

Health News

- The HHS and FDA issued a final rule on drug pricing that will allow states to **import certain prescription drugs from Canada**. Under the rule, eligible prescription drugs will have to undergo testing for authenticity and degradation, be relabeled, and demonstrate significant cost reductions to the American consumer. States will be able to partner with pharmacists or wholesalers to implement their plans, which must comply with federal procedures. Six states have already submitted such plans for review.

[.https://www.fda.gov/news-events/press-announcements/fda-takes-actions-help-lower-us-prescription-drug-prices?utm_medium=email&utm_source=govdelivery](https://www.fda.gov/news-events/press-announcements/fda-takes-actions-help-lower-us-prescription-drug-prices?utm_medium=email&utm_source=govdelivery)

Canada has concerns about the rule. Drug makers are opposed to the rule and in the past suggested that they might try to stop such a policy through a lawsuit.

<https://khn.org/news/trump-approves-final-plan-to-import-drugs-from-canada-for-a-fraction-of-the-price/>

- The FDA warned of problems that can occur with high doses of over-the-counter antihistamine **Benadryl** (diphenhydramine). Recently, teenagers have experienced heart problems, seizures, hallucinations, and other conditions requiring emergency medical care after participating in the "**Benadryl Challenge**" posted on the social media platform TikTok. The FDA reminds parents to keep OTC medications as well as prescription medicines away from their children. If any medication overdose has occurred, seek medical attention and contact poison control at 1-800-222-1222.

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-problems-high-doses-allergy-medicine-diphenhydramine-benadryl>

- The U.S. FDA announced a recall of Sun Pharmaceutical's **Riomet ER** (metformin) due to the presence of higher than allowed levels of NDMA impurity.

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sun-pharmaceutical-industries-inc-issues-voluntary-nationwide-recall-riomet-ertm-metformin>

- The FDA recommended that **dental amalgam** (a liquid mercury and metal mixture) should not be used in certain high risk populations, including pregnant and nursing women, children, people with impaired kidney function, and people with pre-existing neurological disease. Patients who already have amalgam fillings should not have them removed if they are intact as the removal process itself could be more of a health hazard.

<https://www.fda.gov/news-events/press-announcements/fda-issues-recommendations-certain-high-risk-groups-regarding-mercury-containing-dental-amalgam>

- The FDA issued proposed guidance for including **geriatric use information** on drug labels for safe and effective use of drugs in older patients. The last such guidance was issued in October 2001. The comment period will close on November 16.

<https://www.federalregister.gov/documents/2020/09/16/2020-20435/geriatric-information-in-human-prescription-drug-and-biological-product-labeling-draft-guidance-for>

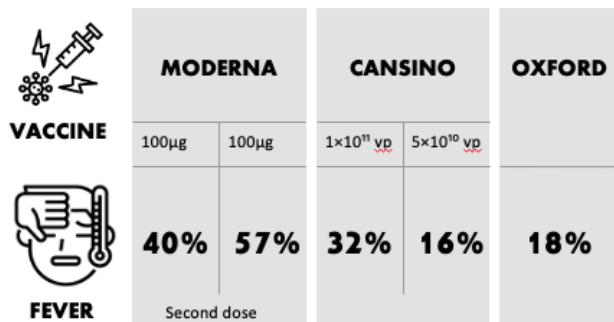
- The FDA is requiring updates to the **boxed warnings on benzodiazepines** to address the serious risks of medication abuse, addiction, physical dependence, and withdrawal reactions. Benzodiazepines are used to treat anxiety, insomnia, seizure disorders, panic disorders, and social phobia. Products include **Xanax** (alprazolam), **Valium** (diazepam), **Ativan** (lorazepam), **Klonopin** (clonazepam), and others.

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class>

Coronavirus News: Vaccines

- Many people will likely experience **side effects** from a new **coronavirus vaccine**, based on results reported so far for potential coronavirus vaccines in stage 3 clinical trials. As developers test various dosages to find a formulation that will provide protection and not cause so many side effects that people will be wary of taking it, it is apparent that all of the test vaccines seem to have a higher incidence of side effects than most other routine vaccinations.

Incidence of fever for these stage-3 vaccines:



VACCINE	MODERNA		CANSINO		OXFORD
	100µg	100µg	1×10 ¹¹ vp	5×10 ¹⁰ vp	
FEVER	40%	57%	32%	16%	18%
	Second dose				

Source: <https://www.newsroom.co.nz/be-prepared-for-covid-19-vaccine-side-effects>

- After a trial participant in the U.K. came down with a rare **spinal cord inflammatory disorder** (transverse myelitis), **AstraZeneca/Oxford** paused its trial for about a week; it has since resumed. However, the trial in the U.S. has not yet resumed, and many questions remain.

<https://www.peoplespharmacy.com/articles/the-inside-story-on-the-az-vaccine-pause>

- **Pfizer** has expanded the enrollment of its Phase 3 COVID-19 vaccine trial to up to approximately 44,000 participants which also allows for the enrollment of new populations. Pfizer released data indicating mild to moderate side effects have been experienced for its vaccine.

<https://www.reuters.com/article/health-coronavirus-pfizer-idUSKBN2670AO>

- The FDA announced that **coronavirus vaccines** will have more stringent requirements than products like tests that have been brought to the market more quickly through emergency use authorizations. The Vaccines and Related Biological Products Advisory Committee will address the general development of COVID-19 vaccines on October 22nd.

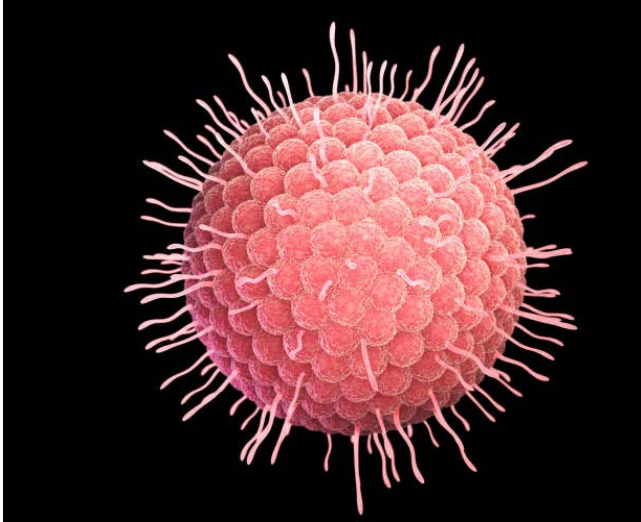
<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-covid-19-vaccines>

Shingrix: The New Vaccine for Shingles: Frequent Side Effects but High Effectiveness

Anyone who has had chicken pox (varicella zoster) is vulnerable to getting the painful rash called shingles. Once infected with chicken pox, the varicella virus remains dormant in the nerve cell clusters along a person's spine. Years later, it can be reactivated and cause the painful rash and illness known as shingles.

Because the chicken pox vaccine was not available in the U.S. until 1995, it is estimated that 99% of adults over

the age of 40 have had chicken pox. The risk of shingles and painful post-herpetic neuralgia (PHN) increases with age.



Varicella zoster virus (source: RoyaltyFree Istockphoto)

The first shingles vaccine, **Zostavax**, was approved in 2006 but is no longer sold in the U.S. It may be available to patients until November 2020, when the last of the already-sold supplies expire. GSK's **Shingrix** (recombinant zoster vaccine) was approved in October 2017 and is now the only vaccine option for adults 50 & older to prevent shingles and its complications. It is administered in two doses, with the second dose required 2-6 months after the first.

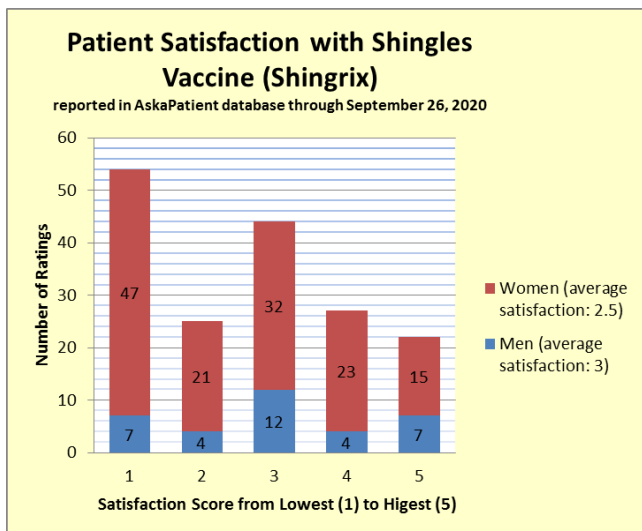
While Shingrix is highly effective (90% or more) at preventing shingles, it comes with more risk of side effects than a typical adult vaccine. In fact, it has by far the **highest number of adverse event reports** (29,000) for routine adult vaccines in the **Vaccine Adverse Event Reporting System (VAERS)** between November 2017 and July 2020. The vaccine with the second highest number of reports in that time frame is **Prevnar-13** (for pneumococcal pneumonia) with 6,385 reports and ranking third is **Fluzone High Dose** with 3,969 reports.

What to expect from the vaccine: almost everyone (about 80%) gets a **sore arm** at the injection site, and about half experience fatigue (myalgia), according to the vaccine label. Other common side effects are fever, chills, and headache. Many health care providers advise their patients to get the shot on a Friday and to plan to have the weekend unscheduled in case they experience uncomfortable reactions. Also, taking an over-the-counter pain medicine such as ibuprofen or acetaminophen after getting Shingrix can help ease discomfort from side effects.

Highlights of Experiences Reported at AskaPatient

About 30% of patients gave the vaccine a highly favorable rating (a 4 or 5). Even those who rated it highly tended to report side effects, but they also advised that the side effects of the vaccine, which tend to not last more than a few days, are far better than enduring the pain, itching, and blisters that occur in a typical shingles outbreak.

On average, men have a better opinion of the vaccine, with an average rating of 3 (somewhat satisfied), while women rated it a 2.5 on average (less than satisfied). However, more women than men provided their experiences. The VAERS database also contains more reports for women than men. The reviews that mention whether a dose was the first or the second suggest that the second dose may be more likely to cause harsher side effects than the first dose.



Experiences with side effects from Shingrix reported by 179 people (as of September 26) to AskaPatient.

[Headache](#) (78 reports)

[Fever](#) (55 reports)

[Joint or muscle aches](#) (100 reports)

Why are the reactions to this vaccine so severe? It could be due to the strength of the vaccine, which includes a component called the **adjuvant**. The adjuvant is the liquid substance, in this case called **AS01_B**, that is mixed with the powdered antigen component right before administration that is used to create a stronger immune response. Severe reactions should be reported to your doctor and/or to VAERS. Signs of anaphylaxis like swelling of the face, difficulty breathing, dizziness, or heart palpitations require immediate medical attention.

Sources and More Reading:

Risks, symptoms, treating, preventing shingles. Fact sheets.

<https://www.cdc.gov/shingles/>

Information on Zostavax, which was discontinued as of July 1.

<https://www.cdc.gov/vaccines/vpd/shingles/public/zostavax/index.html>

Vaccine Adverse Event Reporting System (VAERS)

<https://vaers.hhs.gov/>

Adjuvants in Vaccines

<https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html>

Complete Vaccine label for Shingrix

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0280849d-5c78-4a9d-8941-4eab429f6bd8>

Vaccine information sheet for Shingrix

<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/shingles-recombinant.html>

Why do we need **separate chicken pox and shingles vaccines**? While shingles vaccine does not protect

against chicken pox, the chicken pox vaccine does seem to provide some protection against shingles.

<https://www.theatlantic.com/health/archive/2017/10/shingles-chickenpox-virus/543816/>

A common drug used to treat shingles is the antiviral **Valtrex (generic acyclovir)**. Here are patient experiences:

[Valtrex](#) taken for shingles

[Acyclovir](#) taken for shingles

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[Patient Guide to Coronavirus Websites](#)

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