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PATIENT MEDICATION INFORMATION - content found in Rybelsus® (semaglutide tablets) Product Monograph

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
Active Ingredient: RYBELSUS® (semaglutide tablets)
Read this carefully before you start taking compounded semaglutide and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about compounded semaglutide.

What is Rybelsus® used for?
Rybelsus® contains the active substance semaglutide. It is used to lower blood sugar (glucose) in adults with type 2 diabetes.

- Rybelsus® is used on its own if your blood sugar level is not properly controlled by diet and exercise alone and you cannot use metformin.
- Rybelsus® is used in combination with one or more other medicines for diabetes when they are not enough to control your blood sugar levels.

How does Rybelsus® work?
Rybelsus belongs to a class of medicines called GLP-1 receptor agonists (glucagon-like peptide-1 receptor agonists). Rybelsus® helps your body make more insulin when your blood sugar is high.

What are the ingredients in Rybelsus®?
Medicinal ingredients: semaglutide
Non-medicinal ingredients: magnesium stearate, microcrystalline cellulose, povidone K 90, salcaprozate sodium (SNAC)

What are the ingredients in SubMagna™ SL HMW?
Medium-Chain Triglycerides, Apricot Kernel Oil PEG-6 Esters, PEG-32 Stearate, Phosphatidylcholine, Siraitia Grosvenorii Fruit Extract, Hydrogenated Vegetable Oil, Polysorbate 20, Sucralose, Cocos Nucifera (Coconut)Oil, Carthamus Tinctorius (Safflower) Seed Oil, Cholesterol, Sorbitan Oleate, Polycarbophil, Tocopheryl Acetate

Do not use Rybelsus® or SubMagna™ SL HMW if:

- you are allergic to semaglutide, coconut oil, safflower seed oil, apricot oil, natural peppermint oil, or any of the other ingredients in this medication;
- you or a member of your family has ever had medullary thyroid cancer (MTC);
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2);
- you are pregnant or breastfeeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Rybelsus®.
Talk about any health conditions or problems you may have, including if you:

- or a member of your family has or has had medullary thyroid carcinoma (MTC), or if you have Multiple Endocrine
- Neoplasia syndrome type 2 (MEN 2);

- have type 1 diabetes – a condition where your body does not produce any insulin;
- you develop diabetic ketoacidosis (increased ketones in the blood or urine);
- have ever had an allergic reaction to Rybelsus®;
- have a high heart rate (fast pulse);
- have ever had pancreatitis;
- are breastfeeding or plan to breastfeed;
- are pregnant or plan to become pregnant;
- have end stage renal disease;
- have gastrointestinal (digestive) problems, including severe vomiting, diarrhea and/or dehydration;
- have liver or gallbladder problems;
- have diabetic retinopathy.

Other warnings you should know about:

- Children and adolescents- Rybelsus® is not recommended in children and adolescents under 18 years as the safety and efficacy in this age group have not yet been studied.
- Pregnancy and Breastfeeding- Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. Rybelsus® should not be used during pregnancy and for at least two months before a planned pregnancy because it is not known if it may affect your unborn child. If you could become pregnant while using Rybelsus®, it is recommended to use contraception. Do not use this medicine if you are breastfeeding because it is not known if Rybelsus® passes into breast milk.
- Driving and Using Machines-If you use this medicine in combination with a sulfonylurea or insulin, low blood sugar (hypoglycemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. Talk to your doctor for further information.
- Severe and on-going stomach pain which could be due to acute pancreatitis-If you have severe and on-going pain in the stomach area – see a doctor right away as this could be a sign of acute pancreatitis (inflamed pancreas).
- Effects on the digestive system, including dehydration-During treatment with this medicine, you may feel sick (nausea) or be sick (vomiting), or have diarrhea. These side effects can cause dehydration (loss of fluids). It is important that you drink plenty of fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.
- Diabetic eye disease (retinopathy)- Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. If you have diabetic eye disease and experience eye problems while taking this medication, talk to your doctor.
- Low blood sugar (hypoglycemia)- Taking a sulfonylurea medicine or insulin with Rybelsus® might increase the risk of getting low blood sugar levels (hypoglycemia). Your doctor may ask you to test your blood sugar levels. This will help your doctor decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Tell your healthcare professional about all the medicines you take-including any drugs, vitamins, minerals, natural supplements or alternative medicines. Tell your doctor, pharmacist, or nurse if you are using medicines containing any of the following:

- sulfonylurea;
- insulin;
- levothyroxine – this is because your doctor may need to check your thyroid levels if you are taking Rybelsus® together with levothyroxine.

The following list includes some, but not all, of the drugs that may increase your heart rate. You should check with your doctor or pharmacist before taking any other medication with Rybelsus®:

- drugs to treat hypertension;
- drugs to treat heart failure;
- drugs to treat HIV infection;
- drugs to treat attention deficit-hyperactivity disorder;
- drugs to suppress appetite/cause weight loss;
- decongestants;
- drugs to treat asthma.

How to take Rybelsus®:
Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist, or nurse if you are not sure. Follow these instructions (or the instructions from your doctor) carefully:
Your doctor will prescribe the strength that is right for you. Do not change your dose unless the doctor has told you so. Do not stop this medicine without talking to your doctor. If you stop taking it, your blood sugar levels may increase. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

Overdose:
If you take more Rybelsus® than you should, talk to your doctor right away. You may get more side effects such as feeling sick (nausea). If you think you have taken too much Rybelsus®, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no symptoms.

Missed dose:
If you forget to take a dose, skip the dose for that day, and resume with the next morning's scheduled dose. Do not double the dose.

What are possible side effects from using Rybelsus®?
These are not all the possible side effects you may feel when taking Rybelsus®. If you experience any side effects not listed here, contact your healthcare professional.
Very common: may affect more than 1 in 10 people

- feeling sick (nausea) – this usually goes away over time;
- diarrhea – this usually goes away over time;
- low blood sugar (hypoglycemia) when this medicine is used with insulin or sulfonylureas.

- The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating, or shaking.

Common: may affect up to 1 in 10 people

- being sick (vomiting);
- upset stomach or indigestion;
- inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting);
- reflux or heartburn – also called 'gastro-esophageal reflux disease' (GERD);
- stomach pain;
- bloating of the stomach;
- constipation;
- change in the way food or drink tastes;
- tiredness;
- less appetite;
- gas (flatulence);
- increase of pancreatic enzymes (such as lipase and amylase).

Uncommon: may affect up to 1 in 100 people

- weight loss;
- gallstones;
- burping;
- fast pulse;
- allergic reactions like rash, itching or hives

Rare: may affect up to 1 in 1,000 people

- serious allergic reactions (anaphylactic reactions). You should seek immediate medical help and inform your doctor right away if you get symptoms such as breathing problems, swelling of face and throat, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.
- Other possible side effects include:
  Diabetic retinopathy complications – complications of diabetic eye disease/diabetic eye problems
  - Pancreatitis (severe and ongoing pain in the stomach area which could be a sign of inflamed pancreas)
  - Severe hypoglycemia* (low blood sugar) symptoms: feeling confused, fits and passing out.
  - Severe allergic reaction (anaphylactic reaction) symptoms: breathing problems, swelling of face and throat and a fast heartbeat.

*The risk of severe hypoglycemia is higher depending on the other diabetes medications. If you have a troublesome symptom or side effect that becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Storage: Store this compounded Rybelsus® SubMagna™ SL HMW medication at room temperature (15 °C to 30 °C). Do not use this medicine after the beyond use date which is stated on the label.

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