

# SEMAGLUTIDE NASAL SPRAY

BRYAN ZIEGLER, PHARM.D, MBA  
MOSS COMPOUNDING PHARMACY  
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# TOPICS FOR DISCUSSION

- Introduction of an exciting new dosage form
- Regulatory challenges with compounding Semaglutide
- Pharmacokinetic challenges with Semaglutide
- Key information on the new dosage form
- Dosing recommendations
- Adverse events/Tolerability
- Strength options and pricing
- Rx Template/Resources



# NEW DOSAGE FORM INTRODUCTION - SEMAGLUTIDE



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## SEMAGLUTIDE NASAL SPRAY

0.25% (0.25mg/0.1mL spray)



Convenient dosing option.

Flexible titration.

No injections for the patient.

Dosing can be increased if needed based on patient response, up to a max recommendation 3mg/day.

Side effects are similar to oral/injection forms (nausea, vomiting, GI upset, fatigue, headache).



# REGULATORY CHALLENGES WITH SEMAGLUTIDE

- Base vs Salt form
- Patent protection issues



# PHARMACOKINETIC CHALLENGES WITH SEMAGLUTIDE

- Various dosage routes
  - Subcutaneous Injection (Wegovy®/Ozempic®)
  - Oral tablet (Rybelsus®)
  - Sublingual?
  - Nasal?
- Absorption Challenges (oral)
  - Rapid degradation in GI tract without protection (SNAC)
    - Even with SNAC poor bioavailability
- Absorption challenges (SL)
  - Degradation issues
  - Molecular weight/size
- Bioavailability (nasal) - bioavailability of large peptide molecules ranges from 0.5% to 5%
- Half-life long, steady state in ~4 weeks

<https://accpl.onlinelibrary.wiley.com/doi/full/10.1002/cpdd.938>

<https://juniperpublishers.com/gjpps/pdf/GJPPS.MS.ID.555569.pdf>



# KEY INFO/CLINICAL PEARLS – SEMAGLUTIDE NASAL SPRAY

- Overcoming absorption issues with SL/oral
  - Nasal route been demonstrated with other peptides (Calcitonin, Exenatide)
  - pH of nasal cavity = 6 - 6.5
  - Mucoadhesion and absorption enhancers added to improve absorption
- Limit the number of sprays and volume per spray to reduce drip out of nose or drainage down throat
  - Dosage maxed at 2 sprays (0.1 mL per spray) each nostril daily

<https://pubmed.ncbi.nlm.nih.gov/10196653/>

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/020313s036lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020313s036lbl.pdf)



# DOSING RECOMMENDATIONS – SEMAGLUTIDE NASAL SPRAY

Semaglutide Nasal Spray - Check box for desired dosing

## STANDARD DOSING

**Semaglutide 0.25% (0.25mg/0.1mL spray)**

**Initial Titration:** Qty: 8mL nasal spray bottle

SIG: Use 1 spray (=0.1mL =0.25mg) in each nostril once daily for 4 days per week x 2 weeks, increase by 1 spray daily each week after as tolerated up to 2 sprays/nostril daily maximum.

**Semaglutide 0.25% (0.25mg/0.1mL spray)**

**Maintenance Dosing** Qty: 8mL nasal spray bottle Refills: \_\_\_\_\_

SIG: Use 2 sprays (=0.2mL =0.5mg) in each nostril once daily for 4 days per week. (=1mg daily dose)

**Semaglutide 0.25% (0.25mg/0.1mL spray)**

**Alternative Maintenance Dose:** Qty: 8mL nasal spray bottle Refills: \_\_\_\_\_

SIG: Use \_\_\_\_ sprays (each spray = 0.1mL) in \_\_\_\_ nostril(s) once daily for \_\_\_\_ days per week.



# DOSING RECOMMENDATIONS – SEMAGLUTIDE NASAL SPRAY

- Dosing can be adjusted beyond 1mg/day dosing if needed and tolerated.

## INCREASED DOSE ADJUSTMENT OPTIONS

- Semaglutide 0.5% (0.5mg/0.1mL spray)** Qty: 8mL nasal spray bottle Refills: \_\_\_\_\_  
SIG: Use 2 sprays (=0.2mL =1mg) in each nostril once daily for 4 days per week. (=2mg daily dose)
- Semaglutide 0.75% (0.75mg/0.1mL spray)** Qty: 8mL nasal spray bottle Refills: \_\_\_\_\_  
SIG: Use 2 sprays (=0.2mL =1.5mg) in each nostril once daily for 4 days per week. (=3mg daily dose)





# ADVERSE EVENTS/TOLERABILITY

- No reports with nasal irritation
- pH of nasal spray solution = 6.5-7
- Side effects/tolerability similar to oral/SubQ but more flexibility to titrate dose/frequency theoretically can provide reduced potential for occurring with same severity/frequency
- Common adverse events: nausea, vomiting, constipation, gastroparesis, abdominal pain, headaches
- Serious Adverse Events = Risk of Thyroid C-Cell tumors, Acute pancreatitis, acute gallbladder disease, hypoglycemia, Inc. HR, Hypersensitivity, Acute kidney injury, diabetic retinopathy complications
- Other notable issues reported with early testing of nasal:
  - Mild nasal congestion



# CONTRAINDICATIONS

- Patients with active severe nasal mucosa ulcers (>1.5mm)
- Same as oral/SubQ:
  - personal or family history of certain types of thyroid cancer, specifically thyroid C-cell tumors such as medullary thyroid carcinoma (MTC), or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2)
  - A prior serious hypersensitivity reaction to semaglutide



# STRENGTHS AVAILABLE

- **Semaglutide 0.25% (0.25mg /0.1mL) nasal spray**
  - Use for daily dosing up to 1mg per day
  - Price = \$249 for 8mL bottle (1 month supply)
- **Semaglutide 0.5% (0.5mg/0.1mL) nasal spray**
  - Use for daily dosing up to 2mg per day
  - Price = \$299 for 8mL bottle (1 month supply)
- **Semaglutide 0.75% (0.75mg/0.1mL) nasal spray**
  - Use for daily dosing up to 3mg per day
  - Price = \$349 for 8mL bottle (1 month supply)

\*Note: Price subject to change based on ingredient cost changes from suppliers



# RX TEMPLATES/OTHER RESOURCES

The screenshot shows a web browser window with the URL <https://www.mosscompounding.com/prescriber-only-learning>. The page title is "Prescribers Learning Center". Below the title is a "Content Menu" section with eight green buttons arranged in two rows of four. The buttons are: "Newsletters/Info Sheets", "Compound Medication Guides (Common Formulas)", "Tips for E-Prescribing Compounded Medications", "CBD Oil Information", "Hormone Therapy", "General Compounding Information – Unique Dosage Forms", "Low Dose Naltrexone (LDN)", and "Semaglutide". The "Semaglutide" button is highlighted with a red rectangular border. A scroll bar is visible on the right side of the page.

Content Menu			
Newsletters/Info Sheets	Compound Medication Guides (Common Formulas)	Tips for E-Prescribing Compounded Medications	CBD Oil Information
Hormone Therapy	General Compounding Information – Unique Dosage Forms	Low Dose Naltrexone (LDN)	Semaglutide

# QUESTIONS?

Bryan Ziegler, PharmD, MBA

843.665.0289

[bziegler@mosscompounding.com](mailto:bziegler@mosscompounding.com)





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