

# CHIPS REGIMEN



## BRIDGING THE GAP SEMGLEE - A NEW INSULIN GLARGINE FOR DIABETES

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The FDA has approved Semglee (Mylan), an insulin glargine product similar to Lantus, for treatment of type 1 diabetes in children and adults and type 2 diabetes in adults. Semglee is the second "follow-on" insulin glargine product to become available in the US; Basaglar, which is also similar to Lantus, was the first. Lantus is a recombinant analog of human insulin that forms microprecipitates in subcutaneous tissue, prolonging its duration of action to a mean of about 24 hours with no pronounced peak effect.

**CLINICAL STUDIES** — FDA approval of Semglee was based on the results of one open-label trial in 558 patients with type 1 diabetes (INSTRIDE 1) and one in 560 patients with type 2 diabetes (INSTRIDE 2). Patients were randomized to receive once-daily treatment with Semglee or Lantus in addition to mealtime insulin lispro. In both trials, the mean decrease in A1C levels from baseline to 24 weeks, the primary endpoint, was similar with Semglee and Lantus.

**ADVERSE EFFECTS** — All insulins can cause hypoglycemia and weight gain. Adverse effects of Semglee are similar to those observed with other insulin glargine products.

**PREGNANCY AND LACTATION** — Poorly controlled diabetes increases the risk of pre-eclampsia, spontaneous abortion, and preterm delivery. Administration of insulin glargine to pregnant animals has not been associated with fetal adverse developmental outcomes.

Insulin is a normal component of human breast milk and adequate glycemic control is needed for milk production. Women taking exogenous insulin, which passes into breast milk, can breastfeed.

**DOSAGE AND ADMINISTRATION** — Semglee should be injected subcutaneously once daily at the same time each day. Patients receiving Lantus can switch to Semglee at the same daily dosage.

**CONCLUSION** — Semglee, a "follow-on" version of the long-acting insulin analog insulin glargine, offers a lower-cost alternative to Lantus. Although similar in efficacy and safety to Lantus, to date it has not been approved by the FDA as an interchangeable product and cannot be substituted for Lantus without permission from the prescriber.

### REFERENCES :

1. Another insulin glargine (Basaglar) for diabetes. *Med Lett Drugs Ther* 2017; 59:3.
2. Insulins for type 2 diabetes. *Med Lett Drugs Ther* 2019; 61:65.
3. TC Blevins et al. Efficacy and safety of MYL-1501D vs insulin glargine in patients with type 1 diabetes after 52 weeks: results of the INSTRIDE 1 phase III study. *Diabetes ObesMetab* 2018; 20:1944.
4. TC Blevins et al. Efficacy and safety of MYL-1501D versus insulin glargine in patients with type 2 diabetes after 24 weeks: results of the phase III INSTRIDE 2 study. *Diabetes ObesMetab* 2019; 21: 129.
5. American Diabetes Association. Standards of medical care in diabetes – 2019. *Diabetes Care* 2019; 42(Suppl 1):S1.

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# STUDENTS CORNER

## MEDICATIONS FOR ALCOHOL USE DISORDER

MEDICATIONS	BRAND NAMES	TYPE	EFFECTS	ROUTE OF ADMINISTRATION	FOR WHOM	SIDE EFFECTS
Naltrexone	Revia, Vivitrol	Antagonist	Blocks the pleasurable effects of drinking	Orally - taken daily, or as an intramuscular injection once monthly. In Finland, Naltrexone is only taken directly before drinking. Abstinence required before starting	For patient engaged in binge drinking & seeking	Nausea, headache, weakness, injection site reactions
Acamprosate	Campral	Other, Unknown	Stabilizes areas in the brain that disrupt alcohol withdrawal normalizing those areas	Orally - delayed release tablets taken daily. Only known to work in combination with behavioral therapy or peer support. Abstinence required before starting	For patient with liver cirrhosis	Dizziness, upset gastrointestinal system (GI)
Disulfiram	Antabuse	Other	Prevents alcohol use by causing extremely unpleasant side effects when alcohol is ingested (e.g. vomiting, headaches, sweating, etc.)	Orally - taken daily or as a subcutaneous implant	Only for very motivated patients	Flushing, headache, metallic taste
Topiramate (Not FDA Approved)	Topamax, Trokendi, Qudexy	Anti-convulsant	Anti-seizure medication sometimes used to treat alcohol use disorder. May encourage moderation & help with mood, weight, and weight gain	Orally - taken while drinking	For patient that wants to cut down on drinking, but not stop altogether. May help with weight gain	Cognitive dulling, word finding difficulty, ataxia, paresthesia
Gabapentin (Not FDA Approved)	Grolic, Horizant, Neurontin	Anti-convulsant	Anti-seizure medication to decrease number of drinks & number of heavy drinking days.	Orally - tablet or liquid form - taken orally	For patient that wants to cut down on drinking, but not stop altogether. May help with weight gain	Sedation, dizziness, weight gain

## MEDICATIONS FOR OPIOID USE DISORDER

MEDICATIONS	BRAND NAMES	TYPE	EFFECTS	ROUTE OF ADMINISTRATION	FOR WHOM	SIDE EFFECTS
Injectable Naltrexone	Vivitrol	Antagonist	Blocks the pleasurable effects of opiates to reduce the likelihood of relapse & opiate overdose	Intramuscular injection once monthly	For patients that may struggle to remember to take a daily medication	Nausea, headache, weakness, injection site reactions
Buprenorphine	Buprenex, Belbuca, Butrans, Probuphine, Subutex	Mixed Agonist-Antagonist	Prevents opiate withdrawal & cravings with its agonistic effects, also blocking against opiate overdose through its antagonist action	Orally - take daily or transdermally (skin patch) worn daily	For patients with low likelihood of misuse potential	Headache, dizziness, trouble sleeping, tingling sensation
Buprenorphine + Naloxone	Suboxone, Zubsolv, Bunavail	Mixed Agonist-Antagonist	Prevents opiate withdrawal & cravings with its agonistic effects, also blocking against opiate overdose through its antagonist action. The added naloxone decreases the misuse potential	Orally - sublingual tablets or films taken daily	For patients with opioid use disorder with access to an office-based licensed prescriber. Misuse potential	Constipation, dizziness, drowsiness, headache
Methadone	Dolophine, Methadose	Agonist	Prevents opiate withdrawal and cravings, but at prescribed doses, does not create opiate-like effects	Orally - taken daily, administered by a SAMSHA certified treatment program or clinic	For patients with the proximity & availability to attend a clinic daily. Misuse potential	Sleep problems, anxiety, restlessness, dry mouth, nausea, decreased sex drive
Naloxone	Narcan	Antagonist	Counters the effects of an opiate overdose	Injection or oral spray - administered only during an overdose emergency	For opiate users during an overdose	Chest pain, shortness of breath, nausea, headache, anxiety, confusion

## MEDICATIONS FOR NICOTINE OR SMOKING CESSATION

MEDICATIONS	BRAND NAMES	TYPE	EFFECTS	ROUTE OF ADMINISTRATION	FOR WHOM	SIDE EFFECTS
Nicotine Replacement Therapies (NRT)	Polaron, Transdermal Nicotine Systems	Agonist	Aids in smoking cessation by providing similar effects of tobacco use to decrease cravings, tapering or decreasing dose overtime	Patches, gum, lozenges, for nasal spray & inhalers	For patients seeking to quit smoking by means of satisfying nicotine cravings over time	Racing heartbeat, headache, nausea, throat/skin irritation, nervousness
Varenicline	Chantix	Mixed Agonist-Antagonist	Gives mild nicotine-like effects & eases symptoms of withdrawal. Neutralizes the effects of nicotine if patient smokes while taking this medication	Orally - taken daily for 12 weeks	For patients seeking to quit smoking by means of a 12 week medication program	Trouble sleeping, vivid dreams, headache, nausea, gas, behavioral changes
Bupropion	Wellbutrin, Zyban, Bupropion, Fortivo	Other	Aids in smoking cessation by reducing the severity of nicotine cravings & withdrawal symptoms. Also functions as an unrelated anti-depressant.	Orally - variety of doses & release patterns	For patients who smoke 10 or more cigarettes a day. May be used in combination with NRT	Increase in risk for dry mouth, nausea, vomiting, weight gain/loss, stomach pain

## CLINICAL CONNECTION

### Warfarin and other Anticoagulants: Monitoring of Patients During the COVID-19 Pandemic

**Background:** Warfarin, sold under the brand name Coumadin among others, is a medication that is used as an anticoagulant. It is commonly used to treat blood clots such as deep vein thrombosis and pulmonary embolism, and to prevent stroke in people who have atrial fibrillation, valvular heart disease or artificial heart valves.

**Problem:** Guidance has been published on monitoring of patients on warfarin and other anticoagulants during the COVID-19 pandemic.

**Recommendations:** Healthcare professionals are reminded that:

- \* Acute illness may exaggerate the effect of warfarin and necessitate a dose reduction; patients on warfarin or other vitamin K antagonists should therefore be asked to tell their GP or healthcare team if they have symptoms of, or confirmed, COVID-19 infection.

- \* Continued INR (international normalized ratio) monitoring is important in patients taking warfarin or other vitamin K antagonists if they have suspected or confirmed COVID19 infection, so they can be clinically managed at an early stage to reduce the risk of bleeding. • Both vitamin K antagonists and direct-acting oral anticoagulants (DOACs) may interact with other medicines and if a patient using these oral anticoagulants is also prescribed antibiotics or antivirals, follow advice in the product information for minimization of risk of potential interactions – this includes INR monitoring in patients taking vitamin K antagonists who have recently started new medicines if patients are switched from warfarin to a DOAC, warfarin treatment should be stopped before the DOACs is started to reduce the risk of overanticoagulation and bleeding.

- \* Patients taking vitamin K antagonists should be reminded to carefully follow the instructions for use for anticoagulant medicines (including the patient information leaflet).

**Reference:**

<https://www.gov.uk/drug-safetyupdate/warfarin-and-otheranticoagulants-monitoring-ofpatients-during-the-covid-19- pandemic>.

## STAFF PUBLICATIONS

1. Sundeep Mupparaju, Vidyadhara Suryadevara, Sandeep Doppalapudi. Preparation and Evaluation of Dolutegravir Solid Dispersions. International Journal of Applied Pharmaceutics, Vol 13, Issue 1(Jan-Feb) 2021; 193-198.
2. Dr. Suryadevara Vidyadhara, Doppalapudi Sandeep, Dr. Mikkilineni Bhanu Prasad, AdusumalliChakravarthy, Battula Sowjanya Lakshmi. Multi-Unit Compressible Coated Pellets. Pharma Times; Volume 53, number 2; feb 2021; 11-16.
3. S.Vidyadhara, RLC. Sasidhar, B. Sowjanya Lakshmi, Manisha Lal, P.Nithin. Formulation and evaluation of amoxicillin trihydrate oral lozenges for treating upper respiratory tract infections. Current Trends in Biotechnology and Pharmacy, Vol 15, Issue 1 (Jan-Mar) 2021; 62-69.
4. Sathuluri Vineela, Chinta Manga Devi and Thakur Santh Rani. Neuroprotective Effect of Naringin on Acrylamide-induced Cytotoxicity in U87MG Cells and Wistar Rats: An in-vitro and in-vivo Study. Toxicology International.
5. Sathuluri Vineela and Santh Rani Thakur. Rutin Attenuates Acrylamide Induced Neuropathic Pain via Inhibition ofProinflammatory Cytokines, Up-Regulation of Bcl-2 and Down-Regulation ofBax. International Journal of Life science and Pharma Research.
6. Lakshman Kumar Dogiparthi, Siva Sankar Sana, Sumaya Zikreen Shaik, Maneesha Reddy Kalvapalli. Phytochemical mediated synthesis of silver nanoparticles and theirantibacterial activity. SN Applied Sciences; 3;631 (2021); 1-8.



**COVID Testing Camp**



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