to add...
Prev
Next

Participation is inversely proportional to effort

MedWatch: lengthy, intimidating
M-PROVE®: simpler, leaner, SMARTER

SO WHAT?

- Surveillance is critical to protect public safety and wellbeing

- Addresses one of ORSI's objectives: "Harness Diverse Data through Information Sciences to Improve Health Outcomes"

Value Added by M-PROVE®

- Readily accessible to both consumers and healthcare professionals
- Relatively quick and easy for reporters
- Increased MedWatch participation
  - Faster detection of adverse events
  - Identification of rarer events
  - Better detection of vulnerable subgroups

Feasibility

- Simple addition to an already well implemented google “side bar”
- Data inputs would just need to be automatically inputted into a MedWatch form

Limitations?

- Richness/Comprehensiveness of data collected
- Quality of data
- Requires FDA/Search engine collaboration and agreement

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Google searches could help FDA find drug adverse events

July 17, 2015

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FDA is talking to Google about how the search engine could help the agency identify previously unknown adverse events of medications. Agency officials held a conference call on June 9 with Evgeniy Gabrilovich, a senior Google researcher who cowrote a 2013 paper about using search query data to identify adverse drug reactions.

FDA is talking to Google about how the search engine could help the agency identify previously unknown adverse events of medications. Agency officials held a conference call on June 9 with Evgeniy Gabrilovich, a senior Google researcher who cowrote a 2013 paper about using search query data to identify adverse drug reactions. Microsoft researchers also say they have been working informally with the agency for several years on detecting drug adverse events. FDA spokesman Chris Kelly called the meeting an introduction and a chance "for the agency to begin a discussion on how we might collaborate with Google on identifying adverse event data, using Google's technologies and data." The government's process for tracking adverse events—which involves patients, physicians, and pharmaceutical companies submitting forms that describe possible reactions—has not changed much since the late 1990s. FDA now gets more than a million reports of adverse drug reactions each year. Although the agency has tried to make the data easier to access, critics say the system probably misses many adverse events and can be slow to detect safety problems.

Bloomberg (07/15/15) Tozzi, John; Bass, Dina

Conclusion:

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QUESTIONS?