

# PharmNOTES

Summary about new FDA-approved products,  
new indications, first-time generics,  
and WHAT IS IN THE PIPELINE.

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# NEWS

## DRUG ISSUE

## DATE

## DETAILS

Risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR

02/04/2021

The FDA is alerting that preliminary results from a safety clinical trial showed an increased risk of serious heart-related problems and cancer with Xeljanz, Xeljanz XR (tofacitinib) compared to tumor necrosis factor (TNF) inhibitors. The FDA will evaluate the clinical trial results received to date, work with the drug manufacturer to obtain further information, and will communicate final conclusions and recommendations after completing their review or have more information to share.

### Recommendations for healthcare professionals:

- Advise patients that they should not stop taking tofacitinib without first consulting with their healthcare provider, because doing so may worsen their condition.
- Advise patients to talk with their healthcare provider if they have any questions or concerns.
- Consider the benefits and risks of tofacitinib when deciding whether to initiate or continue patients on the drug.
- Continue to follow the recommendations in the tofacitinib prescribing information.
- Report adverse events or side effects at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)

Additional information can be found at [FDA's Drug Safety and Availability portal](#).

# NEW FDA-APPROVED DRUG PRODUCTS

# NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

## DRUG NAME

VERQUVO (VERICIGUAT) TABLETS

## MANUFACTURER

MERCK

## APPROVAL DATE

01/19/2021

### THERAPEUTIC CLASS

Cardiovascular agent

### FDA-APPROVE INDICATION(S)

VERQUVO is a soluble guanylate cyclase (sGC) stimulator indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

### DOSAGE AND ADMINISTRATION

The recommended dose is 2.5 mg orally once daily. The dose is doubled approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient.

### DOSAGE FORMS AND STRENGTHS

Tablets: 2.5 mg, 5 mg and 10 mg.

Orphan status: N/A

## SAFETY PROFILE

### CONTRAINDICATIONS

- Patients with concomitant use of other soluble sGC stimulators.
- Pregnancy.

### WARNINGS AND PRECAUTIONS

- **Boxed warning:** Embryo-fetal toxicity

### ADVERSE REACTIONS

Most common adverse reactions: hypotension and anemia.

### DRUG INTERACTIONS

- **Other sGC stimulators:** Concomitant use of other sGC stimulators is contraindicated.
- **PDE-5 inhibitors:** Concomitant use is not recommended because of the potential for hypotension.

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Cause fetal harm. Verify the pregnancy status in females of reproductive potential prior to initiating.
- **Females of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and for one month after the final dose.
- **Lactation:** Breastfeeding is not recommended.
- **Pediatric use:** Safety and effectiveness have not been established.
- **Geriatric use:** No dosage adjustment is required in geriatric patients.
- **Renal impairment:** No dosage adjustment recommended in patients with estimated glomerular filtration rate (eGFR)  $\geq 15$  mL/min/1.73m<sup>2</sup> who are not on dialysis. Has not been studied in patients with eGFR.

# NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

## DRUG NAME

**VOCABRIA (CABOTEGRAVIR)  
TABLETS**

## MANUFACTURER

VIIV HEALTHCARE

## APPROVAL DATE

01/21/2021

### THERAPEUTIC CLASS

Anti-infective agent; Antiretroviral

### FDA-APPROVE INDICATION(S)

VOCABRIA is a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI) indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine, for use as: (1) oral lead-in to assess the tolerability of cabotegravir prior to administration of CABENUVA (cabotegravir; rilpivirine) extended-release injectable suspensions; (2) oral therapy for patients who will miss planned injection dosing with CABENUVA.

### DOSAGE AND ADMINISTRATION

The recommended dose is one 30 mg tablet taken orally once daily for approximately 1 month in combination with one tablet of EDURANT 25 mg taken orally once daily.

### DOSAGE FORMS AND STRENGTHS

Tablets: 30 mg.

Orphan status: N/A

## SAFETY PROFILE

### CONTRAINDICATIONS

- Previous hypersensitivity reaction to cabotegravir.
- Co-administration with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine.

### WARNINGS AND PRECAUTIONS

- Hypersensitivity reactions
- Hepatotoxicity
- Depressive disorders
- Risk of adverse reactions or loss of virologic response due to drug interactions
- Risks associated with rilpivirine treatment

### ADVERSE REACTIONS

Most common adverse reactions: headache, nausea, abnormal dreams, anxiety, and insomnia.

### DRUG INTERACTIONS

- Concomitant use with other antiretrovirals: VOCABRIA in combination with EDURANT is a complete regimen and co-administration with other antiretrovirals for the treatment of HIV-1 infection is not recommended. Prior to initiating oral therapy, the prescribing information for CABENUVA (cabotegravir; rilpivirine) extended-release injectable suspensions should be consulted to ensure therapy with CABENUVA will be appropriate.

### DRUG INTERACTIONS (CONTINUATION)

- Potential for other drugs to affect VOCABRIA:
  - Cabotegravir is primarily metabolized by UGT1A1 with some contribution from UGT1A9. Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease cabotegravir plasma concentrations and may result in loss of virologic response; therefore, co-administration is contraindicated.
  - Co-administration of oral cabotegravir with polyvalent cation-containing products may lead to decreased absorption of cabotegravir.
- Established and other potentially significant drug interactions: Refer to the full prescribing information for additional information regarding other potential drug interactions with cabotegravir.

### USE IN SPECIFIC POPULATIONS

- Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VOCABRIA during pregnancy. Healthcare providers are encouraged to register patients.
- Lactation: Breastfeeding is not recommended due to the potential for HIV1 transmission.
- Pediatric use: Safety and effectiveness have not been established.

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### DOSAGE AND ADMINISTRATION

The recommended dose is one 30 mg tablet taken orally once daily for approximately 1 month in combination with one tablet of EDURANT 25 mg taken orally once daily.

### DOSAGE FORMS AND STRENGTHS

Tablets: 30 mg.

Orphan status: N/A

## SAFETY PROFILE (CONTINUATION)

### USE IN SPECIFIC POPULATIONS (CONTINUATION)

- Geriatric use: Clinical did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger subjects. In general, caution should be exercised in elderly patients reflecting greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- Renal impairment: No dose adjustment necessary for patients with mild, moderate, or severe renal impairment. The effect of end-stage renal disease (ESRD) is unknown. As cabotegravir is greater than 99% protein bound, dialysis is not expected to alter exposures of cabotegravir.
- Hepatic impairment: No dose adjustment necessary for patients with mild or moderate hepatic impairment. The effect of severe hepatic impairment is unknown.

(continuation)

# NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

## DRUG NAME

**CABENUVA (CABOTEGRAVIR AND RILPIVIRINE) EXTENDED-RELEASE INJECTABLE SUSPENSION**

## MANUFACTURER

VIIV HEALTHCARE

## APPROVAL DATE

01/21/2021

### THERAPEUTIC CLASS

Anti-infective agent; Antiretroviral

### FDA-APPROVE INDICATION(S)

CABENUVA is a 2-drug co-packaged product of a HIV-1 integrase strand transfer inhibitor (INSTI) and an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

### DOSAGE AND ADMINISTRATION

Oral lead-in dosing should be used for approximately 1 month to assess the tolerability. Then, initiate 600 mg of cabotegravir and 900 mg of rilpivirine on the last day of oral lead-in and continue with 400 mg of cabotegravir and 600 mg of rilpivirine every month thereafter. Administered by intramuscular (IM) injection.

### DOSAGE FORMS AND STRENGTHS

CABENUVA 400-mg/600-mg Kit:

- single-dose vial of 400 mg/2 mL (200 mg/mL) cabotegravir
- single-dose vial of 600 mg/2 mL (300 mg/mL) rilpivirine

CABENUVA 600-mg/900-mg Kit:

- single-dose vial of 600 mg/3 mL (200 mg/mL) cabotegravir
- single-dose vial of 900 mg/3 mL (300 mg/mL) rilpivirine

## SAFETY PROFILE

### CONTRAINDICATIONS

- Previous hypersensitivity reaction to cabotegravir or rilpivirine.
- Co-administration with drugs where significant decreases in cabotegravir and/or rilpivirine plasma concentrations may occur, which may result in loss of virologic response..

### WARNINGS AND PRECAUTIONS

- Hypersensitivity reactions
- Post-injection reactions
- Hepatotoxicity
- Depressive disorders
- Risk of adverse reactions or loss of virologic response due to drug interactions
- Long-acting properties and potential associated risks with CABENUVA

### ADVERSE REACTIONS

Most common adverse reactions: injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash.

### DRUG INTERACTIONS

- Concomitant use with other antiretrovirals: CABENUVA is a complete regimen and co-administration with other antiretrovirals for the treatment of HIV-1 infection is not recommended.
- Use of other antiretrovirals after discontinuation of CABENUVA: Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods. These residual concentrations are not expected to affect the exposures of antiretrovirals that are initiated after discontinuation of CABENUVA.
- Potential for other drugs to affect CABENUVA: Refer to the full prescribing information for VOCABRIA and EDURANT for additional drug interaction information.
- Established and other potentially significant drug interactions: Refer to the full prescribing information for additional information regarding other potential drug interactions with cabotegravir.



# NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

## DRUG NAME

**CABENUVA (CABOTEGRAVIR AND RILPIVIRINE) EXTENDED-RELEASE INJECTABLE SUSPENSION**

## MANUFACTURER

VIIV HEALTHCARE

## APPROVAL DATE

01/21/2021

### THERAPEUTIC CLASS

Anti-infective agent; Antiretroviral

### FDA-APPROVE INDICATION(S)

CABENUVA is a 2-drug co-packaged product of a HIV-1 integrase strand transfer inhibitor (INSTI) and an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

### DOSAGE AND ADMINISTRATION

Oral lead-in dosing should be used for approximately 1 month to assess the tolerability. Then, initiate 600 mg of cabotegravir and 900 mg of rilpivirine on the last day of oral lead-in and continue with 400 mg of cabotegravir and 600 mg of rilpivirine every month thereafter. Administered by intramuscular (IM) injection.

### DOSAGE FORMS AND STRENGTHS

CABENUVA 400-mg/600-mg Kit:

- single-dose vial of 400 mg/2 mL (200 mg/mL) cabotegravir
- single-dose vial of 600 mg/2 mL (300 mg/mL) rilpivirine

CABENUVA 600-mg/900-mg Kit:

- single-dose vial of 600 mg/3 mL (200 mg/mL) cabotegravir
- single-dose vial of 900 mg/3 mL (300 mg/mL) rilpivirine

## SAFETY PROFILE (CONTINUATION)

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VOCABRIA during pregnancy. Healthcare providers are encouraged to register patients.
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV1 transmission.
- **Pediatric use:** Safety and effectiveness have not been established.
- **Geriatric use:** Clinical trials did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger subjects. In general, caution should be exercised in elderly patients reflecting greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- **Renal impairment:** No dose adjustment necessary for patients with mild or moderate renal impairment. In patients with severe renal impairment or ESRD, increased monitoring for adverse effects is recommended. In patients with ESRD not on dialysis, effects are unknown. As cabotegravir and rilpivirine are greater than 99% protein bound, dialysis is not expected to alter exposures of cabotegravir or rilpivirine.

### USE IN SPECIFIC POPULATIONS (CONTINUATION)

- **Hepatic impairment:** No dose necessary for patients with mild or moderate hepatic impairment. The effect of severe hepatic impairment is unknown.

# NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

## DRUG NAME

**LUPKYNIS (VOCLOSPORIN)  
CAPSULES**

## MANUFACTURER

**AURINIA PHARMACEUTICALS,  
INC.**

## APPROVAL DATE

**01/22/2021**

### THERAPEUTIC CLASS

Immunological agent

### FDA-APPROVE INDICATION(S)

LUPKYNIS is a calcineurin-inhibitor indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).

### DOSAGE AND ADMINISTRATION

The recommended starting dose is 23.7 mg orally twice a day.

To be used in combination with mycophenolate mofetil (MMF) and corticosteroids.

Dose modifications are recommended based on eGFR. Dose adjustment is recommended for drug interactions.

### DOSAGE FORMS AND STRENGTHS

Capsules: 7.9 mg.

Orphan status: N/A

## SAFETY PROFILE

### CONTRAINDICATIONS

- Patients concomitantly using strong CYP3A4 inhibitors.
- Known serious or severe hypersensitivity reaction to voclosporin or any of the excipients.

### WARNINGS AND PRECAUTIONS

- Boxed warning: Malignancies and serious infections
- Nephrotoxicity
- Hypertension
- Neurotoxicity
- Hyperkalemia
- QTc Prolongation
- Immunizations
- Aplasia

### ADVERSE REACTIONS

Most common adverse reactions: glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

### DRUG INTERACTIONS

- **Strong and moderate CYP3A4 inhibitors:** Voclosporin is a sensitive CYP3A4 substrate. Co-administration increases voclosporin exposure, which may increase the risk of adverse reactions. Co-administration with strong CYP3A4 inhibitors is contraindicated. When co-administered with moderate CYP3A4 inhibitors, reduce LUPKYNIS daily dosage to 15.8 mg in the morning and 7.9 mg in the evening.
- **Strong and moderate CYP3A4 inducers:** Voclosporin is a sensitive CYP3A4 substrate. Co-administration decreases voclosporin exposure, which may decrease the efficacy of LUPKYNIS. Avoid co-administration.
- **Certain P-gp substrates:** Reduce dose of certain P-gp substrates with a narrow therapeutic window when co-administered with LUPKYNIS.
- **OATP1B1 substrates:** The effect of LUPKYNIS on OATP1B1 substrates (e.g., statins) has not been studied clinically. However, voclosporin is an OATP1B1 inhibitor in vitro, and information suggests an increase in the concentration of these substrates is possible. Monitor for adverse reactions of OATP1B1 substrates when used concomitantly with LUPKYNIS.

# NEW MOLECULAR ENTITIES, NEW ACTIVE INGREDIENTS

## DRUG NAME

**LUPKYNIS (VOCLOSPORIN)  
CAPSULES**

## MANUFACTURER

**AURINIA PHARMACEUTICALS,  
INC.**

## APPROVAL DATE

**01/22/2021**

### THERAPEUTIC CLASS

Immunological agent

### FDA-APPROVE INDICATION(S)

LUPKYNIS is a calcineurin-inhibitor indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).

### DOSAGE AND ADMINISTRATION

The recommended starting dose is 23.7 mg orally twice a day.

To be used in combination with mycophenolate mofetil (MMF) and corticosteroids.

Dose modifications are recommended based on eGFR. Dose adjustment is recommended for drug interactions.

### DOSAGE FORMS AND STRENGTHS

Capsules: 7.9 mg.

Orphan status: N/A

## SAFETY PROFILE (CONTINUATION)

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** May cause fetal harm.
- **Lactation:** Advise not to breastfeed.
- **Pediatric use:** Safety and effectiveness have not been established.
- **Geriatric use:** Clinical trials did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
- **Renal impairment:** No dose adjustment recommended in patients with mild or moderate renal impairment at baseline. Use is not recommended in patients with a baseline eGFR  $\leq 45$  mL/min/1.73 m<sup>2</sup> unless the benefit exceeds the risk. If used in patients with severe renal impairment at baseline, LUPKYNIS should be used at a reduced dose.
- **Hepatic impairment:** Dose reduction is required in patients with mild and moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.

(continuation)

# NEW BIOSIMILAR PRODUCTS

- No new biosimilar product approved during January 2021.

# NEW FORMULATIONS, COMBINATION PRODUCTS, LINE EXTENSIONS

- No new formulation, combination product, or line extension approved during January 2021.

# NEW FIRST-TIME GENERIC APPROVALS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	INDICATION(S)	GENERIC FOR:	DATE
FERUMOXYTOL INTRAVENOUS SOLUTION EQ 510MG IRON/17ML / SANDOZ INC.	Hematopoietic agent; Iron	<ul style="list-style-type: none"> <li>Chronic kidney disease - Iron deficiency anemia</li> <li>Iron deficiency anemia, Intolerant or unsatisfactory response to oral iron</li> </ul>	Feraheme	01/15/2021
IMIQUIMOD TOPICAL CREAM 3.75% / TARO PHARMACEUTICAL INDUSTRIES LTD.	Dermatological agent	<ul style="list-style-type: none"> <li>Actinic keratosis</li> <li>Condyloma acuminatum of the ano-genital region</li> </ul>	Zyclara	01/26/2021

# **NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS**

# NEW FDA-APPROVED INDICATIONS FOR EXISTING DRUGS

DRUG NAME / MANUFACTURER	THERAPEUTIC CLASS	PREVIOUS INDICATION(S)	NEW INDICATION(S)	DATE
XALKORI (CRIZOTINIB) CAPSULES / PFIZER INC.	Antineoplastic agent	Treatment of patients with advanced non-small cell lung cancer whose tumors are ALK-positive or ROS1-positive	Treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK)-positive	01/14/2021
DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ) INJECTION / JANSSEN PHARMACEUTICALS, INC.	Antineoplastic agent	Treatment of multiple myeloma	Treatment of light chain (AL) amyloidosis	01/15/2021
ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI) INJECTION / ASTRAZENECA AND DAIICHI SANKYO COMPANY	Antineoplastic agent	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting	Treatment of adult patients with locally advanced or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen	01/15/2021
OPDIVO (NIVOLUMAB) INJECTION / BRISTOL-MYERS SQUIBB COMPANY	Antineoplastic agent	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma	In combination with CABOMETYX (cabozantinib) for the first-line treatment of patients with advanced renal cell carcinoma	01/21/2021



# PIPELINE

DRUG NAME / MANUFACTURER	DATE	INDICATION(S)	COMMENTS	IMPACT
SOMATROGON / PFIZER INC.	01/04/2021	Treatment for: Pediatric Growth Hormone Deficiency	<p>Somatrogon is an investigational, long-acting human growth hormone that is intended to be administered once-weekly for the treatment of pediatric patients with growth hormone deficiency (GHD).</p> <p>FDA accepted BLA and granted orphan drug designation.</p>	High
KYZATREX (TESTOSTERONE UNDECANOATE) / MARIUS PHARMACEUTICALS	01/05/2021	Treatment for: Hypogonadism; Male	<p>Kyzatrex (testosterone undecanoate) is a novel, soft gelatin capsule testosterone formulation in development for the treatment of primary and secondary hypogonadism in adult men.</p> <p>NDA submitted to the FDA.</p>	Moderate
TRUDHESA (DIHYDROERGOTAMINE MESYLATE) / IMPEL NEUROPHARMA	01/20/2021	Treatment for: Migraine	<p>Trudhesa (dihydroergotamine mesylate) is a nasally administered dihydroergotamine (DHE) formulation in development for the acute treatment of migraine headaches.</p> <p>FDA accepted NDA.</p>	Moderate
ODEVIXIBAT / ALBIREO PHARMA, INC.	01/25/2021	Treatment for: Progressive Familial Intrahepatic Cholestasis (PFIC)	<p>Odevixibat is a once-daily, non-systemic ileal bile acid transport inhibitor (IBATi) in development for the treatment of rare pediatric cholestatic liver diseases, including progressive familial intrahepatic cholestasis (PFIC), biliary atresia and Alagille syndrome.</p> <p>FDA accepted NDA.</p>	High
SULOPENEM / ITERUM THERAPEUTICS PLC	01/25/2021	Treatment for: Bacterial Infection	<p>Sulopenem is an orally bioavailable, broad-spectrum penem <math>\beta</math>-lactam antibiotic in development for the treatment of infections caused by multi-drug resistant bacteria.</p> <p>FDA accepted NDA.</p>	Moderate

## REFERENCES

- U.S. Food and Drug Administration (<https://www.fda.gov/>)
- Drugs.com (<https://www.drugs.com/>)
- IBM Micromedex® (<https://www.micromedexsolutions.com>)
- Pharmacist Letter (<https://www.pharmacistletter.com>)