

**PATIENT INFORMATION LEAFLET:
INFORMATION FOR THE CLINICAL STUDY PARTICIPANT**

Clinical study drug: OligoG CF-5/20, dry powder for inhalation.

Before you start using this medicine, please read this leaflet carefully as it contains important information for you.

- Keep this leaflet with you at all times. You may need to read it again.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects, talk to your doctor or study nurse immediately. This includes any possible side effects not listed in this leaflet
- If you have any further questions, ask your doctor or pharmacist.

What is in this leaflet:

1. What is OligoG and what is its intended use?
2. What you need to know before you take OligoG.
3. How you should take OligoG.
4. Possible side effects.
5. How you should store OligoG.
6. Contents of the pack
7. How to use the inhaler
8. Contact Information

1. What is OligoG and what is its intended use?

The study drug is called OligoG CF-5/20 (OligoG) and it is being developed for the treatment of Cystic Fibrosis. It is an alginate, a natural product derived from seaweed. Laboratory tests have shown that OligoG is highly effective at releasing stagnant mucus from mucosal tissue, as well as breaking down biofilms (an insulating layer surrounding bacteria) that would otherwise protect the bacteria from treatment with antibiotics. When you inhale OligoG, it is expected to work directly on the mucus in the lungs and airways, making it easier to cough up the mucus naturally. OligoG may also improve the effect of antibiotics on bacteria in the lungs. OligoG is an investigational drug currently being evaluated in clinical trials for the treatment of Cystic Fibrosis, which means that it has not yet been approved.

2. What you need to know before you take OligoG

Other medicines and OligoG

Please tell your study doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. OligoG may be given at the same time you receive other medicines for your Cystic Fibrosis without any restrictions on these medicines. However, if you take daily inhalations of hypertonic saline, these should be restricted to two occasions per day. In addition, OligoG should be taken at least 15 minutes after you have completed your inhaled hypertonic saline therapy. This is important as it could reduce the activity of the OligoG.

Pregnancy and breast-feeding

OligoG should not be inhaled by pregnant women. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, inform your study doctor immediately. It is important that you/your partner do not become pregnant during the clinical trial. Talk to your study doctor about ways to avoid pregnancy.

3. How you should take OligoG

OligoG should be inhaled (breathed in) using the inhaler supplied with your study drug package. The study drug is supplied in capsules and these must only be used with the inhaler provided.

- Do not swallow the capsules.
- Do not crush the capsules or try to open them.
- Each blister strip contains 10 capsules, which is the required amount for one inhalation dose.
- The correct dose is 10 capsules in the morning and 10 capsules in the evening.
- OligoG should always be taken AFTER any other medication, except for inhaled antibiotics which are taken last.

- OligoG should always be taken at least 15 minutes AFTER you have completed your inhaled hypertonic saline therapy. This is important as a shorter time interval could reduce the effect of the OligoG.
- Inhaled antibiotics should be taken at least 10 minutes AFTER completion of OligoG inhalation.
- A new inhaler is provided with each weekly box of medication. Do not wash the inhaler.
- Do not cough or breathe into your inhaler.

Instructions on how to use the inhaler are at the end of this leaflet – even if you are familiar with this type of inhaler it is important that you follow these instructions provided in this leaflet.

If you are unsure, check with your study nurse/doctor.

If you forget to inhale OligoG

If you forget to take the morning or evening dose, the missed dose should be taken as soon as you become aware of it, but not if it is less than 2 hours before the next regular inhalation. Please tell your study nurse so they can record this in their notes.

If you stop taking OligoG

If you decide to stop taking OligoG please inform your study doctor immediately. You will be required to return unused capsules to your study site.

If you have any further questions on the use of this product, ask your study doctor.

4. Possible side effects

Like all investigational medicinal products, OligoG can cause side effects, although not every study patient gets them.

Adverse events previously reported have generally not been judged to be related to OligoG.

Adverse events seen in previous studies have been mild and generally unrelated to OligoG. These have included sore throat, cough, difficulty breathing, wheezing, chest discomfort and increased or altered sputum production.

If you notice any side effects, please tell your study doctor.

5. How you should store OligoG

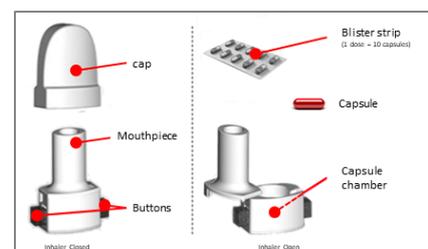
- Keep out of the reach and sight of children.
- Do not use study medication after the expiry date stated on each blister strip and box.
- Store in a dry place at room temperature (15°C-25°C). Do not freeze.
- Store in the original package in order to protect from light.
- Do not discard used/empty blister strips, these should be replaced in the corresponding box and returned to your study doctor at your next study visit. This is a requirement of the study.

6. Contents of the pack

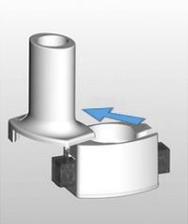
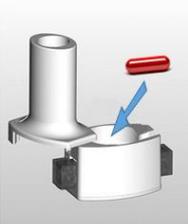
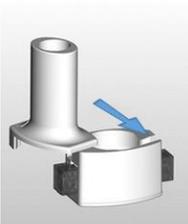
The active ingredient is a low molecular weight sodium alginate. Other components include lactose.

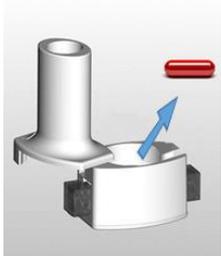
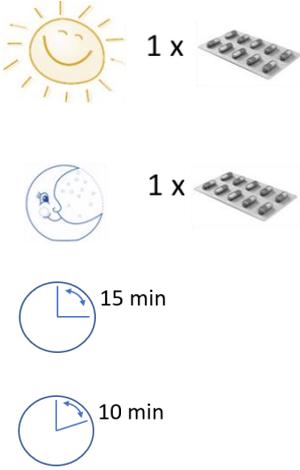
The study drug package contains:

- 14 blister strips, complete medication for one week.
- Each capsule contains either OligoG or placebo dry powder.
- 1 dry powder inhalation device.
- This leaflet.



7. How to use the Inhaler

1		<p>Make sure your hands are clean and dry before handling the inhaler or capsules.</p> <p>Remove the cap from your inhaler.</p>
2		<p>Open the inhaler, by twisting the mouthpiece in the direction of the arrow, to reveal the capsule chamber.</p>
3		<p>Remove a single capsule from the blister. Note each dose consists of 10 capsules. DO NOT squeeze or open the capsules.</p>
4		<p>Load the capsule into the capsule chamber.</p>
5		<p>Close the inhaler.</p>
6		<p>Press and release the two buttons together to pierce the capsule.</p>
7		<p>Breathe out fully before preparing to inhale.</p>

8		<p>Tilt your head back. Put the mouthpiece between your teeth and seal your lips around it. Inhale slowly and deeply to fill your lungs. You will hear a 'rattling' sound as the capsule spins within the inhaler. Hold your breath for 5 seconds, remove the device from your mouth, and breathe out slowly through your nose. Repeat with a second inhalation to ensure you inhale all the powder from each capsule. Do not breathe into the inhaler.</p>
9		<p>Open the inhaler and remove the capsule. Discard the empty capsule, but keep the blister strip for return to the study nurse.</p>
10		<p>Repeat steps 3-9 with each of the capsules from the blister strip, until you have completed the inhalation of all 10 capsules in the dose.</p> <p>Always take your OligoG AFTER any other medication, except inhaled antibiotics which are taken last.</p> <p>Always take OligoG at least 15 minutes AFTER hypertonic saline.</p> <p>Wait at least 10 minutes AFTER OligoG inhalation before taking inhaled antibiotics.</p> <p>On days with planned study visits, the morning inhalation should be taken at the site only after all visit related assessments are done.</p>
		<p>Remember to keep your blister strips for the study nurse to collect at your next visit.</p> <p>DO NOT wash your inhaler.</p> <p>DO take a drink of water between inhalations if you feel it helps.</p> <p>DO NOT use the inhaler for more than 7 days. A new inhaler is provided in each dose box.</p>

8. Contact information

Please contact your study doctor if you have any questions about this clinical trial, OligoG, or use of your inhaler.

An electronic version of this leaflet is also available online.
 Further details and password will be provided by your study nurse/doctor.